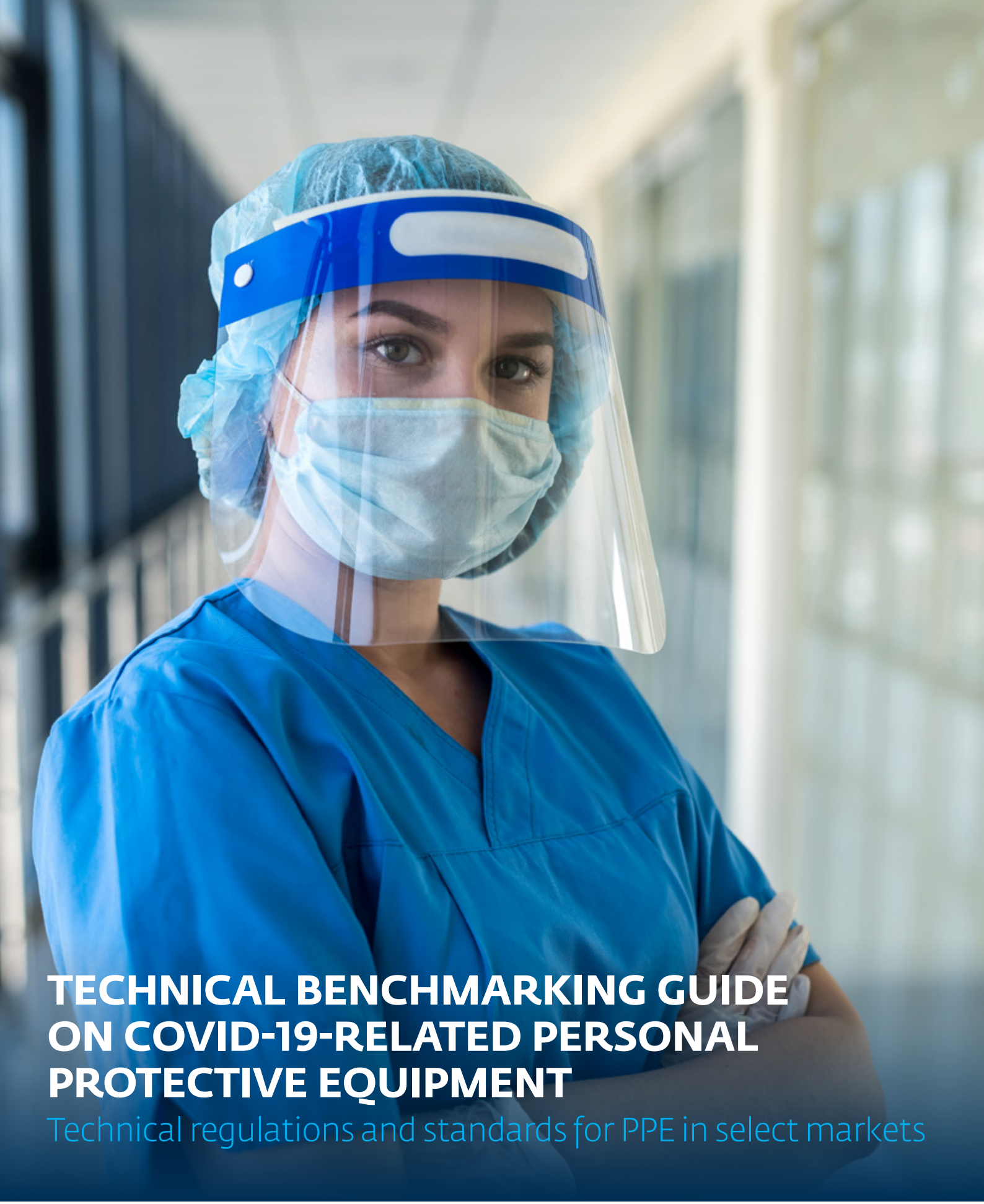


TECHNICAL BENCHMARKING GUIDE ON COVID-19-RELATED PERSONAL PROTECTIVE EQUIPMENT

Technical regulations and standards for PPE in select markets

bsi.

IFC International Finance Corporation
WORLD BANK GROUP

Creating Markets, Creating Opportunities

Disclaimer

2121 Pennsylvania Avenue, N.W.

Washington, D.C. 20433

Internet: www.ifc.org

TABLE OF CONTENTS

ACRONYMS/ABBREVIATIONS

Acronym/ abbreviation	Explanation
AAMI	Association for the Advancement of Medical Instrumentation (US)
AATCC	American Association of Textile Chemists and Colorists
ABNT	Associação Brasileira de Normas Técnicas (Brazilian National Standards Body)
AFNOR	French National Standards Body
ANAB	ANSI National Accreditation Board (US)
ANSI	American National Standards Institute
ANVISA	Agência Nacional de Vigilância Sanitária (Brazilian Health Regulatory Agency)
APEC-SCSC	Asia-Pacific Economic Cooperation Sub-Committee on Standards and Conformance
APR	Air-Purifying Respirator
AQL	Acceptable Quality Limit
ARAC	Arab Accreditation Cooperation
AS	Australian Standard
AS/NZS	Joint Australian/New Zealand Standard
ASEAN	Association of Southeast Asian Nations
ASTM	Formerly known as the American Society for Testing of Materials, now called ASTM International
BFE	Bacterial Filtration Efficiency
BIS	Bureau of Indian Standards
BNQ	Bureau de Normalisation du Québec (Québec Standards Bureau)
BSI	British Standards Institution
CDC	Center for Disease Control (US)
CDSCO	Central Drug Standard Control Organization (India)
CE	EU Mark of Conformity
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CFR	Code of Federal Regulations (US)
CFS	Certificate of Free Sale
CFU	Colony Forming Units (microbiology)
CGCRE	Brazilian National Accreditation Body
cl.	Clause

CONMETRO	National Council of Metrology, Standardization and Industrial Quality (Brazil)
COVID-19	Coronavirus Disease 2019 Caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)
CSA	Canadian Standards Association
CSDT	Common Submission Dossier Template
CWA	CEN Workshop Agreement
DAkkS	Deutsche Akkreditierungsstelle (German National Accreditation Body)
DIN	German National Standards Body
DMEC	Department of Medical Equipment and Construction (Vietnam)
DSM	Department of Standards Malaysia
EA	European Accreditation Cooperation
EEC	European Economic Community
EN	European Standard
EU	European Union
FCDO	Foreign, Commonwealth & Development Office (UK)
FDA	Food and Drug Administration (US)
GB	Chinese National Standard
IAF	International Accreditation Forum
ICONTEC	Instituto Colombiano de Normas Técnicas y Certificación (Colombian National Standards Body)
IEC	International Electrotechnical Commission
IFC	International Finance Corporation
ILAC	International Laboratory Accreditation Cooperation
INMETRO	National Institute of Metrology, Quality and Technology (Brazil)
INVIMA	National Institute for Food and Drug Surveillance (Colombia)
ISEA	International Safety Equipment Association (US)
ISO	International Organization for Standardization
IVD	In Vitro Diagnostic Product (medical device)
JAS/ANZ	Joint Accreditation Service for Australia and New Zealand
JAS-AU	Jordanian Accreditation and Standardization System—Accreditation Unit
JFDA	Jordan Food and Drug Administration
JS	Jordanian Standard
JSMO	Jordan Standards and Metrology Organization

KEBS	Kenya Bureau of Standards
KEMSA	Kenya Medical Supplies Agency
KENAS	Kenya Accreditation Service
KS	Kenyan Standard
L	Large (size)
M	Medium (size)
MaHTAS	Malaysian Health Technology Assessment Section of the Ministry of Health
MDA	Medical Device Authority (Malaysia)
MDEL	Medical Device Establishment Licence (Canada)
MDR (EU)	Medical Devices Regulation (EU) 2017/745
MDR (India)	Medical Devices Rules (India)
MERCOSUL	Southern Common Market (South American Trade Bloc)
MLA	Multilateral Recognition Arrangement (IAF)
MRA	Mutual Recognition Arrangement (ILAC)
MS	Malaysian Standard
n/a	Not Applicable
NABCB	National Accreditation Board for Certification Bodies (India)
NABL	National Accreditation Board for Testing and Calibration Laboratories (India)
NANDO	New Approach Notified and Designated Organizations (EU)
NBR	Brazilian National Standard
NFPA	National Fire Protection Association (US)
NIOSH	National Institute for Occupational Safety and Health (US)
NP	Portuguese Standard
NRL	Natural Rubber Latex
NSC	National Standards of Canada
NTC	Norma Técnica Colombiana (Colombian National Standard)
NWSP	Nonwovens Standard Procedure
ONAC	Organismo Nacional de Acreditación de Colombia (Colombian National Accreditation Body)
OSH	Occupational Safety and Health Law (Vietnam)
OSHA	Occupational Safety and Health Administration (US)
PB	Partial-body (protection)
PPE	Personal Protective Equipment
PVC	Polyvinyl Chloride

RPD	Respiratory Protective Device
RQL	Rejectable Quality Level
S	Small (size)
SABS	South African Bureau of Standards
SADC	Southern African Development Community
SADCMEL	SADC Cooperation in Legal Metrology
SADCSTAN	SADC Cooperation in Standards
SAHPRA	South African Health Products Regulatory Authority
SANS	South African National Standard
SCC	Standards Council of Canada
SINMETRO	National System of Metrology, Standardization and Industrial Quality (Brazil)
SIRIM	SIRIM Berhad (formerly the Standard and Industrial Research Institute of Malaysia)
SITRA	South India Textile Research Association
STAMEQ	Directorate for Standards, Metrology and Quality (Vietnam)
TBT	(WTO) Technical Barriers to Trade Agreement
TCVN	Vietnam National Standard
TGA	Therapeutic Goods Administration (Australia)
TPD	Therapeutic Products Directorate (Canada)
UK	United Kingdom of Great Britain and Northern Ireland
UKAS	United Kingdom Accreditation Service
UKCA	United Kingdom Conformity Assessed marking
UKNI	United Kingdom Northern Ireland marking
UNE	Spanish National Standards Body
US	United States
WHO	World Health Organization
WTO	World Trade Organization
XL	Extra-Large (size)
YY/T	National Pharmaceutical Industry Standard of the People's Republic of China

ACKNOWLEDGEMENTS

This report was produced under IFC's Global PPE Advisory Program, in partnership with the UK government. The program supports select manufacturers in emerging markets to develop their manufacturing capacity and supports governments and industry associations in select emerging markets to improve their knowledge and awareness on PPE quality and standards.

The preparation of this publication was led by Nigel H Croft (Lead Consultant, BSI) and George Bamopoulos (PPE Lab Capacity Development Lead, BSI). The IFC and BSI team that oversaw and contributed to this publication consisted of Majda Stoshikj (Lead Project Manager, BSI), Sumit Manchanda (Senior Operations Officer, IFC), Bin Zhai (Associate Operations Officer, IFC), Anil Jauhri (Consultant, IFC) and Brendon Mendonca (Consultant, IFC).

The team would like to thank Wafa Aranki (former Senior Operations Officer, IFC), Sabine Hertveldt (Senior Operations Officer, IFC), Tania Lozansky (Senior Manager, IFC), Cindy Parokkil (former Project Manager, International Projects, BSI), Nahyun Kim (Project Manager, International Projects, BSI), Mohammad Shohaieb (Principal Consultant, International Projects, BSI), Nathan Shipley (PPE Group Certification & Laboratory Manager, BSI), Graham Clements (former Certification Manager PPE, BSI), Ahmad Al-Khatib (Assurance Business Development and Acting System Certification Director, BSI), and Volodymyr Yakubov (Business Development Director, International Projects, BSI), for their excellent guidance, suggestions and contributions.

The team is grateful for inputs, guidance, comments and feedback received from the colleagues and peer reviewers from other organizations. We would particularly like to thank Jose Sanez (Gerber Technology), Karen Batt (Standards Australia), James Galloway (JAS-ANZ), Raul Casanova (ABNT), Nelson Al Assal Filho (ABNT), Ricardo Fragoso (ABNT), Leonardo Machado Rocha (Inmetro), Bruce Farquhar (SCC), Luisa Pallares (ICONTEC), Subramaniam Sivakumar (SITRA), Ruba Al-Thawabeia (JSMO), Abeer Alzhair (JSMO), Qais Azzam (JSMO), Oyoo T. Otieno (KEBS), Bernard Njiraini (KEBS), Ngari Esther (KEBS), Martin Chesire (KENAS), Vivek Ramchandani (Hela Clothing), Feris Frederick (Standards Malaysia), Shaharul Sadri Alwi (Standards Malaysia), Hussalmizzar Hussain (Standards Malaysia), Norhaliza Binti Arifin (Standards Malaysia), Anuratha Sivam (Standards Malaysia), Atikah Binti Aman (Standards Malaysia), Nur Hadaina binti Hamdan (Standards Malaysia), Sadhvir Bissoon (SABS), Elsie Meintjies (UNIDO), Jeffrey O. Stull (International Personnel Protection, Inc.), Jeff Grove (ASTM International), Teresa Cendrowska (ASTM International), and Le Thi Thuy Hang (Quatest 1, Vietnam).

The report was funded with UK Aid from the UK government, and the team would like to thank Kerry Conway (Head of Manufacturing, FCDO) and Grace Cramer (Manufacturing Africa Advisor, FCDO) for their support and guidance.

FOREWORD

The COVID-19 pandemic has had a profound impact on the dynamics of global supply chains for personal protective equipment (PPE). It necessitated an urgent review and, in some cases, a temporary relaxation of the regulatory requirements and technical specifications in certain markets to ensure the ongoing availability of PPE for health care workers and front-line workers.

In parallel, on the supply side, many non-traditional manufacturers ramped up their production capabilities, with some even manufacturing PPE for the first time to help cope with demand. This has meant that they have had to navigate their way through the many different market requirements to ensure compliance with the relevant standards and technical regulations. These requirements are often similar but not identical, and specify varying test methods and conformity assessment procedures.

By producing this technical benchmarking guide, the International Finance Corporation (IFC) in partnership with the British Standards Institution (BSI) aim to fill a critical knowledge gap on technical regulations and standards for PPE. We hope the guide will also be useful for purchasing organizations on the demand side to better understand the required technical regulations and standards for PPE. This in turn will lead to better informed PPE product orders and help procurement agencies identify potential new suppliers from countries that are starting or expanding their PPE production in recent years.

The guide presents the often complex and sometimes conflicting technical regulations, product standards and conformity assessment criteria in a simple way. It is intended to help manufacturers identify the realities of potential new markets and to act as a starting point for them to delve deeper into the specific product requirements and test methods by consulting the relevant standards and technical regulations as necessary.

By using the two best-known markets, the European Union (EU) and the United States (US), as reference points, it is expected that manufacturers and purchasers alike will benefit from the comparisons that are made using a simple system of color coding, supported by more detailed analysis of the relevant standards. Initially focusing on 13 key markets, the modular design of the guide can facilitate the addition of other markets over time.

Although there is still a paucity of standards and regulations related to sustainability, circularity, and inclusivity and gender-related "fit" requirements for PPE, users of the guide are alerted to the need for these aspects to be taken into account, as referenced in Annex A to this guide. In 2021 and 2022, IFC put the spotlight on the need to move away from plastics-based, single-use, disposable PPE toward more sustainable PPE products and business models through IFC's publication "Innovation in Manufacturing Personal Protective Equipment—Toward Sustainability and Circularity." In November 2021, IFC also convened stakeholders to discuss how PPE procurement and manufacturing can move away from "one size fits all" to cater to specific needs of female and male health care workers with a wider range of products and sizes that fit different body types. Both areas—sustainability and inclusivity/gender—are at the forefront of international attention and represent new opportunities for PPE production and procurement. Standards institutions and governments are expected to develop new technical standards and requirements in both areas.

The guide is part of broader efforts by IFC and others to support global supply chains for PPE and to provide manufacturers and governments with a tool to expand the manufacturing and supply of PPE that is "fit for purpose", that adequately protects all healthcare workers and is produced without harming the environment.

Tania Lozansky, IFC Senior Manager, Manufacturing, Agriculture and Services.

Scott Steedman, BSI Director of Standards

PART 1
GENERAL

1.1 Background

The COVID-19 pandemic increased demand across the world for medical personal protective equipment (PPE) which, coupled with disruptions in supply chains and the high concentration of PPE manufacturers in only a few countries, led to widespread shortages globally. Global demand for medical PPE is expected to remain significant for the foreseeable future, particularly as new variants of the virus or new viruses emerge.

In support of the International Finance Corporation's (IFC) Global Health Platform, IFC launched a Global Advisory Program on PPE in 2020, with funding and support from the UK government's Foreign, Commonwealth and Development Office (FCDO). The program's main objective is to support the diversification of global supply chains for PPE and to work with manufacturers and governments in developing countries to increase the manufacturing and supply of quality PPE in those countries. One critical knowledge gap was a guide that compares technical regulations and standards for PPE across countries.

1.2 Guide objectives and limitations

This technical benchmarking guide forms a key part of IFC's Global Advisory Program and provides manufacturers and purchasers with a tool to navigate through the technical regulations, product specifications and conformity assessment requirements associated with selected markets around the world.

The guide focuses on medical PPE, excluding protective equipment and professional workwear to protect workers in other industries, outside health care.

Overall, the guide seeks to simplify comparisons between the various COVID-19-related PPE categories and markets by using a system of color coding to highlight similarities and differences. For those who need more detail, it also takes a deeper dive into the technical regulations, product standards, and testing criteria for each PPE/market combination. Making these comparisons is a complex process due to:

- The different regulatory approaches and relationships between (mandatory) technical regulations and (voluntary) standards used in different markets
- The different technical regulations associated with PPE and medical devices, with some PPE categories needing to meet one or both sets of regulations simultaneously
- International standards that are evolving quickly to cater to the needs of a rapidly changing PPE landscape but for which the latest versions are not always adopted at a national level or referred to in legislation. This time-lag in adoption can mean that the relevant standard might not be the latest version
- The different testing methods that are required to demonstrate conformity to the various product standards. This can mean that although a specific category of PPE might be manufactured to meet the requirements of multiple markets, it has to undergo testing using different laboratory methods, approaches, or acceptance criteria. These are often expressed in different units of measurement, for which a direct comparison of results is impossible.

It is for these reasons that ***the information provided in this guide should be used with caution***. The guide is intended to be informative and a useful tool that provides a starting point for a more detailed analysis of the specific market requirements for each category of PPE. It should not be used as a substitute for consulting the latest versions of applicable legislation, technical regulations, product standards, and conformity assessment procedures or seeking expert advice, as needed.

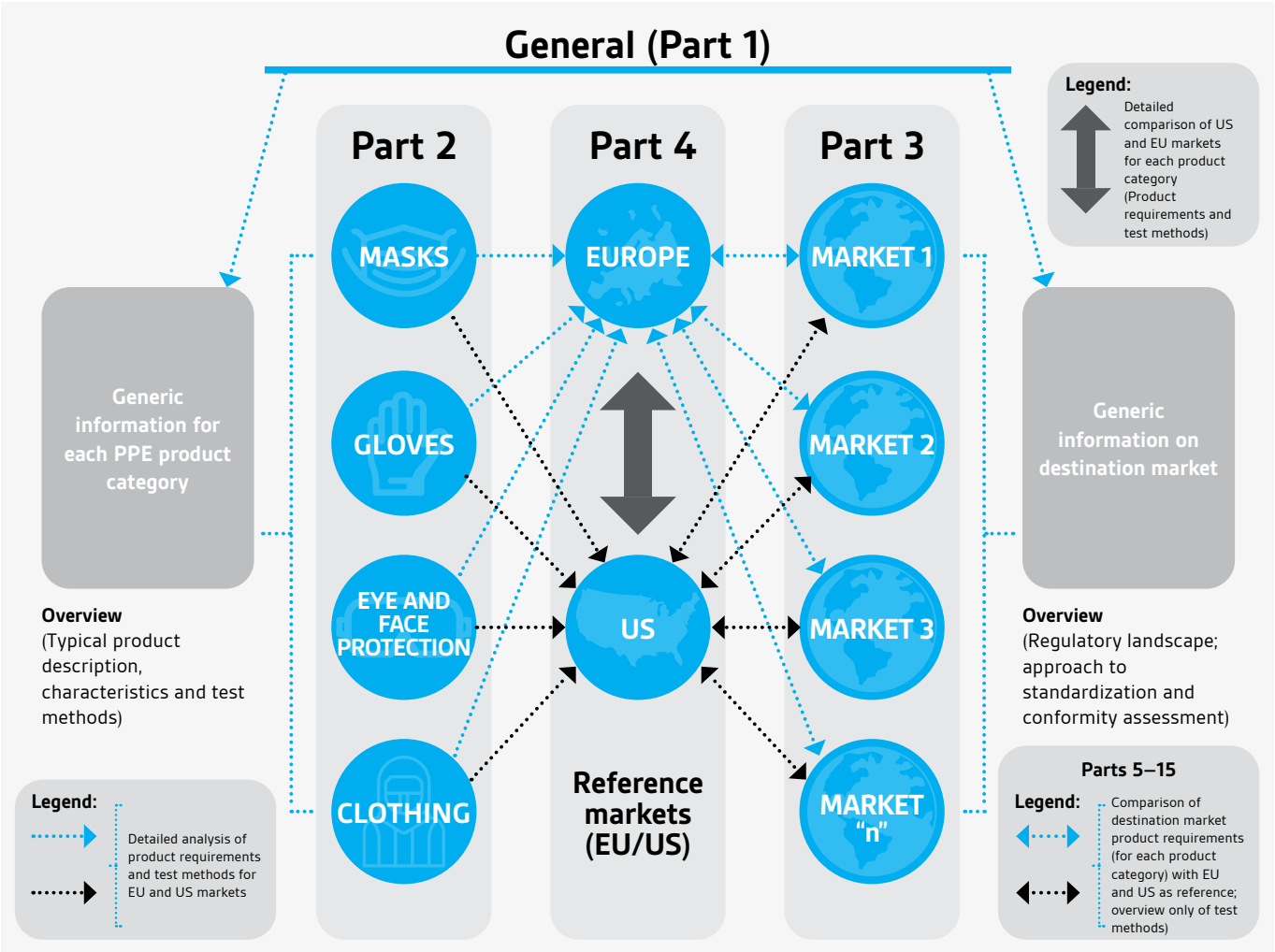
1.3 How to use the guide

The guide is split into sections from which the user can choose the relevant areas to access according to their needs:

- **Part 1:** Introduction and the technical criteria for the various PPE categories in selected markets
- **Part 2:** Generic descriptions of the main technical features for each PPE product category and associated standards for the selected markets
- **Part 3:** Market-specific information, including an overview of each market and generic information about the regulatory environment, approaches to standardization, and conformity assessment
- **Part 4:** Detailed comparisons of the technical requirements for the EU and US markets. International Organization for Standardization (ISO) product standards are also included where available
- **Parts 5–15:** Detailed fact sheets with comparisons (benchmarking) of the specific requirements for each product/market combination against the reference EU/US market requirements
- **Annex A:** Other considerations for manufacturers and purchasers to take into account, including sustainability and diversity/inclusivity (gender) issues, and approaches to conformity assessment and accreditation.

Figure 1.1 shows the architecture of the guide.

Figure 1.1: Schematic diagram showing the overall architecture of the guide



1.4 Products covered by the guide

- **Masks**
  - Respirators
  - Medical face masks
  - Community face coverings
- **Eye and face protection**
  - Protective goggles/glasses
  - Face shields
- **Gloves**
  - Medical examination gloves
  - Surgical gloves
- **Clothing**
  - Full-body garments (including protective suits and coveralls) and partial-body garments (including aprons and shoe/head covers)
  - Gowns (including isolation and surgical gowns)

Part 2 of this guide provides a description of the main characteristics and technical requirements related to the above categories of PPE, used in the context of the COVID-19 pandemic.

1.4.1 Classification: PPE or medical device?

PPE and medical devices—key differences in the context of COVID-19

Definitions vary around the world but put simply:

- PPE protects the wearer from a hazard.
- Medical devices are for the prevention of patient disease or maintaining the clinical integrity of a procedure.

Some products can serve both purposes.

It is important to emphasize that this guide focuses on PPE as defined above and only considers medical devices, also as defined above, in cases where they can have a dual purpose of also protecting the wearer. The regulatory distinction between "PPE" and "medical devices" has implications not only in terms of the requirements to be met for placing products in specific markets but also regarding the applicable standards.

Table 1.1 shows examples within the European context, but similar criteria also apply to most other markets. It is not always immediately clear whether certain categories of product are covered by PPE or medical device regulations (or both). Much depends on the manufacturer's claims about the product, which are key to determining the applicable requirements in any jurisdiction.

An example in Table 1.1 would be a manufacturer of surgical gowns (usually classified as medical devices) that also claims that the gowns protect the wearer from infective agents (in which case they would also fall under the PPE regulations).

Table 1.1: Examples of European regulations and standards related to PPE and medical devices

PPE	Medical device
Regulation	
Regulation (EU) 2016/425 on personal protective equipment (the PPE Regulation) covers the design, manufacture, and marketing of PPE. It defines legal obligations to ensure that PPE on the EU internal market provide the highest level of protection against risks.	**Regulation (EU) 2017/745 on medical devices (the MDR). The regulation has applied since May 26, 2021.** Manufacturers must comply with the regulation when placing new medical devices on the market. It repeals Directive 93/42/EEC on medical devices.

Table 1.2: Examples of applicable standards

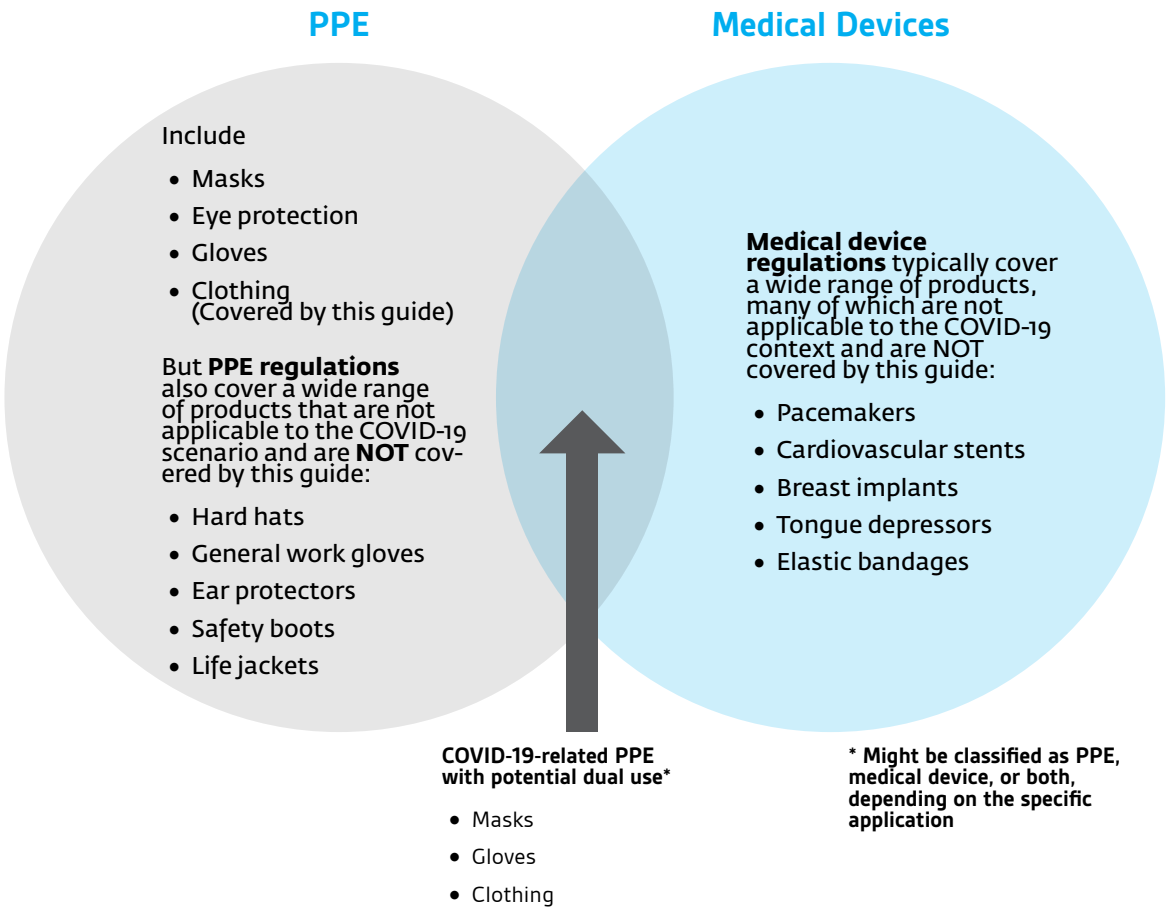
EN 149:2001+A1:2009 Respiratory protective devices—filtering half-masks to protect against particles—requirements, testing, marking	**EN 14683:2019** Medical face masks—requirements and test methods
EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms	**EN 455-3:2015** Medical gloves for single use—Part 3: Requirements and testing for biological evaluation
EN 14126:2003 Protective clothing—performance requirements and test methods for protective clothing against infective agents	**EN 13795-1:2019** Surgical clothing and drapes—requirements and test methods—Part 1: Surgical drapes and gowns

It is generally accepted good regulatory practice for technical regulations to specify "essential requirements" (usually based on generic performance criteria) while the technical details such as material performance characteristics, test methods, and so on are contained in (voluntary) standards.

If a product conforms to the pertinent standard (called "harmonized standard" in the EU) then it is assumed that it fulfils the essential requirements (presumption of conformity). This approach allows for technical progress to be accommodated through amendments or new editions of standards, while the technical regulation itself remains relatively stable. In some other situations, voluntary standards can become compulsory when directly referenced in the regulations.

Typically, this means that regulations might refer to a wide range of PPE and medical devices, only some of which are relevant for COVID-19-related applications. This can be seen schematically in Figure 1.2.

Figure 1.2: Schematic representation of the interactions between PPE and medical devices



1.4.2 Classification of products covered by this guide

Masks:

- Medical devices if they are used for the prevention of patient disease or maintaining the clinical integrity of a procedure, and do not have a tight seal on the face (for example, "surgical masks")
- PPE if they protect the wearer from infectious agents generated by the patient or the medical environment, or from exposure to harmful substances (for example, "respirators")
- Some masks may be dual purpose and perform both functions. Valved masks without exhalation filters generally are not considered to be medical devices.

Eye and face protection:

- In most countries, eye and face protection will be considered as PPE—it is primarily worn to protect the wearers' eyes and face from liquid droplets or splashes, but can also be used for infection control purposes.

Gloves:

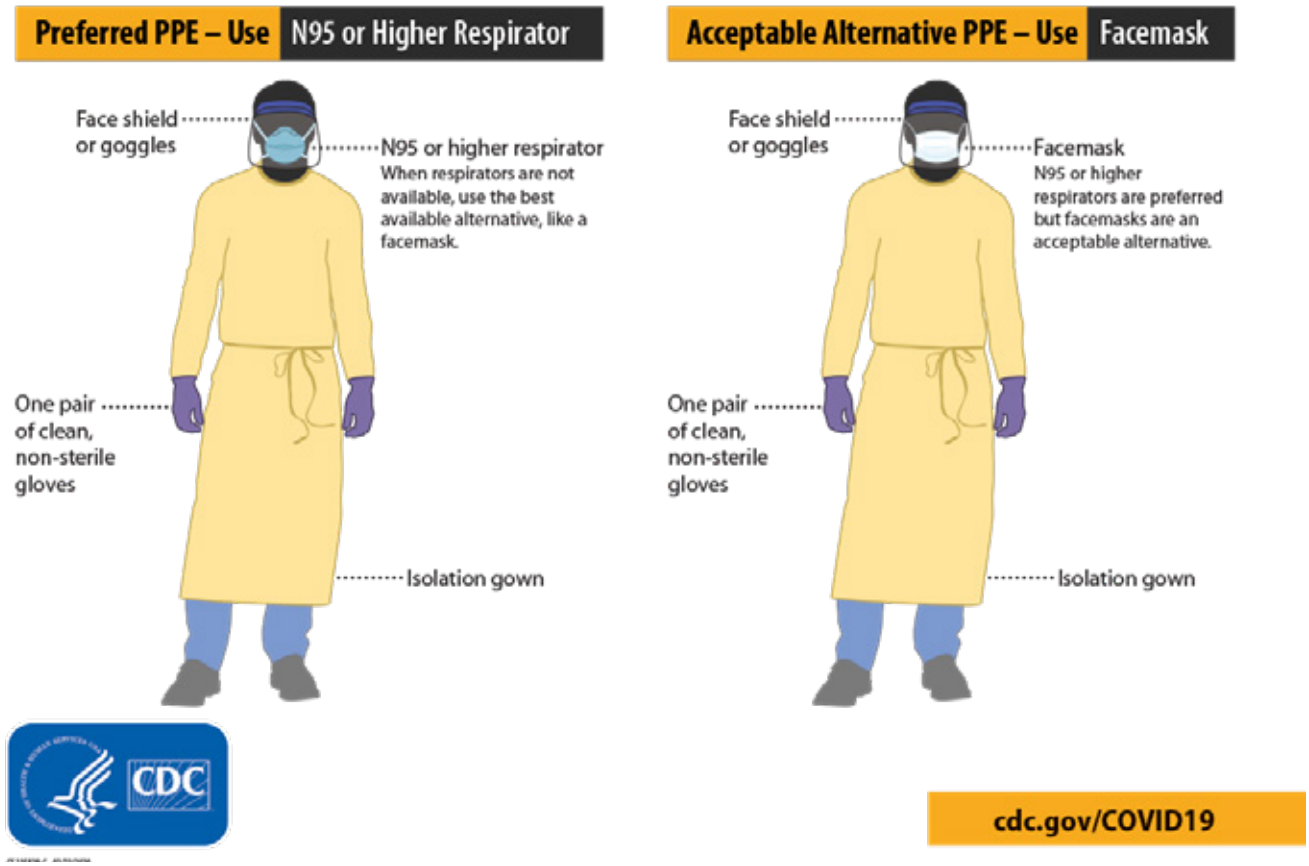
- Medical devices if they are for the prevention of patient disease or maintaining the clinical integrity of a procedure (for example, surgical and examination gloves)
- PPE if they protect the wearer from infectious agents generated by the patient or the medical environment, or from exposure to harmful substances (for example, protective gloves)
- Gloves may be dual purpose and perform both functions.

Clothing:

- Medical devices if they are for the prevention of patient disease or maintaining the clinical integrity of a procedure
- PPE if it is to protect the wearer from infectious agents generated by the patient or the medical environment, or from exposure to related harmful substances (for example, harsh disinfectants or dangerous drugs)
- Gowns and garments may be dual purpose and perform both functions.

Figure 1.3 shows some of the guidance provided by the US Center for Disease Control (CDC) for COVID-19 situations where all these generic categories of PPE are used simultaneously.

Figure 1.3: Use of PPE when caring for patients with confirmed/suspected COVID-19



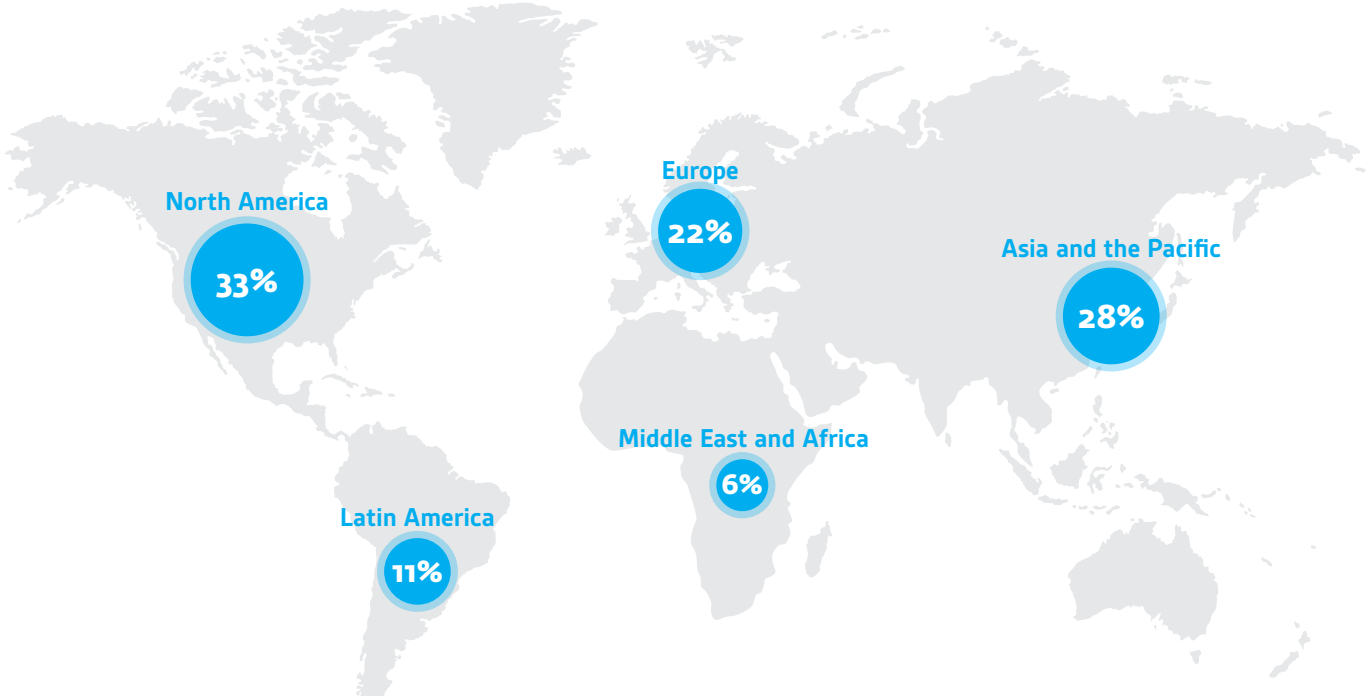
1.5 Markets covered by the guide

This guide has focused initially on the following 13 countries/regions, which are from the largest markets for health care-related PPE (see Figure 1.4), with North America and Europe alone comprising 55 percent (in value) of the total global market.

- Australia
- Brazil
- Canada
- Colombia
- EU
- India
- Jordan
- Kenya
- Malaysia
- South Africa
- UK
- United States
- Vietnam

These countries and regions were selected to provide a cross-section of the global market based on their size and geographical distribution. The availability of data on technical regulations and standards from the respective standardization bodies and regulatory authorities also played an important role. The modular nature of this guide means that additional markets can be added over time, as well as updates to the information provided.

Figure 1.4: Health care-related PPE market share by region (2019)[1]



1 December 2020 (updated March 2021). COVID-19 – PPE Demand and Supply Perspectives. Final report. UK Aid. Source: Mordor Intelligence (updated in November 2020), Asian Development Bank

1.5.1 Approaches to standards and technical regulations

Nowadays, most developed and many developing economies have similar conceptual approaches to the ways in which technical regulations relate to or depend on national, regional, or international standards. But there are still important differences in the details from one country to another. These are explained in more detail in Part 3 of the guide.

ISO/IEC Guide 2[2] defines a standard as a "document, established by consensus and approved by a recognized body that provides, for common and repeated use, rules, guidelines, or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context." It goes on to say that "standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefit." Standards encode knowledge regarding usability, quality, safety, performance, or any other characteristics required by users, into technical specifications for products, services, processes, and systems, as well as guidance on best practices.

In the context of the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement (which in principle applies to most international transactions for the PPE covered by this guide), the term "standard" is defined slightly differently than in ISO/IEC Guide 2, as follows:

"**Document** approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, **with which compliance is not mandatory**."

The relation between (voluntary) standards and (mandatory) technical regulations is defined in Article 2.4 of the TBT agreement:

"**Where technical regulations are required and relevant international standards exist or their completion is imminent, members shall use them**, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance, because of fundamental climatic or geographical factors or fundamental technological problems."

It is also important to recognize that, although the WTO/TBT model emphasizes the need to separate the "voluntary" nature of standards from the "compulsory" nature of technical regulations, this is not always the current reality. This is particularly true in some developing countries and transition economies, where certain standards are viewed as being compulsory and continue to be used as de facto technical regulations.

For manufacturers and purchasers of PPE, the main categories of standards that are most relevant are the following:

Product standards that provide information (usually in the form of requirements) regarding the materials, processing methods, and acceptance criteria for specific categories of PPE. Some standards apply to a range of products, while others can be specific to a product or material.

Prescribed **test methods** by which conformity to the product standards can be demonstrated

Quality management system standards (such as ISO 9001[3]) that apply to manufacturers of PPE and are aimed at providing confidence in the supplier's "ability to consistently provide products that meet customer and applicable statutory/regulatory requirement." For producers of medical devices (including some PPE with a dual function—see 1.4.1) the requirements are defined in ISO 13485.[4]

Conformity assessment standards (such as ISO/IEC 17025 for laboratories,[5] ISO/IEC 17020 for inspection bodies,[6] ISO/IEC 17021-1 for management system certification bodies[7], and ISO/IEC 17065 for product

2 ISO/IEC Guide 2. 2004. *Standardization and Related Activities—General Vocabulary.*

3 ISO 9001. 2015. "Quality management systems—requirements."

4 ISO 13485. 2016. "Medical devices—quality management systems—requirements for regulatory purposes."

5 ISO/IEC 17025. 2017. "General requirements for the competence of testing and calibration laboratories."

6 ISO/IEC 17020. 2012. "Conformity assessment—requirements for the operation of various types of bodies performing inspection."

7 ISO/IEC 17021-1. 2015. "Conformity assessment—requirements for bodies providing audit and certification of management systems."

certification bodies[8]) that are used as a basis for accreditation of conformity assessment bodies.

For the PPE covered in this guide, most developed countries adopt (to a greater or lesser extent) the principle of "presumption of conformity" by which demonstrated conformity to the (voluntary) standards mentioned is accepted as evidence of conformity to the relevant technical regulation. This is described further in Part 3 of the guide.

1.5.2 Key standards for PPE in the markets covered by this guide

The standards that apply in the EU and US markets are undoubtedly the best-known to most exporters and potential exporters from developing economies and are the ones most commonly adopted or referred to in those countries. For those reasons, they are used as a reference throughout this guide, against which the requirements of the other markets can be compared and benchmarked.

Although there is a tendency (and an inherent preference as stated in the WTO/TBT Agreement) to use international standards as a basis for demonstrations of conformity to technical regulations, regulatory agencies in the various markets typically reference the relevant national or regional standards. These may or may not be national adoptions of regional or international standards. Part 2 of the guide provides a high-level overview in which readers can see where there are similarities in the approach and the core standards used in different countries.

In Europe, "EN" standards are issued by the European Committee for Standardization (CEN) and are formally adopted by the various member states as, for example, "DIN EN 149" (in Germany) or "UNE EN 455-1" in Spain, and so on. In a number of cases, the EN standards are themselves adoptions of standards published by the ISO, meaning that their contents are essentially identical. These are identified by the prefix "EN ISO" or, in the case of National Standards, NP EN ISO 9001 (in Portugal, for example).

In the United States, different standards development organizations are recognized (accredited) by the American National Standards Institute (ANSI) to publish national standards. In the context of PPE, the prevalent standards development organization is ASTM International (formerly known as the American Society for Testing of Materials), many of whose standards have a global reach and are also adopted as national standards in some economies.

In other economies and markets, there is typically only one national standards body, which may use one (or a combination) of the following options for the standards it develops and publishes:

- National adoption of an ISO standard. This can be identical (thereby facilitating the benchmarking process) or similar/technically equivalent (where national modifications are made)
- National adoption of an EN standard (typically applicable when there is no ISO equivalent)
- National adoption of other relevant standards such as those developed by ASTM
- Independent (standalone) national standard that has been developed locally.

Examples of national standards bodies include the BSI, Associação Brasileira de Normas Técnicas (ABNT), and Standards Council of Canada (SCC). Part 3 of this guide presents further details for each of the markets considered.

1.5.3 Overall regulatory approaches for PPE

Standards and product testing are typically used to underpin regulatory requirements for PPE and their associated attestations of product conformity as follows:

- Regional mandatory product certification schemes such as those requiring CE Marking (EU Mark of Conformity) in the EU
- National mandatory product certification schemes such as that of the National Institute for Occupational Safety and Health (NIOSH) in the United States

8 ISO/IEC 17065. 2012. "Conformity assessment—requirements for bodies certifying products, processes and services."

- Voluntary product certification through an accredited body, which may or may not be directly mandated as part of the individual standard (for example, Underwriters' Laboratories third-party certification of emergency medical protective clothing, applied globally where claims are made for compliance).

The summary of requirements shown in Table 1.3 is adapted from the WHO publication "Technical Specifications for Personal Protective Equipment for COVID-19—Interim Guidance 13 November 2020."[9]

It is important to note that, due to limited manufacturing capacity, some products might come from other economic regions or might have "emergency use authorizations" by regulatory agencies. Therefore, the requirements listed below might apply only for a limited period during the COVID-19 pandemic and are likely to be updated. Some differences in the specific scope and details of the requirements may well exist at a national level where these temporary allowances are made.

9 https://www.who.int/publications/i/item/WHO-2019-nCoV-PPE_specifications-2020.1.

Table 1.3: Summary of requirements for COVID-19-related PPE

Topic	Requirements
General technical requirements	According to the technical specifications of PPE specific for COVID-19
Primary packaging	Labeling on the primary packaging needs to include: • Name and/or trademark of the manufacturer • Model or product reference • Information for particular storage conditions (temperature, pressure, light, humidity)
Quality management system from the manufacturer, for the PPE types	• General quality management (for example, ISO 9001), for non-medical devices • EU Module C2 or D conformity to type certificate (Category III PPE only) • Certified quality management system for medical devices (for example, ISO 13485) and application of risk management to medical devices (for example, ISO 14971[10]), if applicable.
Regulatory approval/ certification[11]	Free sales certificate of medical device and related infection prevention and control products. Certificate for exportation of medical device and related infection prevention and control products, provided by the authority in manufacturing country (in case of imported goods). National local regulatory approval (of recipient country, as applicable). Proof of regulatory compliance, as appropriate, per the product's risk classification, for example, • Europe: CE marking and declaration of conformity and/or EU type examination certificate as applicable, for example, PPE Category III for respirators • US Food and Drug Administration (FDA) approval, emergency use authorization, or temporary enforcement policy. Ability for purchaser to check authenticity directly with the issuing regulatory authority (for example, online database of active licenses). Category I PPE may accept self-declaration with declaration of conformity (COVID-19 context). Authorized representative must be identified and document expiration date (valid until …).
Test reports	Official test reports (all pages, in English) must either originate from test laboratories accredited to ISO/IEC 17025, preferably by a signatory of the International Laboratory Accreditation Cooperation (ILAC) mutual recognition arrangement (MRA) or from an EU notified body. Test reports should clearly indicate the accredited laboratory name and accreditation (for regulators or purchasers to be able to check the authenticity of test reports). Test standard must be within the accreditation scope of the laboratory. EU-type examination certificates for category III PPE should mention the notified body name/number. Instructions for authentication of the test report(s) and certificates should be provided. Ability for purchaser to check authenticity directly with the accredited test laboratory (for example, online uploading of test report and automatic version check, or emailing the test facility).

10 ISO 14971:2019. "Medical devices—application of risk management to medical devices."

11 Note: Regulatory approval or compliance may not always require formal certification.

1.6 Guidance for purchasers of COVID-19-related PPE

In order for purchasers (governments, health care organizations, distributors of medical consumables and/or purchasing agents) to have confidence in the PPE they are buying, they need be aware of the following recommendations:

- Check any applicable regulations for the specific PPE you are purchasing. Although it is the legal obligation of suppliers to ensure that the PPE meets all applicable regulatory requirements, they might not always be familiar with the requirements of your particular market. Establish a dialogue with the supplier before agreeing to any contract.

- Specify clearly what it is that you want to buy, including any regulatory requirements (for example, related to PPE or medical device regulations in your country) and (where possible) the relevant standards and test methods that are applicable (including the appropriate revision dates). You might want to agree on any alternatives that might be acceptable to regulators in your country (for example, PPE that meets foreign regulations)—possibly on a temporary/emergency basis. See section 1.5.3.

- Selection of suppliers can include the following considerations:

    - Using your traditional manufacturers, importers and distributors where you already have confidence in their ability to meet your requirements

    - Recommendations from reputable purchasers in other markets, based on the supply of similar products

    - The manufacturer's accredited certification to a recognized quality management system standard such as ISO 9001 or, in the case of PPE that is also classified as a medical device, ISO 13485. Check the validity date on any certificates and that their scope covers the PPE categories that are being purchased

    - If the PPE you are purchasing is not covered by regulations in your country, it may be prudent to request the supplier to provide evidence of regulatory approval in another country, or accredited certifications to recognized (preferably international) standards.

- Verify any claims by suppliers that they are "approved" or "certified." During the COVID-19 pandemic there have been false or fraudulent claims made of conformity to technical regulations and specific product or quality management system standards such as those mentioned in this guide. This verification process can be quite complex, as explained below, but it should avoid unpleasant surprises for purchasers. Ironically, the more seals, stamps, and marks are shown on a certificate, the more likely it is to have been falsified.

- The only claims of conformity to product or quality management system standards that you can trust are those that are supported by a certificate issued by a recognized certification body. This typically means that the certification body has been officially recognized by your government or ACCREDITED by an accreditation body that is in turn listed on the International Accreditation Forum (IAF) website as a signatory to the IAF Multilateral Recognition Arrangement (MLA- see Annex A3). Such certificates will typically (but not always) bear the following mark:

If in doubt, or if the IAF logo does not appear, the certificate will show the logo and an identification number of the issuing certification body's accreditation body (for example, ANAB, UKAS, DAkkS, and so on). You can consult the certification body that issued the certificate to confirm its validity and the accreditation body to ensure that the certification body is duly accredited as competent to issue the certification. All accreditation bodies have searchable databases on their websites to provide this information on accredited certification bodies. All accredited certification bodies under the IAF framework are obliged

to provide verification of certificates issued by them. In addition, the IAF has established a centralized database of certificates at https://www.iafcertsearch.org/ in which participation is voluntary. All certificates mentioned in this database can be trusted, but their absence does not necessarily mean the certificate is not authentic. However, the logo of the accreditation body belonging to the IAF's system is a must for a certificate to be credible.

Some PPE may necessitate the use of independent "notified bodies" (or equivalent designations) to demonstrate product conformity. Such bodies are typically "designated" by the regulators in each country or region (see, for example, section 3.1.3). It is essential to verify from the website of the regulator that the notified body issuing the attestations of conformity has been duly designated. It has been found that some certification bodies, which are not designated by the regulators, have been issuing certificates for conformity to technical regulations, such as those that form the basis for applying the EU's CE mark.

- Ensure that any test reports or certificates used to support supplier claims of conformity are issued by a laboratory that is recognized by your government, or ACCREDITED to ISO/IEC 17025 by an accreditation body that is listed on the ILAC website as being a signatory to the ILAC Mutual Recognition Arrangement (MRA). Such certificates will typically (but not always) bear the following mark:

  If in doubt, or where the ILAC logo does not appear, the test report or certificate will show the logo and an identification number of the issuing test laboratory's accreditation body (for example, ANAB, UKAS, and DAkkS). You can consult the test laboratory that issued the test report or certificate to confirm its validity, and the accreditation body to ensure that the test laboratory is duly accredited as competent to carry out the testing (and that the tests performed are within the published scope of their accreditation). All such accreditation bodies are required to have searchable databases to provide this information. Where a test report does not show an accreditation mark, or if the tests are not within the accreditation scope of the test laboratory, the purchaser should proceed with caution. It might still be possible to accept the test report, but in this case the purchaser should contact the laboratory to determine the competence of the laboratory to conduct such tests. Remember, regardless of the logos that appear on a certificate, it is always prudent to check the issuer's accreditation status using the following steps:

  - Start by consulting the ILAC or IAF website
  - Select the appropriate economy (country)
  - Consult the listed accreditation body (bodies) within that economy
  - Locate the laboratory or other conformity assessment body on the accreditation body's website and check the scope and validity of their accreditation

- Depending on the level of confidence they have in the supplier, it may be appropriate for large purchasers to consider subcontracting accredited inspection agencies to conduct independent pre-shipment inspections

- Large purchasers with ongoing contracts with specific suppliers may also find it prudent to undertake their own market surveillance of the PPE they have purchased, by making random checks on quality by testing product samples in an accredited laboratory

- If any problems are encountered with purchased PPE (and in particular regarding its conformity to technical regulations) it is important to provide feedback to the relevant regulators so they can take appropriate actions and make this information available to others.

PART 2
OVERVIEW OF PRODUCT CATEGORIES

This part of the guide provides a generic description of each category of COVID-19-related PPE, and a high-level overview of the standards used in each of the selected markets. More detailed descriptions and comparisons are provided later in Parts 4 and 5–15 of this guide.

Table 2.1 shows at a macro level where national product standards are based on or are similar to versions of other national, regional, or international standards. Links are provided for users to access the detailed information provided in the remainder of Part 2 and in Part 3.

Users are advised to use caution with the comparisons provided throughout Part 2, which necessarily simplify the complex nature of the relationships between the various standards. The reasons for this are explained in more detail in section 1.2 of the guide.

Table 2.1: High-level overview of the basis for PPE standards in each of the selected markets

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

Link to market overview	n/a	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11	3.12	3.13	Link to product details
	ISO	EU	United States	Australia	Brazil	Canada	Colombia	India	Jordan	Kenya	Malaysia	South Africa	UK	Vietnam	
Respirators															2.1.1
Medical face masks															2.1.2
Community face coverings															2.1.3
Face shields															2.2.1
Protective goggles/glasses															2.2.2
Medical examination gloves															2.3.1

Link to market overview	n/a	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11	3.12	3.13	Link to product details
	ISO	EU	United States	Australia	Brazil	Canada	Colombia	India	Jordan	Kenya	Malaysia	South Africa	UK	Vietnam	
Surgical gloves															2.3.2
Suits and coveralls															2.4.1.1
Aprons															2.4.1.2
Shoe and head covers															2.4.1.2
Gowns															2.4.2

Notes:

- In some cases, the market standard mentioned is based on older versions of the EU/US/ISO standard, meaning there may no longer be any equivalence.
- Standards from other countries or regions may be accepted by the relevant authorities in specific markets. These are not included here.
- In some cases, two colors are used to indicate that two product standards are recognized for those product/market combinations.
- Users are referred to the relevant parts of the guide for more detailed information (including testing standards).

2.1 Masks

Masks are generally items worn by the individual on their face which offer protection from the inhalation of hazardous substances. They act as a form of source control to limit the transmission of respiratory aerosols, or both. There are three main types of masks that are used as PPE in the COVID-19 context: respirators, medical face masks and community face coverings (sometimes called barrier face coverings). Respirators can include single-use or reusable half-masks or full-face masks that have replaceable filters.

Figure 2.1: The three main categories of disposable masks

Note: Clause numbers refer to ASTM F3502-21 for barrier face coverings.

Source: ASTM International

Figure 2.2: Typical reusable half- and full-mask respirators[12]

2.1.1 Respirators

Respirators (respiratory protective equipment or filtering facepiece respirators)[13] are considered to be PPE and are normally regulated as such, though in some jurisdictions they are also considered as medical devices. They fit the face tightly and provide certain filtration efficiency levels to help reduce wearer exposure to pathogenic airborne particles in a health care or related exposure setting. They use filters to remove contaminants from the air being breathed in and are thus designed to protect the wearer from breathing harmful substances.

12 https://www.fit2fit.org/wp-content/uploads/2021/04/Essential_technical_specifications_PPE_and_medical_devices-vo.3_Oct2020_accessible.pdf

13 For detailed definitions, see ISO 16972: 2020. "Respiratory protective devices—vocabulary and graphical symbols."

Respirators can be either:

- Non-powered—relying on the wearer's breathing to draw air through the filter
- Powered—using a motor to pass air through the filter to give a supply of clean air, for example, powered air-purifying respirator.

Note: In the context of the COVID-19 pandemic, this benchmarking guide focuses only on disposable/reusable non-powered respirators.

A key component of any respirator is the filter. This can be an integral part of a disposable device or come separately so it can be changed on a reusable respirator. It is vital that the filter is effective against the hazard. For COVID-19 settings this will typically be a high-efficiency (P2) particle filter as defined in Europe or a minimum N95 as established in the United States, which will be suitable for respiratory protection during aerosol-generating procedures or other human activity such as breathing, talking and singing.

Respirator filters, especially those used in disposable respirators, are typically made from three layers but can include additional layers:

- Inner and outer layers of spunbond non-woven fabric
- A middle layer of meltblown fabric

Typical characteristics for respirators:

- Fit
- Total inward leakage
- Filtration efficiency
- Biocompatibility
- Carbon dioxide content
- Breathing resistance (inhalation)
- Breathing resistance (exhalation)

Table 2.2 provides an overview of the main national product standards for respirators in the markets covered by this guide and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 2.2: Overview of the standards for respirators in each of the selected markets

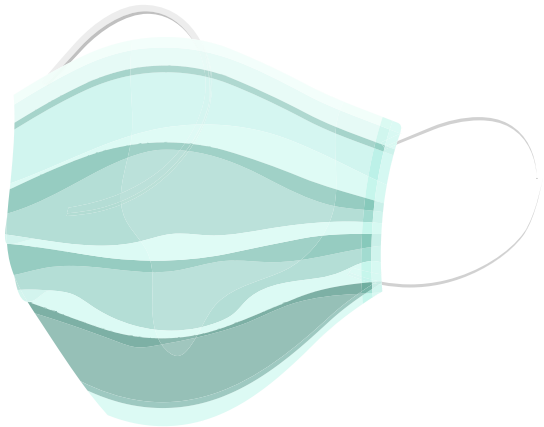
Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- ☐ Blank: No applicable national standard

Market	Main product standards	More details (link)
ISO standards (for comparison)	**ISO 17420-1:2021** Respiratory protective devices (RPD)—performance requirements—Part 1: General **ISO 17420-2:2021** Respiratory protective devices—performance requirements—Part 2: Requirements for filtering RPD	4.1.1.3
EU	**EN 149:2001+A1:2009** RPD—filtering half-masks to protect against particles—requirements, testing, marking **EN 143:2021** Respiratory protective devices— particle filters—requirements, testing, marking	4.1.1.1

United States	**42 CFR 84.170** Air-purifying particulate respirators	4.1.1.2
Australia	**AS/NZS 1712:2012** Respiratory protective devices	5.1.1
Brazil	**ABNT NBR 13698:2011** Respiratory protective devices—filtering half-mask to protect against particles. Based on **EN 149:1992**, since revised **ABNT NBR 13697:2010** Respiratory protective devices—particle filters. Based on **EN 143:2000**, since revised	6.1.1
Canada	**CSA Z94.4:2018** Selection, use and care of respirators	7.1.1
Colombia	**NTC 3852:2020** Respiratory protective devices—filtering half-masks to protect against particles—requirements, testing, marking. Identical to **EN 149:2001 +A1:2009**	8.1.1
	NTC 6486:2020 Respiratory protective devices. For N series respirators, adopts **42 CFR part 84** requirements	
India	**IS 9473:2002 (reaffirmed 2019)** Respiratory protective devices—filtering half-masks to protect against particles—specification. Based on **EN 149:1991 version** (since revised)	9.1.1
Jordan	**JS 1943:2011** Respiratory protective devices—filtering half-masks to protect against particles—requirements, testing, marking. Identical to **EN 149:2001,** since amended	10.1.1
Kenya	**KS 2409-6:2018** Health care wastes management commodities. Specification–Part 6: Filtering face masks to protect against particles. Based on (but not identical to) **EN 149:2001,** since amended	11.1.1
Malaysia	**MS 2323:2010** Respiratory protective devices—filtering half-masks to protect against particles—requirements, testing, marking. Identical to **EN 149:2001,** since amended	12.1.1
South Africa	**SANS 50149:2003** Respiratory protective devices—filtering half-masks to protect against particles—requirements, testing, marking. Identical to **EN 149:2001,** since amended **SANS 50143:2003** Respiratory protective devices - Particle filters - Requirements, testing, marking. Identical to **EN 143:2000**, since revised	13.1.1
UK	**BS EN 149:2001 +A1:2009** RPD—filtering half-masks to protect against particles—requirements, testing, marking **BS EN 143:2021** Respiratory protective devices—particle filters—requirements, testing, marking	14.1.1
Vietnam	n/a	15.1.1

2.1.2 Medical face masks



This is a mask that covers the user's nose and mouth primarily for the purposes of source control, that is, limiting the number of droplets that can be expelled from the wearer that can contaminate others. Medical face masks include surgical masks (having ties to allow adjustment) and procedure or isolation masks (having ear loops) which provide a physical barrier to fluids and particulate materials. The main intended use of medical face masks is to minimize transfer of infectious agents by large-particle droplets between health care staff and a patient during surgical procedures and other medical/health care settings with similar requirements.

Although these are generally considered to be medical devices, they are often used as community masks, worn by patients and other persons to reduce the risk of spreading infections, particularly in epidemic or pandemic situations.

The materials used for medical masks are typically the same as those for respirators—inner and outer layers of spunbond non-woven fabric with a middle layer of meltblown fabric that often has a lower filtration efficiency compared to those used in respirator filters.

Typical characteristics for medical face masks:

- Bacterial filtration efficiency (BFE)
- Sub-micron particulate filtration efficiency using a different size particle and test conditions than used for respirators
- Fluid (splash) resistance
- Microbial cleanliness (bioburden)
- Biocompatibility
- Breathability
- Internal and external faces clearly identified (sometimes by color)
- Generally only provided in a single size

Table 2.3 provides an overview of the main national product standards for medical face masks in the markets covered by this guide and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 2.3: Overview of the standards for medical face masks in each of the selected markets

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

Market	Main product standards	More details (link)
ISO standards (for comparison)	n/a	-
EU	**EN 14683:2019** Medical face masks—requirements and test methods	4.1.2.1
United States	**ASTM F2100-21** Standard specification for performance of materials used in medical face masks	4.1.2.2
Australia	**AS 4381:2015** Single-use face masks for use in health care	5.1.2
Brazil	**ABNT NBR 15052:2021** Masks for dental-medical-hospital use—requirements and test methods	6.1.2
Canada	n/a	7.1.2
Colombia	**NTC 1733:2020** Medical face masks—requirements and test methods. Identical to **EN 14683:2019**	8.1.2
	NTC 6436:2020 Standard specification for performance of materials used in medical face masks. Identical to **ASTM F2100-20**, since revised	
India	**IS 16289:2014 (reaffirmed 2019)** Medical textiles—surgical face masks—specification	9.1.2
Jordan	**JS 1745:2007** Disposable surgical masks—requirement and test methods. Based on **EN 14683:2005**, since revised	10.1.2

Kenya	**KS 2636:2021** Medical face masks—specification. Based on (but not identical to) **EN 14683:2019**	11.1.2
Malaysia	**MS EN 14683:2021** Medical face masks—requirements and test methods. Identical to **EN 14683:2019**	12.1.2
South Africa	**SANS 1866-1:2018** Medical devices. Part 1: Medical face masks. Based on **ASTM F2100**, most recently revised in 2021 **SANS 1866-2:2018** Medical devices. Part 2: Medical respirators. Based on **ASTM F2100** and **42 CFR part 84**	13.1.2
UK	**BS EN 14683:2019** Medical face masks—requirements and test methods	14.1.2
Vietnam	**TCVN 8389-1: 2010** Medical face mask. Part 1: Normal medical face mask **TCVN 8389-2:2010** Medical face mask. Part 2: Medical face mask preventing bacteria	15.1.2

2.1.3 Community face coverings[14]

These are neither PPE (in the strict sense) nor medical devices. They are not usually subject to regulations other than those for general product safety.

Typical characteristics for community face coverings:

- Covers wearer's nose and mouth
- Offers good breathability
- Has some level of filtration efficiency as established by a specific test (either particulate or bacterial)
- Internal and external faces should be clearly identified
- Can be single-use or reusable
- May be offered in different sizes

Table 2.4 provides an overview of the main national product standards for community face coverings in the markets covered by this guide and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 2.4: Overview of the standards for community face coverings in each of the selected markets

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

Market	Main product standards	More details (link)
Relevant ISO standards	n/a	-
EU	**CWA 17553:2020** Community face coverings—guide to minimum requirements, methods of testing and use	4.1.3.1

14 Sometimes referred to as "community face masks," "barrier face coverings," or (in everyday speech and by the media) as "face masks."

United States	**ASTM F3502-21** Standard specification for barrier face coverings **AATCC M14** Guidance and considerations for general purpose textile face coverings	4.1.3.2
Australia	n/a	5.1.3
Brazil	**ABNT PR 1002:2020 Edition 2** Masks for non-professional respiratory protection—guide with basic requirements for testing, manufacture and use	6.1.3
Canada	**BNQ 1922-900:2020** Masks intended for working environments—Attestation Document (for Province of Québec)	7.1.3
Colombia	**NTC 6449:2020** Masks (face masks) for use in environments other than the health sector	8.1.3
India	n/a	9.1.3
Jordan	n/a (under development)	10.1.3
Kenya	**KS 2924:2020** Personal protective equipment—face masks—masks for public use—specification	11.1.3
Malaysia	n/a	12.1.3
South Africa	n/a (under development)	13.1.3
UK	**BSI Flex 5555:2021** Community face coverings—specification	14.1.3
Vietnam	n/a	15.1.3

2.2 Eye and face protection[15]

Eye/face protection for COVID-19 settings is designed to protect the wearers' eyes and face from splashes and droplets of biological fluids. The two main types of protection are protective glasses/goggles and face shields.

2.2.1 Protective goggles/glasses

These are typically made with a flexible plastic frame and one or two lenses[16] with a flexible elastic headband. They provide barrier protection to the eyes against exposure to liquid droplets and splashes. Protective goggles are distinguished from protective glasses in providing better coverage (protection) to the wearer's face around the lens of the goggles, whereas protective glasses generally only provide direct (straight-on) and side protection. Protective goggles also come as different types which may have ventilation holes for the prevention of fogging.

Typical characteristics for protective goggles/glasses:

- Clear lens with anti-fog and scratch-resistant treatments
- Lenses are free from defects that could impair the wearer's vision
- Easily fit face contours with even pressure
- Enclose eyes and the surrounding areas (side shields only for protective glasses)
- Accommodate wearers with needs for prescription lenses
- Have adjustable band to secure firmly so as not to become loose during clinical activity
- May include direct or indirect venting to avoid fogging
- Provide impact resistance
- May also shield from droplets/splashes

15 For detailed definitions, see ISO 4007: 2018, "Personal protective equipment—eye and face protection—vocabulary."

16 For the purposes of eye and face protection, the word "lens" includes afocal lenses, corrective lenses, and prescription lenses.

Figure 2.3: Safety glasses and non-ventilated goggles

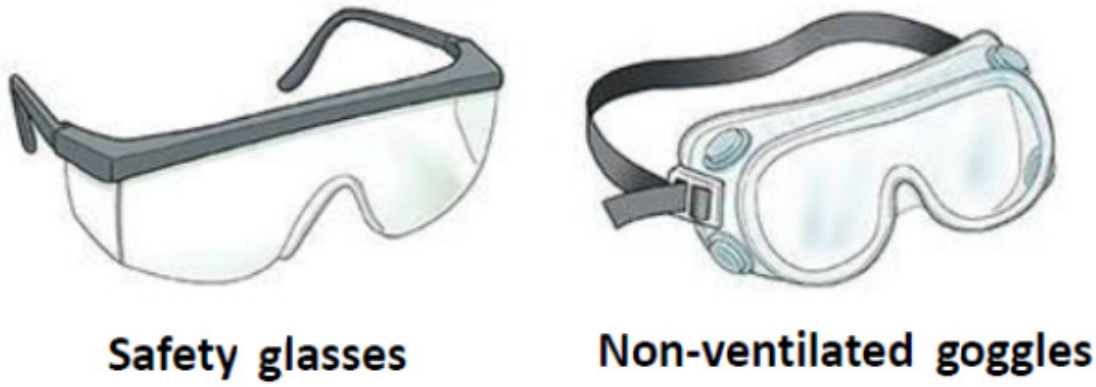


Table 2.5 provides an overview of the main national product standards for protective goggles/glasses in the markets covered by this guide and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 2.5: Overview of the standards for protective goggles/glasses in each of the selected markets

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

Market	Main product standards	More details (link)
ISO standards (for comparison)	**ISO 16321-1:2021** Eye and face protection for occupational use—Part 1: General requirements	4.2.3
EU	**EN 166:2001** Personal eye-protection—specifications	4.2.1
United States	**ANSI/ISEA Z87.1-2020** Occupational and educational personal eye and face protection devices **ANSI/ISEA Z87.62-2021** American national standard for occupational and educational personal eye and face protection devices for preventing exposures caused by sprays or spurts of blood or body fluids	4.2.2
Australia	**AS/NZS 1337.1:2010 (+ AMDT 1:2012 + AMDT 2:2018)** Personal eye-protection—Part 1: Eye and face protectors for occupational applications. Based on (but not identical to) **EN 166**	5.2
Brazil	n/a (Legislation refers to **ANSI Z87.1:2015**)	6.2
Canada	**CSA Z94.3-2020 (revised May 2021)** Eye and face protectors **CSA Z94.3.1-2016** Guideline for selection, use, and care of eye and face protectors	7.2

Colombia	**NTC 6493:2020** Individual eye protection. Specifications. Identical to **EN 166:2001**	8.2
	NTC 3610:2020 Eye and face personal protection devices at work and education. Identical to **ANSI/ISEA Z87.1: 2015**, since revised	
India	**IS 5983:1980 (reaffirmed 2018)** Specification for eye protectors. Based on **ISO 4849**, since replaced by **ISO 16321-1**	9.2
Jordan	**JS 268:2008** Personal eye-protection—specifications. Identical to **EN 166:2001**	10.2
Kenya	**KS 2409-8:2018** Health care wastes management commodities. Specification—Part 8: Safety goggles. References **ISO 4849**, since replaced by **ISO 16321-1**	11.2
Malaysia	n/a	12.2
South Africa	**SANS 50166:2002** Personal eye-protection—specifications. Identical to **EN 166:2001**	13.2
	SANS 1404:2009 Eye-protectors for industrial and non-industrial use	
UK	**BS EN 166:2002** Personal eye-protection—specifications	14.2
Vietnam	n/a	15.2

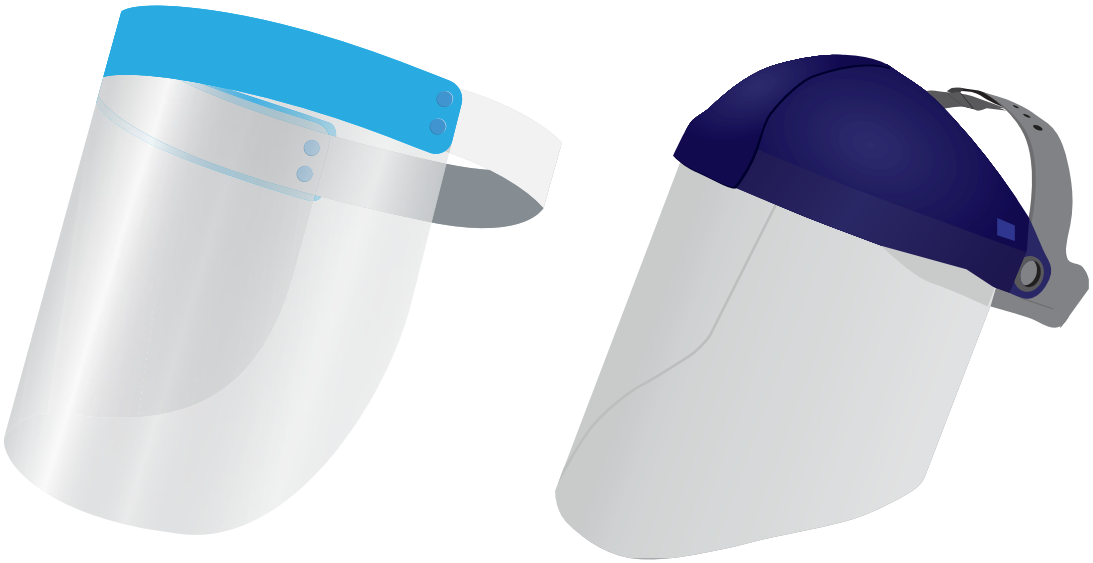
2.2.2 Face shields

These have one large visor with a frame and an adjustable head harness or are mounted on a helmet. Most can be worn with prescription glasses. They provide barrier protection against liquid splashes to the face but do not fully enclose the eyes. These products may be rugged and reusable or disposable in nature depending on their materials and design. Face shields may also be integrated into some types of medical masks as a disposable transparent layer that rises above the individual wearer's nose.

Typical characteristics of face shields:

- Made of clear plastic and providing good visibility to both the wearer and the patient
- Potentially have adjustable band or headgear to attach firmly around the head and fit snugly against the forehead
- May be fog resistant (preferable)
- Completely cover the sides and length of the face
- May be reusable (made of robust material which can be cleaned and disinfected) or disposable

Figure 2.4: Disposable and industrial face shields



Disposable face shield **Industrial face shield**

Table 2.6 provides an overview of the main national product standards for face shields in the markets covered by this guide and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 2.6: Overview of the standards for face shields in each of the selected markets

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

Market	Main product standards	More details (link)
ISO standards (for comparison)	**ISO 16321-1:2021** Eye and face protection for occupational use—Part 1: General requirements	4.2.3
EU	**EN 166:2001** Personal eye-protection—specifications	4.2.1
United States	**ANSI/ISEA Z87.1:2020** American national standard for occupational and educational personal eye and face protection devices **ANSI/ISEA Z87.62-2021** American national standard for occupational and educational personal eye and face protection devices for preventing exposures caused by sprays or spurts of blood or body fluids	4.2.2
Australia	**AS/NZS 1337.1:2010 (+ AMDT 1:2012 + AMDT 2:2018)** Personal eye-protection—Part 1: Eye and face protectors for occupational applications. Based on (but not identical to) **EN 166**	5.2
Brazil	**ABNT PR 1009:2021** Face protection for health care applications—guide with basic requirements for testing, manufacture, and use. Based on **ANSI Z87.1:2015**	6.2
Canada	**CSA Z94.3-2020 (revised May 2021)** Eye and face protectors **CSA Z94.3.1-2016** Guideline for selection, use, and care of eye and face protectors	7.2
Colombia	**NTC 6493:2020** Individual eye protection—specifications. Identical to **EN 166:2001** **NTC 3610:2020** Eye and face personal protection devices at work and education. Identical to **ANSI/ISEA Z87.1: 2015**	8.2
India	**IS 5983:1980 (reaffirmed 2018)** Specification for eye protectors. Based on **ISO 4849**, since replaced by **ISO 16321-1** **IS 8521-1:1977 (reaffirmed 2018)** Specification for industrial face shields—Part 1: With plastic visor	9.2
Jordan	**JS 268:2008** Personal eye protection—specifications. Identical to **EN 166:2001**	10.2
Kenya	**KPAS 2919:2020** Personal protective equipment—face shield—specification	11.2
Malaysia	n/a	12.2
South Africa	**SANS 50166:2002** Personal eye protection—specifications. Identical to **EN 166:2001** **SANS 1404:2009** Eye protectors for industrial and non-industrial use	13.2
UK	**BS EN 166:2002** Personal eye protection—specifications	14.2
Vietnam	n/a	15.2

2.3 Gloves

Although different countries use slightly different names to describe the various kinds of gloves that are used as COVID-19-related PPE, the two main categories considered in this guide are medical examination gloves and surgical gloves, both for single use. The definition of medical gloves for single use given in the standard EN 455-1[17] is "gloves intended for use in the medical field to protect patient and user from cross-contamination; intended to be used on one individual during a single procedure."

2.3.1 Medical examination gloves

The standard EN 455-2 defines an examination glove (sometimes called a procedure glove) as a "sterile or non-sterile medical glove, which may or may not be anatomically shaped, intended for conducting medical examinations, diagnostic, and therapeutic procedures and for handling contaminated medical material." These products are also a primary precaution for contact with any contaminated surfaces by the wearer. The gloves are generally very thin in order to fit intimately on the wearer's hand and to have minimal impact on hand function.

Medical examination gloves are typically produced as non-sterile, powder-free single-use gloves made from nitrile, latex, polychloroprene or PVC, with a total length that extends past the wearer's wrists and thicknesses ranging from 0.05 mm to 0.25 mm. They are typically produced in sizes S (small), M (medium), or L (large) and often are of an ambidextrous design.

Typical characteristics for medical examination gloves:

- Provide freedom from holes
- Tensile properties for breaking strength and elongation
- Often free of powder residue
- Non-irritating for the skin
- Offered in multiple sizes and are ambidextrous

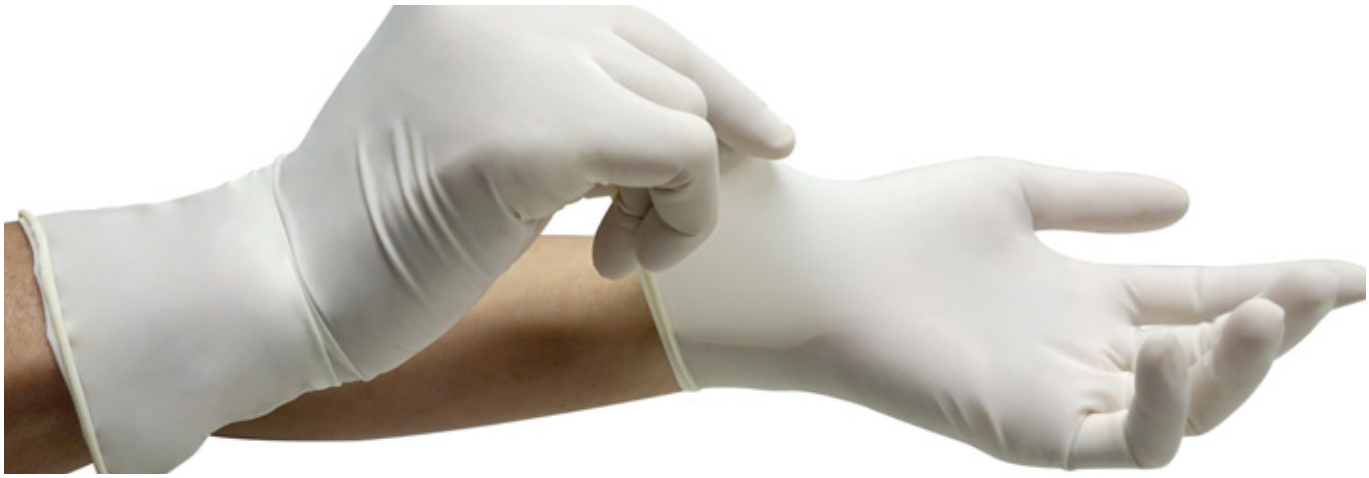


Table 2.7 provides an overview of the main national product standards for medical examination gloves in the markets covered by this guide and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

17 EN 455-1: 2020. "Medical gloves for single-use—Part 1: Requirements and testing for freedom from holes."

Table 2.7: Overview of the standards for medical examination gloves in each of the selected markets

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

Market	Main product standards	More details (link)
ISO standards (for comparison)	**ISO 11193-1:2020** Single-use medical examination gloves—Part 1: Specification for gloves made from rubber latex or rubber solution **ISO 11193-2:2006** Single-use medical examination gloves—Part 2: Specification for gloves made from poly(vinyl chloride) **ISO 21420:2020** Protective gloves–general requirements and test methods **ISO 374-5:2016** Protective gloves against dangerous chemicals and micro-organisms—requirements for micro-organisms risks	4.3.1.3
EU	**EN 455 series** (Medical gloves for single use) **EN 455-1: 2020** Requirements and testing for freedom from holes **EN 455-2: 2015** Requirements and testing for physical properties **EN 455-3: 2015** Requirements and testing for biological evaluation **EN 455-4: 2009** Requirements and testing for shelf-life determination **EN ISO 21420:2020** Protective gloves—general requirements and test methods **EN ISO 374-5: 2016** Protective gloves against dangerous chemicals and micro-organisms - Requirements for micro-organisms risks	4.3.1.1
United States	**ASTM D5250-19** Standard specification for poly(vinyl chloride) gloves for medical application **ASTM D6319-19** Standard specification for nitrile examination gloves for medical application **ASTM D3578-19** Standard specification for rubber examination gloves **ASTM D6977-19** Standard specification for polychloroprene examination gloves **NFPA 1999 (2018)** Standard on protective clothing and ensembles for emergency medical operations **ANSI/ISEA 105-2016** American national standard for hand protection classification	4.3.1.2
Australia	**AS/NZS 4011.1:2014** Single-use medical examination gloves–Part 1: Specification for gloves made from rubber latex or rubber solution. Adopted with national modifications from **ISO 11193-1:2008**, since revised **AS/NZS 4011.2:2014** Single-use medical examination gloves—Part 2: Specification for gloves made from poly(vinyl chloride. Adopted with national modifications from **ISO 11193-2:2006**	5.3.1
Brazil	**ABNT NBR ISO 11193-1:2015** Single-use medical examination gloves (rubber latex/rubber). Identical to **ISO 11193-1:2008 + AMD 1:2012**, since revised **ABNT NBR ISO 11193-2:2013** Single-use medical examination gloves (poly[vinyl chloride]). Identical to **ISO 11193-2:2006**	6.3.1
Canada	n/a	7.3.1
Colombia	**NTC-ISO 11193-1:2020** Single-use medical examination gloves—Part 1: Specification for gloves made from rubber latex or rubber solution). Identical to **ISO 11193-1: 2008** (since revised) **NTC-ISO 11193-2:2020** Single-use medical examination gloves. Part 2: Specification for gloves made from poly(vinyl chloride). Identical to **ISO 11193-2:2006**	8.3.1

India	**IS 15354-1:2018** Single-use medical examination gloves—Part 1: Specification for gloves made from rubber latex or rubber solution. Identical to **ISO 11193-1: 2008** (since revised) **IS 15354-2:2018** Single-use medical examination gloves—Part 2: Specification for gloves made from poly(vinyl chloride). Identical to **ISO 11193-2: 2006**	9.3.1
	IS 6994-7:2021 Protective gloves—general requirements and test methods. Identical to **ISO 21420:2020** **IS 6994-5: 2021** Protective gloves against dangerous chemicals and micro-organisms—requirements for micro-organisms risks. Identical to **ISO 374-5:2016**	
Jordan	**JS 809 series** (Medical gloves for single use) **JS 809-1:2005** Requirements and testing for freedom from holes. Identical to **EN 455-1:2000** (since revised) **JS 809-2: 2014** Requirements and testing for physical properties. Identical to **EN 455-2:2009** (since revised) **JS 809-3: 2014** Requirements and testing for biological evaluation. Identical to **EN 455-3: 2006** (since revised) **JS 809-4: 2014** Requirements and testing for shelf-life determination. Identical to **EN 455-4: 2009**	10.3.1
Kenya	**KS ISO 11193-1:2020** Single-use medical examination gloves—Part 1: Specification for gloves made from rubber latex or rubber solution). Identical to **ISO 11193-1:2008** with **AMD1: 2012** (since revised) **KS ISO 11193-2:2006** Single-use medical examination gloves. Part 2: Specification for gloves made from poly(vinyl chloride). Identical to **ISO 11193-2:2006** (current)	11.3.1
Malaysia	**MS 2299-1:2010** Medical gloves for single use—Part 1: Requirements and testing for freedom from holes. Identical to **EN 455-1:2000**, (since revised) **MS 2299-3:2010** Medical gloves for single use—Part 3: Requirements and testing for biological evaluation. Identical to **EN 455-3:2006** (since revised)	12.3.1
South Africa	**SANS 11193-1:2010**, Single-use medical examination gloves—Part 1: Specification for gloves made from rubber latex or rubber solution). Identical to **ISO 11193-1: 2008** (since revised)	13.3.1
UK	**BS EN 455 series** (Medical gloves for single use) **BS EN 455-1: 2020** Requirements and testing for freedom from holes **BS EN 455-2: 2015** Requirements and testing for physical properties **BS EN 455-3: 2015** Requirements and testing for biological evaluation **BS EN 455-4: 2009** Requirements and testing for shelf-life determination **BS EN ISO 21420:2020** Protective gloves—general requirements and test methods **BS EN ISO 374-5: 2016** Protective gloves against dangerous chemicals and micro-organisms—requirements for micro-organisms risks	14.3.1
Vietnam	**TCVN 6343-1:2007** Single-use medical examination gloves—Part 1: Specification for gloves made from rubber latex or rubber solution. Identical to **ISO 11193-1: 2002** with **AMD 1: 2007** (since revised) **TCVN 6343-2:2007** Single-use medical examination gloves. Part 2: Specification for gloves made from poly(vinyl chloride) Identical to **ISO 11193-2:2006** (current) **TCVN 12326-5:2018** Protective gloves against dangerous chemicals and micro-organisms—Part 5: Terminology and performance requirements for micro-organisms risks. Identical to **ISO 374-5:2016** (current)	15.3.1

2.3.2 Surgical gloves

The standard EN 455-2 defines a surgical glove as a "sterile, anatomically shaped medical glove with the thumb positioned toward the palmar surface of the index finger rather than lying flat and intended for use in invasive surgery." Many surgical gloves also make claims as PPE, protecting the wearer from infective agents, aggressive medical chemicals, and pharmaceuticals for chemotherapy. These will comply with EN 420 (replaced by EN ISO 21420), EN ISO 374-1, and EN 374-5, as well as EN 388 where claims of mechanical protection are made.

The standard ISO 10282:2014[18] describes two main types of surgical gloves: those made primarily from natural rubber latex and those made primarily from nitrile rubber latex, isoprene rubber latex, polychloroprene rubber latex, styrene-butadiene rubber solution, styrene-butadiene rubber emulsion, or thermoplastic elastomer solution. They normally have long cuffs that ideally reach to the mid-forearm and a minimum thickness of 0.10 mm. They come in a wide range of sizes and are of a hand-specific design.

Typical characteristics for surgical gloves:

- Provide a higher level of integrity (freedom from holes) compared to examination gloves
- Anatomically designed (more precise range of sizing than medical examination gloves)
- Tensile properties generally higher than for medical examination gloves
- Free of powder residue
- Biocompatible
- Non-irritating for the skin

Regardless of the material, it is generally accepted that surgical gloves are provided in a sterile condition for use in surgical procedures, whereas examination gloves are used in non-surgical procedures and are not usually sterile. They are all medical gloves, but the level of dexterity needed for examination gloves means that their design is often less anatomically shaped and can include flat stamped gloves.

Table 2.8 provides an overview of the main national product standards for surgical gloves in the markets covered by this guide and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

18 ISO 10282:2014. "Single-use sterile rubber surgical gloves—specification."

Table 2.8: Overview of the standards for surgical gloves in each of the selected markets

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

Market	Main product standards	More details (link)
ISO standards (for comparison)	**ISO 10282:2014** Single-use sterile rubber surgical gloves—specification **ISO 21420:2020** Protective gloves—general requirements and test methods **ISO 374-5:2016** Protective gloves against dangerous chemicals and micro-organisms—requirements for micro-organisms risks	4.3.2.3
EU	**EN 455 series** (Medical gloves for single use) **EN 455-1: 2020** Requirements and testing for freedom from holes **EN 455-2: 2015** Requirements and testing for physical properties **EN 455-3: 2015** Requirements and testing for biological evaluation **EN 455-4: 2009** Requirements and testing for shelf-life determination **EN ISO 21420:2020** Protective gloves—general requirements and test methods **EN ISO 374-5:2016** Protective gloves against dangerous chemicals and micro-organisms—requirements for micro-organisms risks	4.3.2.1
United States	**ASTM D3577 – 19** Standard specification for rubber surgical gloves	4.3.2.2
Australia	**AS/NZS 4179:2014** Single-use sterile rubber surgical gloves—specification. Adopted with national modifications from **ISO 10282:2014**	5.3.2
Brazil	**ABNT NBR ISO 10282:2014** Single-use sterile rubber surgical gloves	6.3.2
Canada	n/a	7.3.2
Colombia	n/a	8.3.2
India	**IS 13422:1992 (reaffirmed 2018)** Disposable surgical gloves specification. Based on **ASTM D3577-88** (since revised) **IS 6994-7:2021** Protective gloves—general requirements and test methods. Identical to **ISO 21420:2020** **IS 6994-5: 2021** Protective gloves against dangerous chemicals and micro-organisms—requirements for micro-organisms risks. Identical to **ISO 374-5:2016**	9.3.2
Jordan	**JS 809 series** (Medical gloves for single use) **JS 809-1:2005** Requirements and testing for freedom from holes. Identical to **EN 455-1:2000** (since revised) **JS 809-2: 2014** Requirements and testing for physical properties. Identical to **EN 455-2:2009** (since revised) **JS 809-3: 2014** Requirements and testing for biological evaluation. Identical to **EN 455-3: 2006** (since revised) **JS 809-4: 2014** Requirements and testing for shelf-life determination. Identical to **EN 455-4: 2009**	10.3.2
Kenya	**KS ISO 10282:2014** Single-use sterile rubber surgical gloves. Identical to **ISO 10282:2014** (current)	11.3.2
Malaysia	**MS 2299-1:2010** Medical gloves for single use—Part 1: Requirements and testing for freedom from holes. Identical to **EN 455-1:2000**, (since revised) **MS 2299-3:2010** Medical gloves for single use—Part 3: Requirements and testing for biological evaluation. Identical to **EN 455-3:2006** (since revised)	12.3.2
South Africa	**SANS 68:2003** Single-use sterile rubber surgical gloves. Identical to **ISO 10282:2002** (since revised)	13.3.2
UK	**BS EN 455 series** (Medical gloves for single use) **BS EN 455-1: 2020** Requirements and testing for freedom from holes **BS EN 455-2: 2015** Requirements and testing for physical properties **BS EN 455-3: 2015** Requirements and testing for biological evaluation **BS EN 455-4: 2009** Requirements and testing for shelf-life determination **BS EN ISO 21420:2020** Protective gloves—general requirements and test methods **BS EN ISO 374-5: 2016** Protective gloves against dangerous chemicals and micro-organisms—requirements for micro-organisms risks	14.3.2
Vietnam	**TCVN 6344:2007** Single-use sterile rubber surgical gloves. Identical to **ISO 10282:2002** (since revised)	15.3.2

2.4 Clothing

In the case of protective clothing, the ways in which requirements are specified in different parts of the world can vary significantly. Some standards are generic and apply to all kinds of protective clothing, while others are aimed at specific sub-categories. Test methods, such as those for protection against infective agents using synthetic blood, are often common to all categories. For example, ASTM F1670/F1670M[19] (resistance to penetration by synthetic blood) applies to "finished items of protective clothing including gloves, arm shields, aprons, gowns, coveralls, hoods, and boots."

Typical characteristics for (most types of) clothing:

- Innocuousness (absence of allergenic/ carcinogenic substances; azo dyes that are often used to treat textiles)
- Designs offer comfort/freedom of movement
- Some materials may be breathable
- Aging resistance (dimensional change after cleaning and legibility of marking for reusable products)
- Mechanical properties (tensile strength, abrasion, puncture, tear and flex-cracking resistance)
- Penetration resistance to infective agents
- Requirements for seams, joins and assemblages (strength and resistance to penetration by liquids)
- May also offer chemical resistance (permeation by chemicals, repellence of and penetration by liquids)
- Not of a highly flammable nature

This guide has taken the approach of separating clothing into two main categories, as follows:

- Full-body and partial-body (PB) garments, which are typically regulated as PPE and addressed by common (generic) standards:
  - Full-body garments include protective suits and coveralls
  - Partial-body garments include aprons and shoe/head covers
- Surgical/isolation gowns (which are covered by medical device regulations in most jurisdictions).

19 ASTM F1670/F1670M -17a. "Standard test method for resistance of materials used in protective clothing to penetration by synthetic blood."

Note: One type of clothing often referred to in the general health care context is "surgical scrubs" that may be worn under protective clothing. According to WHO recommendations these are considered to be regular "on-duty" wear and not PPE.

2.4.1 Full-body and partial-body garments

2.4.1.1 Full-body garments (including protective suits/coveralls)

There are no internationally recognized COVID-19-specific definitions of these garments, but the following can be considered to apply:

- (From standard ISO 16602[20]) "Chemical protective suit—clothing worn to protect against chemicals that covers the whole, or greater part of the body

  Note 1: A chemical protective suit can consist of garments combined together to provide protection to the body. A suit can also have various types of additional protection such as hood or helmet, boots, and gloves joined with it.

  Note 2: These garments are full-body protective clothing, that is, covering trunk, arms, and legs, such as one-piece coveralls or two-piece suits, with or without hood or visors, with or without foot protection."

  Chemical protective clothing can be effective against infective agents when additional testing is performed, for example, to ISO 16603, ISO 16604, ISO 22610, ISO/DIS 22611 or ISO 22612.

  Most coveralls have a zipper in the front.

- (From Indian Standard IS 17423:2021[21]) "Bio-protective coverall is a type of personal protective equipment intended to be worn by health care personnel for the purpose of isolating all parts of the body from a potential hazard."

Table 2.9 provides an overview of the main national product standards for full-body garments in the markets covered by this guide and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

20 ISO 16602: 2007 (amended in 2012). "Protective clothing for protection against chemicals—classification, labeling and performance requirements."

21 Bureau of Indian Standards. IS 17423:2021. "Medical textiles—bio-protective coveralls—specification."

Table 2.9: Overview of the standards for full-body garments in each of the selected markets

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

Market	Main product standards	More details (link)
ISO standards (for comparison)	**ISO 13688:2013 + AMD 1:2021** Protective clothing—general requirements **ISO 16602:2007+AMD 1:2012** Protective clothing for protection against chemicals—classification, labeling and performance requirements	4.4.1.3
EU	**EN ISO 13688:2013 + A1:2021** Protective clothing—general requirements **EN 14126:2003** Protective clothing—performance requirements and tests methods for protective clothing against infective agents **EN 13034:2005+A1:2009** Protective clothing against liquid chemicals—performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment) **EN 14605:2005 +A1:2009** Protective clothing against liquid chemicals—performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])	4.4.1.1
United States	**NFPA 1999 (2018)** Standard on protective clothing and ensembles for emergency medical operations	4.4.1.2
Australia	**AS/NZS 4501.2:2006** Occupational protective clothing—Part 2: General requirements. Identical adoption of **EN 340:2004** (since replaced by **EN ISO 13688 + A1:2021**)	5.4.1
Brazil	**ABNT NBR 16693:2018** Textile products for health—non-surgical gowns and private clothing used for non-surgical procedure professionals and patients—requirements and test methods	6.4.1
Canada	n/a	7.4.1
Colombia	**NTC 6434:2020** Protective clothing. Requirements and test methods for clothing protection against biological agents. Identical to **EN 14126:2003** (current) **NTC-EN 14605:2020** Protective clothing against liquid chemicals. Requirements performance for clothing with liquid-tight seams (Type 3) or with spray-tight joints (Type 4), including garments that offer protection only to certain parts of the body (Types PB [3] and PB [4]). Identical to **EN 14605:2005+A1:2009** (current) **NTC-EN 13034:2020** Protective clothing against liquid chemicals. Requirements performance for chemical protective clothing that offers protection limited against liquid chemicals (Type 6 and PB [6] equipment). Identical to **EN 13034:2005+A1:2009** (current)	8.4.1
India	**IS 17423:2021** Medical textiles—bio-protective coveralls—specification	9.4.1
Jordan	**JS 1899:2009** Protective clothing for protection against chemicals—classification, labeling, and performance requirements. Identical to **ISO 16602:2007,** since amended	10.4.1
Kenya	**KS ISO 13688:2013** Protective clothing—general requirements. Identical to **ISO 13688:2013,** since amended. **KS 2409-07:2018** Health care wastes management commodities Part 7: Overall clothings—specification	11.4.1
Malaysia	**MS ISO 13688:2020** Protective clothing—general requirements. Identical to **ISO 13688:2013**, since amended	12.4.1
S. Africa	n/a	13.4.1
UK	**BS EN ISO 13688:2013+A1:2021** Protective clothing—general requirements **BS EN 14126:2003** Protective clothing—performance requirements and tests methods for protective clothing against infective agents **BS EN 13034:2005+A1:2009** Protective clothing against liquid chemicals—performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Types 6 and PB [6] equipment) **BS EN 14605:2005 +A1:2009** Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])	14.4.1

Vietnam	**TCVN 6689:2021** Protective clothing - General requirements. Identical to **ISO 13688:2013 + AMD1:2021**	15.4.1

2.4.1.2 Partial-body garments

Aprons

There is no international product-specific standard for aprons, so these are normally considered under more generic PPE performance standards and regulations. In particular, aprons can claim to offer partial-body protection (denoted as PB in ISO 16602) according to that standard, or EN 14126, which is more specific for health care environments. Alternatively, apron manufacturers can demonstrate compliance of their product directly with the essential health and safety requirements of the PPE Regulation in Europe (sections 1 and 2 of Annex II of the regulation). A common definition of an apron is "an outer garment covering the front of the body for protection of clothing during surgery or certain nursing procedures."[22]

Aprons can be further divided into three sub-categories:[23]

I. Heavy-duty aprons, typically made of 100 percent polyester with a PVC coating, 100 percent PVC, 100 percent rubber, 100 percent reusable and biodegradable material, or other fluid-resistant coated material. They are waterproof, with a sewn strap for neck and back fastening or made from single material cut film. They are typically reusable (provided appropriate arrangements for decontamination are in place) or biodegradable.

II. Light-duty single-use straight sleeveless and seamless protective aprons that are stain resistant and liquid-proof (resistant to water and disinfectant [70 percent ethanol and 0.05 percent chlorine solution]).

III. Thumb-looped aprons, intended to be used in situations where exposure to splashes, droplets and fluids containing infectious agents or chemicals is likely. A thumb-looped apron is made from a plastic, such as low-density polyethylene, constructed in a similar manner to a gown and has thumb loops to ensure that the cuff remains in place during use and when, for example, gloves are donned. Thumb-looped aprons are usually non-sterile and are also referred to as thumb-looped gowns.

Light-duty aprons and thumb-looped aprons are unlikely to pass the mechanical requirements of ISO 16602 or other PPE clothing standards and so may be the subject of a local technical specification in order to demonstrate compliance. The EU has made clear that these cannot be used as PPE, but the UK's National Health Service, for example, has developed its own technical requirements to satisfy national regulations.

Typical heavy-weight apron

Typical light-weight apron

Typical thumb-looped apron

Table 2.10 provides an overview of the main national product standards for aprons in the markets covered by this guide and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

22 As defined in The Free Dictionary, https://medical-dictionary.thefreedictionary.com/apron.

23 World Health Organization. November 2020. *Technical Specifications of Personal Protective Equipment for COVID-19*. Interim Guidance, 13.

Table 2.10: Overview of the standards for aprons in each of the selected markets

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

Market	Main product standards	More details (link)
ISO standards (for comparison)	**ISO 13688:2013 + AMD 1:2021** Protective clothing—general requirements **ISO 16602:2007+AMD 1:2012** Protective clothing for protection against chemicals—classification, labeling and performance requirements	4.4.1.3
EU	**EN ISO 13688:2013+A1:2021** Protective clothing—general requirements **EN 14126:2003** Protective clothing—performance requirements and tests methods for protective clothing against infective agents **EN 13034:2005+A1:2009** Protective clothing against liquid chemicals—performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment) **EN 14605:2005 +A1:2009** Protective clothing against liquid chemicals—performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])	4.4.1.1
United States	**NFPA 1999 (2018)** Standard on protective clothing and ensembles for emergency medical operations	4.4.1.2
Australia	**AS/NZS 4501.2:2006** Occupational protective clothing—Part 2: General requirements. Identical adoption of **EN 340:2004** (since replaced by **EN ISO 13688 + A1:2021**)	5.4.1
Brazil	**ABNT NBR 16693:2018** Textile products for health—non-surgical gowns and private clothing used for non-surgical procedure professionals and patients—requirements and test methods	6.4.1
Canada	n/a	7.4.1
Colombia	**NTC 6434:2020** Protective clothing. Requirements and test methods for clothing protection against biological agents. Identical to **EN 14126:2003** (current) **NTC-EN 14605:2020** Protective clothing against liquid chemicals. Requirements performance for clothing with liquid-tight seams (Type 3) or with spray-tight joints (Type 4), including garments that offer protection only to certain parts of the body (Types PB [3] and PB [4]). Identical to **EN 14605:2005+A1:2009** (current) **NTC-EN 13034:2020** Protective clothing against liquid chemicals. Requirements performance for chemical protective clothing that offers protection limited against liquid chemicals (Types 6 and PB [6] equipment). Identical to **EN 13034:2005+A1:2009** (current)	8.4.1
India	n/a	9.4.1
Jordan	**JS 1899:2009** Protective clothing for protection against chemicals—classification, labeling, and performance requirements. Identical to **ISO 16602:2007,** since amended	10.4.1
Kenya	**KS 2409-3:2018** Health care wastes management commodities. Specification- Part 3: Plastic apron	11.4.1
Malaysia	**MS ISO 13688:2020** Protective clothing—general requirements. Identical to **ISO 13688:2013**, since amended	12.4.1
South Africa	n/a	13.4.1

UK	**BS EN ISO 13688:2013+A1:2021** Protective clothing—general requirements **BS EN 14126:2003** Protective clothing—performance requirements and tests methods for protective clothing against infective agents **BS EN 13034:2005+A1:2009** Protective clothing against liquid chemicals—performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment) **BS EN 14605:2005 +A1:2009** Protective clothing against liquid chemicals—performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])	14.4.1
Vietnam	**TCVN 6689:2021** Protective clothing—general requirements. Identical to **ISO 13688:2013 + AMD1:2021**	15.4.1

Shoe/head covers

These two categories fall into a gray area as far as COVID-19-related PPE is concerned. In defining the relevant technical regulations and standards to be considered, it is important to remember that PPE is "intended to protect the ***wearer*** from a hazard."

Typical shoe covers

Typical head cover

Although often used as PPE for filovirus outbreaks (such as Ebola), according to the WHO the likelihood of COVID-19 transmission via footwear is very low. However, it is good practice in sterile environments to use hygienic foot coverings that typically just extend over the base of the user's normal footwear. These do not provide any protection to the wearer and are therefore not considered to be PPE, although they may be considered as medical devices if the purpose is to minimize the transmission of disease by the wearer. On the other hand, a foot covering that extends up over the ankle and claims to protect that part of the wearer's body would be considered as PPE.

A similar rationale applies to head coverings, which are only considered PPE if they claim to be capable of protecting the wearer. Otherwise, they would be considered as medical devices. Therefore, it can be stated for both head and shoe coverings that they can claim to offer partial-body protection.

Table 2.11 provides an overview of the main national product standards for shoe/head covers in the markets covered by this guide and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 2.11: Overview of the standards for shoe/head covers in each of the selected markets

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

Market	Main product standards	More details (link)
ISO standards (for comparison)	**ISO 13688:2013 + AMD 1:2021** Protective clothing—general requirements **ISO 16602:2007+AMD 1:2012** Protective clothing for protection against chemicals—classification, labeling and performance requirements	4.4.1.3
EU	**EN ISO 13688:2013+A1:2021** Protective clothing—general requirements **EN 14126:2003** Protective clothing—performance requirements and tests methods for protective clothing against infective agents **EN 13034:2005+A1:2009** Protective clothing against liquid chemicals—performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment) **EN 14605:2005 +A1:2009** Protective clothing against liquid chemicals—performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])	4.4.1.1
United States	n/a	4.4.1.2
Australia	**AS/NZS 4501.2:2006** Occupational protective clothing—Part 2: General requirements. Identical adoption of **EN 340:2004** (since replaced by **EN ISO 13688 + A1:2021**)	5.4.1
Brazil	**ABNT NBR 16693:2018** Textile products for health—non-surgical gowns and private clothing used for non-surgical procedure professionals and patients—requirements and test methods	6.4.1
Canada	n/a	7.4.1
Colombia	**NTC 6457:2020** Disposable hats/caps **NTC 6451:2020** Disposable foot covers	8.4.1
India	n/a	9.4.1
Jordan	n/a	10.4.1
Kenya	n/a	11.4.1
Malaysia	**MS ISO 13688:2020** Protective clothing—general requirements. Identical to **ISO 13688:2013**, since amended	12.4.1
South Africa	n/a	13.4.1
UK	**BS EN ISO 13688:2013+A1:2021** Protective clothing—general requirements **BS EN 14126:2003** Protective clothing—performance requirements and tests methods for protective clothing against infective agents **BS EN 13034:2005+A1:2009** Protective clothing against liquid chemicals—performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment) **BS EN 14605:2005 +A1:2009** Protective clothing against liquid chemicals—performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])	14.4.1
Vietnam	**TCVN 6689:2021** Protective clothing—general requirements. Identical to **ISO 13688:2013 + AMD1:2021**	15.4.1

2.4.2 Gowns

These can be disposable (for single use) and made from non-woven material, or reusable and made from woven material. Laminate films or additional layers are used for some products to provide higher levels of liquid penetration resistance. Gowns typically come in sizes S, M, L, and XL with a length down to the mid-calf.

In the United States, gowns are subdivided into two specific categories, as follows:

- (From ASTM F3352-19) "Isolation gown: item of protective clothing/apparel used to protect health care personnel, visitors, and patients from the transfer of micro-organisms and body fluids in patient isolation situations"

- (From ASTM F2407-20) "Surgical gown: protective clothing that is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of micro-organisms, body fluids, and particulate matter."

Based on their intended use, the main difference between the two is that a surgical gown is sterile (with a back area that is not necessarily protective) while an isolation gown (used in a medical setting other than surgery) is not necessarily sterile but is expected to provide 360° protection to the health care worker. Because they have a medical purpose, isolation gowns are also considered to be medical devices.[24]

In both cases, critical zones may be required to be more fluid resistant than non-critical zones and reusable gowns should meet the minimum performance requirements after the maximum suggested laundering cycles.

Gowns are most often constructed from polypropylene or polyester fibers, using a non-woven technique such as SMS (spunbond, meltblown, spunbond). They can be separated into different categories based on their level of protection. This is usually based on liquid barrier performance involving spray impact penetration testing and hydrostatic pressure tests. The spray impact test determines if the product is protective or not. The hydrostatic pressure test result determines the level of protection, typically ranging from 1 to 4 (US classification) as follows:

- Level 1: Minimal risk, to be used during basic care, standard isolation, cover gown for visitors, or in a standard medical unit

- Level 2: Low risk, to be used during blood draw, suturing, in the intensive care unit, or a pathology lab

- Level 3: Moderate risk, to be used during arterial blood draw, inserting an intravenous line, in the emergency room, or for trauma cases

- Level 4: High risk, to be used during long, fluid-intense procedures, surgery when pathogen resistance is needed or (non-airborne) infectious diseases are suspected. This level includes surgical gowns and protective apparel.

Example of an isolation gown

Example of a surgical gown

24 Other types of gowns may include patient gowns (intended to be worn by patients in a clinical setting) and professional examination gowns, to be used by health care staff, sometimes over scrub suits, while examining patients.

Table 2.12 provides an overview of the main national product standards for gowns in the markets covered by this guide and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 2.12: Overview of the standards for gowns in each of the selected markets

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

Market	Main product standards	More details (link)
ISO standards (for comparison)	n/a (Future product standard under development **ISO 20384** Medical gowns, surgical drapes and protective apparel—performance requirements, performance levels and test methods)	-
EU	**EN 13795-1:2019** Surgical clothing and drapes—requirements and test methods—Part 1: Surgical drapes and gowns	4.4.2.1
United States	**ASTM F2407-20** Standard specification for surgical gowns intended for use in health care facilities **ASTM F3352-19 S**tandard specification for isolation gowns intended for use in health care facilities **ANSI/AAMI PB70:2012** Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities	4.4.2.2
Australia	**AS 3789.2–1991+AMDT 1 (1992)** Textiles for health care facilities and institutions—theatre linen and pre-packs	5.4.2
Brazil	**ABNT NBR 16064:2021** Textiles for health—surgical drapes and gowns— requirements and test methods. Based on **EN 13795-1:2019**	6.4.2
Canada	**CSA Z314-2018** Canadian medical device reprocessing. Partially based on **ANSI/AAMI PB 72**	7.4.2
Colombia	**NTC 5623:2020** Surgical drapes and sheets. Requirements and test methods. Part 1: Surgical drapes and gowns. Identical to **EN 13795-1:2019**	8.4.2
India	**IS 17334:2019** Medical textiles—surgical gowns and surgical drapes— specification	9.4.2
Jordan	**JS 983-1:2007** Surgical drapes, gowns, and clean air suits, used as medical devices for patients, clinical staff, and equipment. Part 1: General requirements for manufacturers, processors, and products. Equivalent to **EN 13795-1:2002**, since revised **JS 983-2:2007** Surgical drapes, gowns, and clean air suits, used as medical devices for patients, clinical staff, and equipment. Part 2: Test methods. Equivalent to **EN 13795-2: 2002,** since revised **JS 983-3:2008** Surgical drapes, gowns, and clean air suits, used as medical devices for patients, clinical staff, and equipment. Part 3: Performance requirements and performance levels. Equivalent to **EN 13795-3:2006**, since merged with **EN 13795-1** and **EN 13795-2**	10.4.2
Kenya	n/a	11.4.2
Malaysia	n/a	12.4.2
South Africa	**SANS 53795:2015** Surgical drapes, gowns, and clean air suits, used as medical devices for patients, clinical staff, and equipment—general requirements for manufacturers, processors, and products; test methods, performance requirements, and performance levels. Identical to **EN 13795**, since replaced by **EN 13795-1** and **EN 13795-2**	13.4.2
UK	**BS EN 13795-1:2019** Surgical clothing and drapes—requirements and test methods—Part 1: Surgical drapes and gowns	14.4.2
Vietnam	n/a	15.4.2

PART 3
OVERVIEW OF MARKET REQUIREMENTS

3.1 European Union

3.1.1 Regulatory landscape for COVID-19-related PPE

In the EU, all PPE is subject to regulation (EU) 2016/425 on personal protective equipment (the PPE Regulation) which covers the design, manufacture, and marketing of PPE. It defines legal obligations to ensure that PPE on the EU internal market provides the highest level of protection against risks. The CE marking affixed to PPE provides a declaration of compliance of the product with the applicable EU legislation.

Annex I of the PPE Regulation classifies protective equipment according to its level of risk, as follows:

Category I is exclusively for minimal risks such as:

- Superficial mechanical injury
- Contact with cleaning materials of weak action or prolonged contact with water
- Contact with hot surfaces not exceeding 50°C
- Damage to the eyes due to exposure to sunlight (other than during observation of the sun)
- Atmospheric conditions that are not of an extreme nature.

Category II relates to risks other than those listed in categories I and III.

Category III exclusively includes risks that may cause very serious consequences such as death or irreversible damage to health including, among others:

- Substances and mixtures which are hazardous to health
- Atmospheres with oxygen deficiency
- Harmful biological agents.

Most of the COVID-19-related PPE covered by this guide is classified as Categories II or III.

Users are also referred to the PPE Regulation Guidelines (1st edition—April 2018) issued by the European Commission,[25] which aim to facilitate a common understanding and implementation of the PPE Regulation.

With regards to the PPE Regulation, manufacturers are required to:

- Ensure that the PPE has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Annex II of the regulation
- Draw up the technical documentation referred to in Annex III (technical file) and carry out the applicable conformity assessment procedure

25 https://ec.europa.eu/docsroom/documents/29201/attachments/1/translations/en/renditions/native.

- Draw up the EU declaration of conformity and affix the CE marking
- Keep the technical documentation and the EU declaration of conformity for 10 years after the PPE has been placed on the market
- Ensure that procedures are in place for series production to remain in conformity with the regulation
- Keep a register of complaints, of non-conforming PPE and PPE recalls, and keep distributors informed of any such monitoring
- Ensure that the PPE which they place on the market bears marking allowing its identification or, where the size or nature of the PPE does not allow it, on the packaging or in a document accompanying the PPE
- Indicate on the PPE their name, registered trade name or registered trademark and the postal address at which they can be contacted, or where that is not possible, on its packaging or in a document accompanying the PPE
- Ensure that the PPE is accompanied by instructions and information in a language which can be easily understood by consumers and other end users, as determined by the member state concerned
- Where the PPE presents a risk, immediately inform the competent national authorities of the relevant member state(s), giving details of the non-conformity and of any corrective measures taken
- Further to a reasoned request from a competent national authority, provide all the information and documentation necessary to demonstrate the conformity of the PPE in paper or electronic form, in a language which can easily be understood by that authority.

Many items of COVID-19-related PPE can also be subject to regulations related to medical devices, depending on their specific application. Therefore, it is important to refer back to section 1.4 of this guide for a more detailed conceptual explanation.

For medical devices, Regulation (EU) 2017/745 (the Medical Devices Regulation, or MDR) has been applicable since May 26, 2021, following a four-year transition period. The MDR repealed Directive 93/42/EEC on medical devices and Directive 90/385/EEC on active implantable medical devices, and manufacturers must comply with the MDR when placing new medical devices on the market. This is particularly relevant because where the intended use of a product is both as PPE and as a medical device, the full extent of both regulations is applied.

3.1.2 Approach to standardization and key product standards for PPE

In the context of PPE, the European Committee for Standardization (CEN) is responsible for the development and publication of regional (EN) standards.[26] These are then adopted by each member state's national standards body as its own national standards and any conflicting national standards are withdrawn. CEN also participates in the development of ISO standards under the so-called Vienna Agreement. Where an EN standard is an adoption of an ISO standard, it receives the designation "EN ISO." National adoptions—for example, in Portugal—are referred to as "NP EN" or "NP EN ISO" standards to emphasize that they are identical in content.

Both the PPE Regulation (EU 2016/425) and the MDR (EU 2017/745) are based on the "New Approach Directives" (introduced in 1985) aligned to the EU's more recent (2010) "New Legislative Framework" policy. This means that manufacturers or their authorized representatives in the EU must demonstrate compliance with the essential health and safety or performance requirements of the applicable regulation either directly or by demonstrating conformity to the associated harmonized EN standards (a "presumption of conformity" to the regulation). Because the regulations are often very generic and performance-based in their requirements (which in some cases can apply to broad families of products), demonstration of conformity

26 The European Committee for Electrotechnical Standardization (CENELEC) also develops regional standards, but these are not normally applicable to PPE or the medical devices under consideration in this guide.

to the harmonized standards is often the preferred way of demonstrating conformity to the regulation.

Table 3.1 provides an overview of the main product standards for PPE in the EU market.

Table 3.1: Overview of COVID-19-related PPE standards in the EU market

PPE	Main product standards	More details (link)
Respirators	**EN 149:2001+A1:2009** RPD—filtering half-masks to protect against particles-requirements, testing, marking **EN 143:2021** Respiratory protective devices—particle filters—requirements, testing, marking	4.1.1.1
Medical face masks	**EN 14683:2019** Medical face masks—requirements and test methods	4.1.2.1
Community face coverings	**CWA 17553:2020** Community face coverings—guide to minimum requirements, methods of testing and use	4.1.3.1
Face shields	**EN 166:2001** Personal eye protection—specifications	4.2.1
Protective goggles	**EN 166:2001** Personal eye protection—specifications	4.2.1
Medical examination gloves	**EN 455 series** (Medical gloves for single use) **EN 455-1: 2020** Requirements and testing for freedom from holes **EN 455-2: 2015** Requirements and testing for physical properties **EN 455-3: 2015** Requirements and testing for biological evaluation **EN 455-4: 2009** Requirements and testing for shelf-life determination **EN ISO 21420:2020** Protective gloves—general requirements and test methods **EN ISO 374-5: 2016** Protective gloves against dangerous chemicals and micro-organisms—requirements for micro-organisms risks	4.3.1.1
Surgical gloves	**EN 455 series** (Medical gloves for single use) **EN 455-1: 2020** Requirements and testing for freedom from holes **EN 455-2: 2015** Requirements and testing for physical properties **EN 455-3: 2015** Requirements and testing for biological evaluation **EN 455-4: 2009** Requirements and testing for shelf-life determination **EN ISO 21420:2020** Protective gloves—general requirements and test methods **EN ISO 374-5:2016** Protective gloves against dangerous chemicals and micro-organisms—requirements for micro-organisms risks	4.3.2.1
Suits and coveralls	**EN ISO 13688:2013 + A1:2021** Protective clothing—general requirements **EN 14126:2003** Protective clothing—performance requirements and tests methods for protective clothing against infective agents **EN 13034:2005+A1:2009** Protective clothing against liquid chemicals— performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment) **EN 14605:2005 +A1:2009** Protective clothing against liquid chemicals— performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])	4.4.1.1
Aprons	**EN ISO 13688:2013+A1:2021** Protective clothing—general requirements **EN 14126:2003** Protective clothing—performance requirements and tests methods for protective clothing against infective agents **EN 13034:2005+A1:2009** Protective clothing against liquid chemicals— performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment) **EN 14605:2005 +A1:2009** Protective clothing against liquid chemicals— performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])	4.4.1.1

Shoe and head covers	**EN ISO 13688:2013+A1:2021** Protective clothing—general requirements **EN 14126:2003** Protective clothing—performance requirements and tests methods for protective clothing against infective agents **EN 13034:2005+A1:2009** Protective clothing against liquid chemicals— Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment) **EN 14605:2005 +A1:2009** Protective clothing against liquid chemicals— performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])	4.4.1.1
Gowns	**EN 13795-1:2019** Surgical clothing and drapes—requirements and test methods—Part 1: Surgical drapes and gowns	4.4.2.1

3.1.3 Approach to conformity assessment

In Europe, all PPE and medical devices must comply with the associated regulation and bear the CE marking. The CE marking on a product indicates that the manufacturer or importer of that product affirms its compliance with the relevant EU legislation and the product may be made available anywhere in the European Economic Area. It is a criminal offence to affix a CE marking to a product that is not compliant or to offer it for sale.

Within Europe, accreditation of conformity assessment bodies is coordinated by the European Accreditation Cooperation (EA). EA was formally appointed by the European Commission via Regulation (EC) No 765/2008 to develop and maintain a multilateral arrangement of mutual recognition of national accreditation bodies (the EA multilateral arrangement) based on a harmonized accreditation infrastructure. There can be only one recognized accreditation body per EU member state. Examples include Accredia (Italy), DAkkS (Germany) and SNAS (Slovakia).

Depending on the risk classification, certain categories of PPE and medical devices are subject to conformity assessment by a notified body. Notification is an act whereby an EU member state informs the European Commission and the other member states that a body, which fulfils the relevant requirements, has been designated to carry out conformity assessment according to an EU directive or regulation. Notification of conformity assessment bodies and their withdrawal are the responsibility of the notifying member state. Full details of notified bodies can be found in the NANDO (New Approach Notified and Designated Organizations) information system.[27]

The "preferred" method for appointing notified bodies is through accreditation. But, if another method is used, the competent authority of the member state concerned has to be able to demonstrate that the method is technically equivalent to accreditation. Medical devices are one area where alternative routes are used in a number of EU countries.

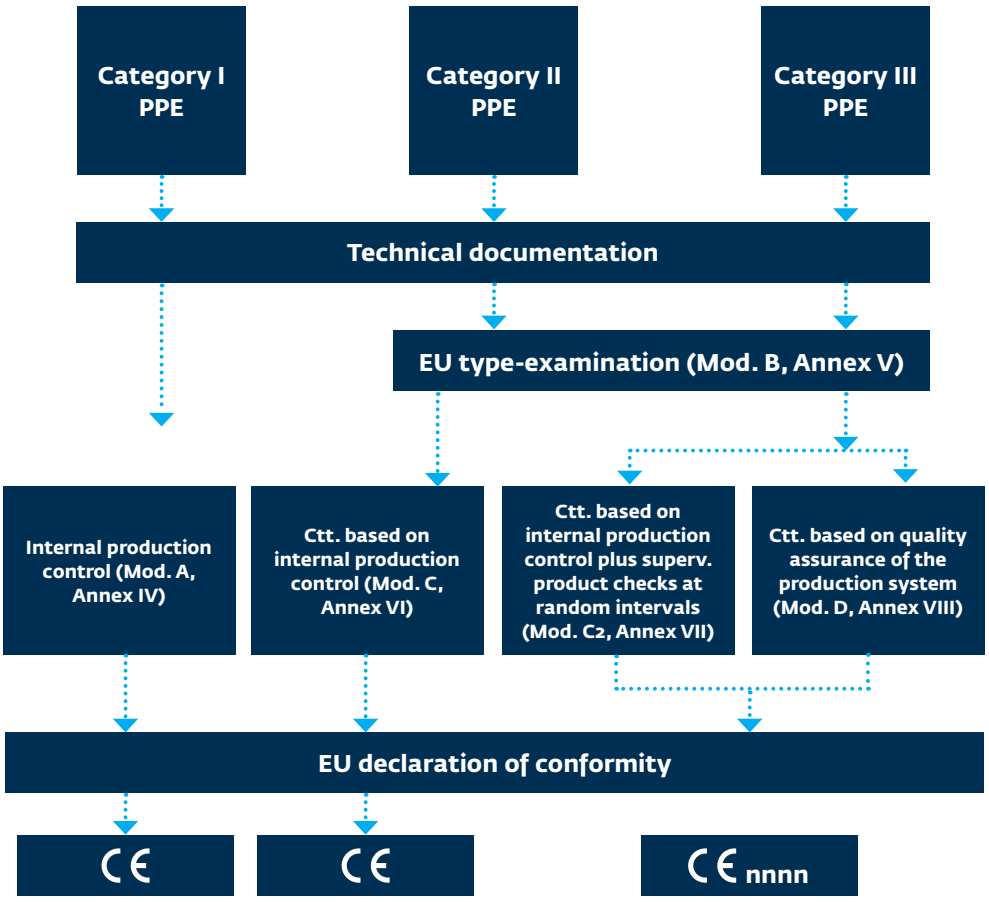
For PPE, there are a number of ways of demonstrating conformity depending on the product category and associated risks. This is shown schematically in Table 3.2 and in Figure 3.1.

27 https://ec.europa.eu/growth/tools-databases/nando/index.cfm.

Table 3.2: Conformity assessment per the EU PPE Regulation for different product categories

PPE category	Activity	PPE Regulation (EU) 2016/425
I (Simple PPE)	Placing product onto the market	Module A (Annex IV) Manufacturers self- declaration of conformity
II (Intermediate) and III (Complex PPE)	Initial product approval	Module B (Annex V) EU-type examination
II (Intermediate PPE)	Internal production control	Module C (Annex VI)
III (Complex PPE only)	Ongoing surveillance through testing OR	Module C2 (Annex VII)
	Ongoing surveillance through factory auditing	Module D (Annex VIII)

Figure 3.1: EU criteria for conformity assessment of PPE



Note: "Ctt" = "Conformity to type"

Note that for PPE classified as medical devices the risk categories defined in Annex VIII of the MDR also have to be respected. Medical devices included in the present guide are all Class I (low risk) and all conformity assessment activities are carried out by the manufacturer. The exception is sterile Class I products which require the intervention of a notified body, but only for assessing the manufacturer's ability to secure and maintain sterile conditions.

However, all Class I devices have to be registered with an EU member state's competent authority, and if the device is imported into the EU, an authorized representative of the manufacturer must be appointed within the EU.

3.2 United States

3.2.1 Regulatory landscape for COVID-19-related PPE

The Code of Federal Regulations (CFR) is the codification of the general and permanent regulations published in the Federal Register by the executive departments and agencies of the federal government of the United States. The overall regulatory landscape is quite complex, often with a number of different agencies involved for specific topics and some overlap in jurisdictions. The three main federal agencies involved in the regulation of PPE are the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH)—part of the Centers for Disease Control and Prevention (CDC) within the US Department of Health and Human Services—and the Food and Drug Administration (FDA). According to the FDA, "PPE refers to protective clothing, helmets, gloves, face shields, goggles, face masks and/or respirators, or other equipment designed to protect the wearer from injury or the spread of infection or illness."[28]

The CFR is divided into 50 titles representing broad areas subject to federal regulation. The US regulations in Title 29 Part 1910 all pertain to OSHA, which directs employers to comply with specific safety standards. For example, 29 CFR Part 1910.132 provides general requirements for employers to provide appropriate PPE to their employees based on a hazard assessment. While citing some basic PPE standards, these regulations do not generally address PPE in the context of infective agents. The only specifically relevant OSHA regulations are 29 CFR Part 1910.134—which defines the elements of a workplace respiratory protection program—and a separate standard for bloodborne pathogens directed to the health care sector, found in 29 CFR Part 1910.1030. Both regulations have relatively simple PPE requirements. These OSHA regulations on respirators are important because they require the selection of specific respirator types based on airborne hazards and, more importantly, require that individual wearers undergo fit testing to show the adequacy of the specific respirator.

3.2.2 Approach to standardization and key product standards for PPE

The US approach to standardization and key product standards for PPE can be confusing to those who are not familiar with its concepts and structure. The United States Standards Strategy,[29] published in 2020, serves as a statement of purpose and ideals resulting from a re-examination of the principles and strategy that guide how the United States develops standards and participates in the international standards-setting process. This takes into consideration the fact that the United States is a highly diversified society with a market-driven economy and its standards system reflects this diversity, encompassing multiple and varied standards sources. While the American National Standards Institute (ANSI) is the only national standards body, it does not itself develop standards, but instead oversees the development process by accrediting the procedures of a number of standards development organizations within the private-sector voluntary standardization system.

In the context of COVID-19-related PPE, the predominant source of standards is ASTM International. However, other standards development organizations also publish standards that are relevant for specific products. These include the:

- American Association of Textile Chemists and Colorists (AATCC)
- Association for the Advancement of Medical Instrumentation (AAMI)

28 https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control.

29 https://www.ansi.org/resource-center/publications-subscriptions/usss.

- International Safety Equipment Association (ISEA)
- National Fire Protection Association (NFPA)
- US Pharmacopeia (USP)

In some cases, prescriptive performance requirements for PPE are specified directly in the applicable government regulations, without further reference to voluntary standards. One example is 42 CFR Part 84 Subpart K for air-purifying particulate respirators, which includes N95 respirators.

Although the US system aims to produce standards that are consistent with the principles of the WTO/TBT Agreement, most standards related to PPE in the United States are national standalone ones, rather than being adoptions of "traditional" international standards such as those developed by ISO. However, it can be argued that many standards developed by ASTM and others follow the good standardization practice recommended by the WTO TBT Committee decision on international standards and a number of ASTM standards have indeed been adopted in other economies or formed the basis for ISO standards.

Table 3.3 provides an overview of the main product standards for PPE in the US market.

Table 3.3: Overview of COVID-19-related PPE standards in the US market

PPE	Main product standards	More details (link)
Respirators	**42 CFR 84.170** Air-purifying particulate respirators	4.1.1.2
Medical face masks	**ASTM F2100-21** Standard specification for performance of materials used in medical face masks	4.1.2.2
Community face coverings	**ASTM F3502-21** Standard specification for barrier face coverings **AATCC M14** Guidance and considerations for general-purpose textile face coverings	4.1.3.2
Face shields	**ANSI/ISEA Z87.1:2020** American national standard for occupational and educational personal eye and face protection devices **ANSI/ISEA Z87.62-2021** American national standard for occupational and educational personal eye and face protection devices for preventing exposures caused by sprays or spurts of blood or body fluids	4.2.2
Protective goggles/ glasses	**ANSI/ISEA Z87.1-2020** Occupational and educational personal eye and face protection devices **ANSI/ISEA Z87.62-2021** American national standard for occupational and educational personal eye and face protection devices for preventing exposures caused by sprays or spurts of blood or body fluids	4.2.2
Medical examination gloves	**ASTM D5250-19** Standard specification for poly(vinyl chloride) gloves for medical application **ASTM D6319-19** Standard specification for nitrile examination gloves for medical application **ASTM D3578-19** Standard specification for rubber examination gloves **ASTM D6977-19** Standard specification for polychloroprene examination gloves **NFPA 1999 (2018)** Standard on protective clothing and ensembles for emergency medical operations **ANSI/ISEA 105-2016** American national standard for hand protection classification	4.3.1.2
Surgical gloves	**ASTM D3577-19** Standard specification for rubber surgical gloves	4.3.2.2
Suits and coveralls	**NFPA 1999 (2018)** Standard on protective clothing and ensembles for emergency medical operations	4.4.1.2
Aprons	**NFPA 1999 (2018)** Standard on protective clothing and ensembles for emergency medical operations	4.4.1.2
Shoe and head covers	n/a	4.4.1.2
Gowns	**ASTM F2407-20** Standard specification for surgical gowns intended for use in healthcare facilities **ASTM F3352-19** Standard specification for isolation gowns intended for use in healthcare facilities **ANSI/AAMI PB70:2012** Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities	4.4.2.2

3.2.3 Approach to conformity assessment

The following is a summary of the conformity assessment and approval processes in the United States for the PPE and medical devices referred to in this guide.[30] Specifically for PPE, the recently published ASTM F3050-21 (Standard Guide for Conformity Assessment of Personal Protective Clothing and Equipment) applies. Briefly:

- All respirators are subject to approval by the NIOSH according to specific national regulations
- PPE used in healthcare or for medical purposes is subject to FDA oversight
    - Moderate-risk PPE (medical face masks, "Level 3 and 4" gowns and gloves) are subject to a clearance process involving comparison with already marketed products
    - Low-risk PPE (face shields, eyewear, "Level 1 and 2" gowns) have to meet FDA "general controls" that require registration and certain product practices
- The NFPA 1999 governs PPE for emergency responders
    - Requires independent third-party certification
- Other standards generally involve minimal conformity assessment requirements.

A summary of the criteria for the various categories of PPE covered by this guide is shown in Figure 3.2 and a typical approval process (for respirators) is shown in Figure 3.3.

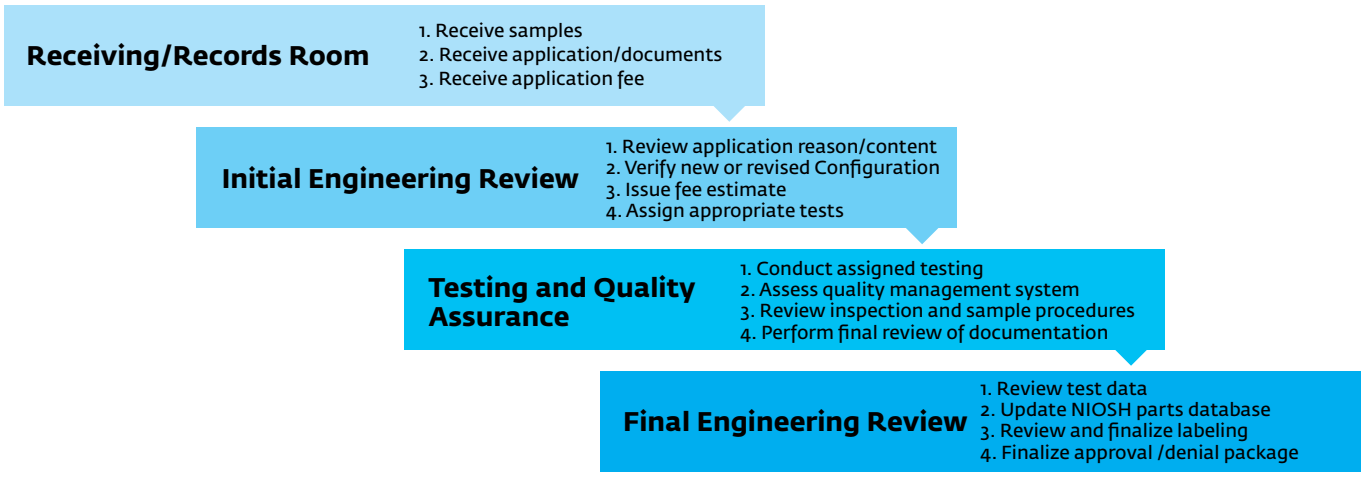
Figure 3.2: Summary of US regulatory oversight for various categories of PPE

Respirators	Face masks	Face shields / eyewear	Gloves	Gowns	Other apparel
• NIOSH-approved • Small fraction under FDA oversight	• Surgical masks FDA cleared • Addressed by industry standard	• Limited FDA oversight • Limited utility of industry standard	• Must be cleared by FDA • Multiple industry standards	• High end gowns FDA cleared • Limited FDA oversight for other gowns • Some industry standards	• Limited FDA oversight • Limited industry standards

Source: International Personnel Protection, Inc.

30 Jeffrey O. Stull. International Personnel Protection, Inc., Austin, Texas.

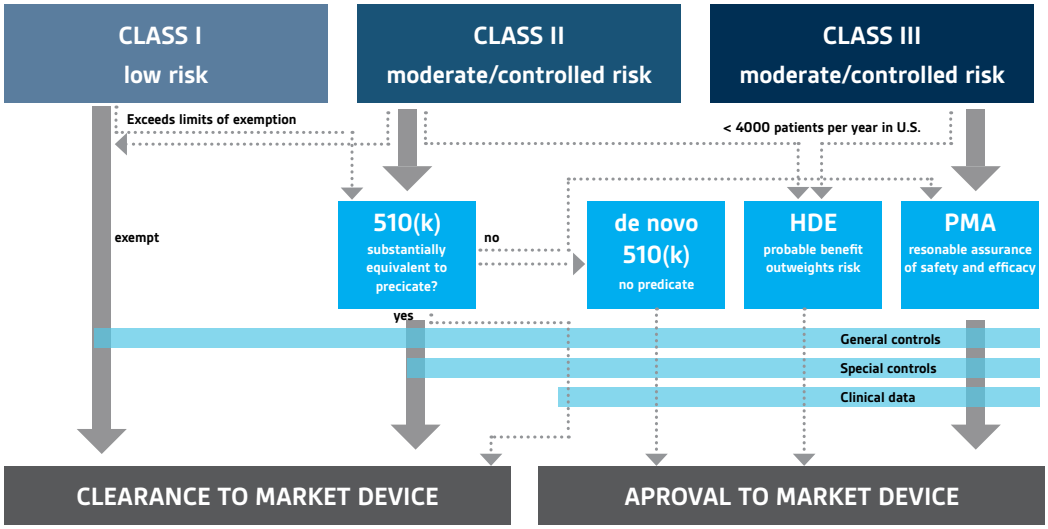
Figure 3.3: Overview of the NIOSH approval process for respirators



Source: International Personnel Protection, Inc.

For those devices that come under FDA oversight, Figure 3.4 provides a simplified view of the conformity assessment and approval procedures that are required.

Figure 3.4: Schematic of the process for FDA approval



- **Class I devices**
  - Manufacturer meets general controls
    - Manufacturer and device registration; good manufacturer practice; traceability
- **Class II devices**
  - Applied to medical masks, certain gowns
  - Require 510(k) submission according to US FDA regulations (21 CFR Part 807 Subpart E)

An "FDA 510(k)" submission[31] is required for all Class II medical device PPE and for some non-exempt Class I medical device PPE, such as examination or surgical gloves, typically including the following steps:

- Demonstration of substantial equivalence to product that has already been cleared by the FDA.[32] This demonstration involves:
  - Comparison of the proposed product to the already cleared product in terms of the general design, construction, labeling and—most importantly—safety and efficacy data that include the results of product testing to key areas of performance

31 For details on the FDA clearance process via a 510(k), see the FDA website at https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances.

32 The word "clearance" is used in lieu of "approval," which is reserved for Class III medical devices.

  - Use of, or reference to, FDA guidance documents on the specific product area. However, these documents can sometimes be outdated or not include all of the pertinent information

- Use of product standards recognized by the FDA that establish relevant design, performance and labeling requirements

- Technical product details

  - Information completely defining materials, components, design, and product claims

- Provision of safety and efficacy data by the manufacturer

  - Generally, product performance data provided at sampling levels meeting a specified acceptable quality limit (AQL)

  - For example, the FDA now requires an AQL of 4.0 percent or other specified level when applied to certain medical PPE. In the case of an AQL of 4.0 percent for a certain lot size, the sample size for testing is 32 where 29 of 32 specimens must pass the established criteria. Most recently, the expectation for products is that this performance be separately demonstrated for three non-sequential lots of products.

Once again, within the free market competitive landscape in the United States, there are multiple (mainly private sector) accreditation bodies that oversee the conformity assessment processes (laboratory testing, inspection, and product/system certification). Many of these are signatories of the relevant IAF MLA and ILAC MRA.

3.3 Australia

3.3.1 Regulatory landscape for COVID-19-related PPE

The Therapeutic Goods Administration (TGA), part of the Department of Health, is the medical and therapeutic regulatory agency of the Australian government. The TGA regulates the quality, supply, and advertising of medicines, pathology devices, medical devices, blood products, and most other therapeutics. Any items that claim to have a therapeutic effect, are involved in the administration of medication, or are otherwise covered by the Therapeutic Goods Act (1989), the Therapeutic Goods Regulations 1990, or a ministerial order must be approved by the TGA and registered in the Australian Register of Therapeutic Goods before they can be supplied.

Item 1 of Schedule 1 to the Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020 specifically states that the following items are considered to be medical devices: "articles that are non-sterile personal protective equipment or safety apparel (including but not limited to aprons, face masks, gloves, goggles, gowns, and visors) intended, by the person under whose name the articles are or are to be supplied, to be used for the prevention of the transmission of disease between persons, including where that intention may be ascertained from the articles being represented as suitable for use in surgery, or clinical, medical, or other health services."

The TGA further clarifies[33] that they will "infer the intended use for the PPE from the labeling on the packaging, instructions for use, advertising, and information in the manufacturer's technical documentation. If any of these materials suggest that the goods are suitable for use in surgery, or clinical, medical, or other health services, the TGA will conclude that the PPE is intended to be used for prevention of the transmission of disease between people. However, even if these materials do not suggest use in surgery, clinical, medical, or other health services, other aspects of the PPE's presentation could still suggest that it is for the prevention of the transmission of disease."

PPE will generally be regulated as a:

33 https://www.tga.gov.au/behind-news/regulation-personal-protective-equipment-and-covid-19.

- Class I medical device
- Class Is (sterile) medical device
- Class IIa medical device

Manufacturers can check the classification of their medical device using the online classification tool at https://www.tga.gov.au/sme-assist/what-classification-my-medical-device#100

Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002 sets out 15 essential principles with which manufacturers must comply. There are six general essential principles that apply to all devices and nine further essential principles.

General essential principles

- Use of medical devices not to compromise health and safety
- Design and construction of medical devices to conform to safety principles
- Medical devices to be suitable for intended purpose
- Long-term safety
- Medical devices not to be adversely affected by transport or storage
- Benefits of medical devices to outweigh any side effects.

Design and construction: essential principles

These nine essential principles apply to devices on a case-by-case basis:

- Chemical, physical and biological properties
- Infection and microbial contamination
- Construction and environmental properties
- Medical devices with a measuring function
- Protection against radiation
- Medical devices connected to or equipped with an energy source
- Information to be provided with medical devices
- Clinical evidence
- Principles applying to in vitro diagnostic product (IVD) medical devices only

3.3.2 Approach to standardization and key product standards for PPE

Although the use of standards to demonstrate compliance with the essential principles is not mandated under the regulations, the TGA recognizes certain standards to assist manufacturers in complying with the conformity assessment procedures and the essential principles.[34]

Standards Australia is the national standards body and most product standards that apply to PPE in the Australian market are either Australian (AS) or Joint Australian/New Zealand (AS/NZS) Standards. In

34 This is similar to the "presumption of conformity" principle that is widely adopted in the EU.

general, for PPE, the situation is mixed: there are some standalone national standards and some adoptions (occasionally with modifications) of ISO or regional (for example, CEN) standards.[35] There is also acceptance by the TGA of some applicable product standards issued by other national and international standards bodies and the widespread referencing of test method standards issued by ISO, CEN, ASTM, BSI, and others.

Table 3.4 provides an overview of the main product standards for PPE in the Australian market and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 3.4: Overview of COVID-19-related PPE standards in the Australian market

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

PPE	Main product standards	More details (link)
Respirators	**AS/NZS 1712:2012** Respiratory protective devices	5.1.1
Medical face masks	**AS 4381:2015** Single-use face masks for use in health care	5.1.2
Community face coverings	n/a	5.1.3
Face shields	**AS/NZS 1337.1:2010 (+ AMDT 1:2012 + AMDT 2:2018)** Personal eye protection—Part 1: Eye and face protectors for occupational applications. Based on (but not identical to) **EN 166**	5.2
Protective goggles	**AS/NZS 1337.1:2010 (+ AMDT 1:2012 + AMDT 2:2018)** Personal eye protection —Part 1: Eye and face protectors for occupational applications. Based on (but not identical to) **EN 166**	5.2
Medical examination gloves	**AS/NZS 4011.1:2014** Single-use medical examination gloves—Part 1: Specification for gloves made from rubber latex or rubber solution. Adopted with national modifications from **ISO 11193-1:2008** (since revised) **AS/NZS 4011.2:2014** Single-use medical examination gloves—Part 2: Specification for gloves made from poly(vinyl chloride. Adopted with national modifications from **ISO 11193-2:2006**	5.3.1
Surgical gloves	**AS/NZS 4179:2014** Single-use sterile rubber surgical gloves—specification. Adopted with national modifications from **ISO 10282:2014**	5.3.2
Suits and coveralls	**AS/NZS 4501.2:2006** Occupational protective clothing—Part 2: General requirements. Identical adoption of **EN 340:2004** (since replaced by **EN ISO 13688 + A1:2021**)	5.4.1
Aprons	**AS/NZS 4501.2:2006** Occupational protective clothing—Part 2: General requirements. Identical adoption of **EN 340:2004** (since replaced by **EN ISO 13688 + A1:2021**)	5.4.1
Shoe and head covers	**AS/NZS 4501.2:2006** Occupational protective clothing—Part 2: General requirements. Identical adoption of **EN 340:2004** (since replaced by **EN ISO 13688 + A1:2021**)	5.4.1
Gowns	**AS 3789.2–1991+AMDT 1 (1992)** Textiles for health care facilities and institutions—theatre linen and pre-packs	5.4.2

35 https://www.standards.org.au/news/information-to-support-covid-19-national-response-and-australian-manufacturers.

3.3.3 Approach to conformity assessment

All classes of medical devices need conformity assessment evidence before they can be manufactured and placed on the Australian market. Conformity assessment includes the systematic and ongoing examination of evidence and procedures to ensure that a medical device complies with the essential principles (see section 3.3.1). The classification of a medical device determines the conformity assessment procedures a manufacturer can choose to ensure that the device is adequately assessed. Higher risk-class devices must undergo more stringent conformity assessment.

Manufacturers of all medical devices manufactured and/or supplied in Australia need to ensure that they have:

- Appropriate conformity assessment procedures in place for the device
- Appropriate documentation demonstrating compliance of the device with the essential principles.

All medical devices to be placed on the Australian market must have a sponsor, who is the legally responsible entity for the importation and/or supply of the device within Australia. Sponsors must be an Australian-based legal entity. Extensive guidance on obtaining the necessary approvals to place PPE on the Australian market is available on the TGA website.[36]

In general, any laboratory testing, inspection, product, or management system certification has to be carried out by conformity assessment bodies accredited by the Joint Accreditation Service for Australia and New Zealand (JAS-ANZ) or by an accreditation body that is recognized under the relevant IAF MLA or ILAC MRA.

3.4 Brazil

3.4.1 Regulatory landscape for COVID-19-related PPE

All PPE in Brazil is subject to approval by the Ministry of Labour and Social Security, in accordance with Regulatory Rule NR06 (mandatory by law) and PPE Ordinance 672, of November 8, 2021. This establishes the essential requirements for PPE as well as the conformity assessment procedures to be followed. Table 1 of the ordinance specifies the national and international standards that must be met to obtain a certificate of approval (CA) for the various categories of PPE.

Agência Nacional de Vigilância Sanitária (Brazilian Health Regulatory Agency, or ANVISA) is the Brazilian health regulatory agency, responsible for the regulation of all medical devices. As part of the Ministry of Health and the Brazilian National Health System, it acts as the coordinator of the Brazilian Health Regulatory System (SNVS), present throughout the national territory. ANVISA issues market authorizations depending on the risk classification of the medical device. Devices are classified into four classes based on risk, with Class I being the lowest risk and Class IV the highest. In addition to approvals from the Ministry of Labour, PPE for use by medical and hospital workers is required to be registered with ANVISA, normally falling into Classes I and II. Market authorizations for products categorized as Risk Classes I and II do not expire but they can be cancelled if irregularities or fraud is detected during market surveillance activities. Although some registration requirements were relaxed at the start of the COVID-19 pandemic, the requirements were re-enforced in 2021.

The National Institute of Metrology, Quality and Technology (INMETRO) acts as Executive Secretariat of the National Council of Metrology, Standardization and Industrial Quality (CONMETRO). Among its many attributes, INMETRO coordinates Brazilian government policy for both voluntary and compulsory conformity assessment activities.

36 https://www.tga.gov.au/publication/medical-device-inclusion-process.

3.4.2 Approach to standardization and key product standards for PPE

Associação Brasileira de Normas Técnicas (Brazilian National Standards Body, or ABNT) is a non-profit organization, founded in 1940 and recognized by a governmental resolution of 1992 as Brazil's national standards body. ABNT is a founding member of ISO and has been a member of the IEC since 1940. It is also active in the Pan-American Standards Commission and the MERCOSUL Association for Standardization, being responsible for its Executive Secretariat.

A number of European and American multinational companies began manufacturing PPE in Brazil during the country's industrialization in the 1950s, bringing with them a strong influence on the approach to standards from their home countries. However, in recent years ABNT's policy has been for all its technical committees to follow and adopt International Standards published by ISO and the IEC where possible. When international standards do not exist or are not widely used, ABNT adopts standards such as EN or ANSI standards.

Although many technical regulations in Brazil already refer to Brazilian National Standards (NBR), ABNT is beginning to play a much bigger role within the Brazilian government's new agenda to modernize its current regulatory model. This transformation, scheduled for implementation in the 2021–2025 timeframe, is similar to the European-style approach, whereby regulations are simplified to include only essential (performance-based) requirements and there is a presumption of conformity to these technical regulations if the associated NBR standards are met. It is not yet clear to what extent these changes will affect PPE.

Table 3.5 provides an overview of the main product standards for PPE in the Brazilian market and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 3.5: Overview of COVID-19-related PPE standards in the Brazilian market

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

PPE	Main product standards	More details (link)
Respirators	**ABNT NBR 13698:2011** Respiratory protective devices—filtering half-mask to protect against particles. Based on **EN 149:1992**, since revised **ABNT NBR 13697:2010** Respiratory protective devices—particle filters. Based on **EN 143:2000**, since revised	6.1.1
Medical face masks	**ABNT NBR 15052:2021** Masks for dental-medical-hospital use—requirements and test methods	6.1.2
Community face coverings	**ABNT PR 1002:2020 Edition 2** Masks for non-professional respiratory protection—guide with basic requirements for testing, manufacture and use	6.1.3
Face shields	**ABNT PR 1009:2021** Face protection for health care applications—guide with basic requirements for testing, manufacture and use. Based on **ANSI Z87.1:2015**	6.2
Protective goggles	n/a (Legislation refers to **ANSI Z87.1:2015**)	6.2
Medical examination gloves	**ABNT NBR ISO 11193-1:2015** Single-use medical examination gloves (rubber latex/rubber). Identical to **ISO 11193-1:2008 + AMD 1:2012**, since revised **ABNT NBR ISO 11193-2:2013** Single-use medical examination gloves (poly(vinyl chloride)). Identical to **ISO 11193-2:2006**	6.3.1
Surgical gloves	**ABNT NBR ISO 10282:2014** Single-use sterile rubber surgical gloves	6.3.2
Suits and coveralls	**ABNT NBR 16693:2018** Textile products for health—non-surgical gowns and private clothing used for non-surgical procedure professionals and patients—requirements and test methods	6.4.1
Aprons	**ABNT NBR 16693:2018** Textile products for health—non-surgical gowns and private clothing used for non-surgical procedure professionals and patients—requirements and test methods	6.4.1
Shoe and head covers	**ABNT NBR 16693:2018** Textile products for health—non-surgical gowns and private clothing used for non-surgical procedure professionals and patients—requirements and test methods	6.4.1
Gowns	**ABNT NBR 16064:2021** Textiles for health—surgical drapes and gowns—requirements and test methods. Based on **EN 13795-1:2019**	6.4.2

3.4.3 Approach to conformity assessment

Table I of the PPE Ordinance 672 (see section 3.4.1) specifies the criteria to be fulfilled in order to obtain a certificate of approval (CA) for the various categories of PPE. The CA is issued by the Ministry of Labour and Social Security after receiving a report attesting to the characteristics of the PPE in question. For products that are subject to compulsory assessment, including, for example, respirators and surgical gloves, this requires a certificate of product conformity, issued by an ISO/IEC 17065-accredited product certification body in accordance with the conformity assessment procedures defined by INMETRO, as well as providing the associated documentation and product labeling.

For categories of PPE not subject to compulsory product certification, the appropriate testing has to be conducted by a national test laboratory accredited to ISO/IEC 17025.

In the case of foreign manufacturers, the same requirements apply as for PPE manufactured in Brazil, with tests and certifications carried out by Brazilian laboratories and certifying bodies. Exceptions are specified in Ordinance 672, which details when tests and certifications from overseas are accepted.

It is important to remember that for any PPE used in a medical or hospital context, registration with ANVISA is also compulsory (in addition to the Certificate of Approval).

The officially recognized accreditation body in Brazil for conformity assessment activities is the Brazilian National Accreditation Body (CGCRE)—an independent arm of INMETRO—which is a signatory to the ILAC MRA for laboratory testing, as well as to the IAF MLA for product and management system certification, among others.

3.5 Canada

3.5.1 Regulatory landscape for COVID-19-related PPE

Health Canada (a department of the national government) defines PPE as items worn to provide a barrier to help prevent potential exposure to infectious disease. PPE sold for medical purposes in Canada are classified as medical devices. The Therapeutic Products Directorate (TPD), part of Health Canada, applies the Medical Devices Regulations under the authority of the Food and Drugs Act (1985) to ensure that the medical devices offered for sale in Canada are safe, effective, and of high quality (through Statutory Orders and Regulations, SOR 98-282). These regulations are applied to various types of PPE including medical masks, respirators, gowns, face shields, goggles, gloves, and decontamination equipment for PPE.

The Canadian medical device regulations establish four classes of medical devices ranging from Class I (lowest risk) to IV (highest risk). The aforementioned types of PPE are classified as follows:

- Class I: Masks, respirators, gowns, face shields. These devices are at the lowest classification because they are non-invasive
- Class II: Gloves, decontamination equipment for PPE. Gloves are deemed Class II because they are non-invasive devices which can come into contact with breached skin.

All medical devices, including Class I medical devices, are subject to certain general minimum safety and effectiveness requirements:

- The device is designed so that it will not adversely affect the safety or health of the user or patient
- Its performance does not degrade under the expected conditions of use
- The device does not pose any undue risk to the user or patient, such as through flammability
- Minimum labeling is provided with the device which includes the name of the device, name, and address of the manufacturer, the way the device is identified, the number of items in the package (if not evident), the expiration date, the intended use, directions for the safe and effective use, and the storage conditions.

During the COVID-19 pandemic, Health Canada is also temporarily allowing certain medical devices that may not fully meet Canadian regulatory requirements but are manufactured to comparable standards to be imported and sold. This is being done through an exceptional import and sale interim order, in force as of February 21, 2022:

https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/interim-order-3-import-sale-medical-devices.html

The use of medical devices as PPE is governed by the Canadian Centre for Occupational Health and Safety. The Centre is an independent departmental corporation under Schedule II of the Financial Administration Act (1985) and is accountable to Parliament through the Minister of Labour. There are 14 jurisdictions in Canada—one federal, 10 provincial and three territorial—each having its own occupational health and safety legislation, outlining the general rights and responsibilities of the employer, the supervisor, and the worker. The Centre establishes regulatory requirements at the federal level for employers to provide appropriate PPE to their employees. It also provides information about the use of PPE as a hazard control in the workplace to help protect workers from COVID-19. Similar information is generally offered by the provinces and territories.

3.5.2 Approach to standardization and key product standards for PPE

The Standards Council of Canada (SCC) is the principal standards coordination organization within Canada. The SCC accredits standards development organizations to develop the National Standards of Canada (NSCs). It also coordinates representation of Canada on technical committees and subcommittees of the ISO and the IEC. The development of NSCs makes use of international standard development best practices and safeguards the interests of Canadians. NSCs may be nationally developed or may be adoptions of international standards.

SCC-accredited standards development organizations relevant to PPE include:

- ASTM International
- Bureau de Normalisation du Québec (Québec Standards Bureau, or BNQ)
- Canadian General Standards Board
- Canadian Standards Association (CSA)

Relatively few specific standards have been developed locally for COVID-19-related PPE. For this reason, Canada has relied on ASTM and ISO standards, as well as US regulatory requirements for different forms of PPE.

Table 3.6 provides an overview of the main product standards for PPE in the Canadian market and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 3.6: Overview of COVID-19-related PPE standards in the Canadian market

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

PPE	Main product standards	More details (link)
Respirators	**CSA Z94.4:2018** Selection, use and care of respirators	7.1.1
Medical face masks	n/a	7.1.2
Community face coverings	**BNQ 1922-900:2020** Masks intended for working environments—attestation document (for Province of Québec)	7.1.3
Face shields	**CSA Z94.3-2020** (revised May 2021) Eye and face protectors **CSA Z94.3.1-2016** Guideline for selection, use, and care of eye and face protectors	7.2
Protective goggles	**CSA Z94.3-2020** (revised May 2021) Eye and face protectors **CSA Z94.3.1-2016** Guideline for selection, use, and care of eye and face protectors	7.2
Medical examination gloves	n/a	7.3.1
Surgical gloves	n/a	7.3.2
Suits and coveralls	n/a	7.4.1
Aprons	n/a	7.4.1
Shoe and head covers	n/a	7.4.1
Gowns	**CSA Z314-2018** Canadian medical device reprocessing. Partially based on **ANSI/ AAMI PB 72**	7.4.2

Table 3.7 provides an overview of other accepted, referenced standards that are being directly applied to medical PPE in Canada.

Table 3.7: Standards applied and referenced in Canada for COVID-19 PPE

Product area	Standards development organization or authority	Designation	Title
Disposable single-use respirators (N95)	US NIOSH	42 CFR Part 84	Respirator protective devices
Medical masks	ASTM International	F2100	Standard specification for performance of materials used in medical face masks
Examination gloves	ISO	11193-1	Single-use medical examination gloves
	ASTM International	D3578	Specification for rubber examination gloves (additional standards apply for gloves made of different materials)
Surgical gloves	ISO	10282	Single-use sterile rubber surgical gloves—specification

A useful source of information is the list of specifications for COVID-19 products published by Public Services and Procurement Canada.[37]

3.5.3 Approach to conformity assessment

Conformity assessment for COVID-19 PPE in Canada is contingent on the classification of the medical device and the referenced standard with the following provisions by device type:

- Disposable single-use respirators are required to have US NIOSH approval unless exemptions are made for accepting respirators qualified to analogous standards from other regions or countries. Health Canada makes reference to CE FFP2 (EN 149-2001), P2 (AS/NZ 1716:2012), Korea 1st Class (KMOEL—2017-64), and DS (Japan JMHLW-Notification 214, 2018) as equivalent international specifications. Health Canada also references Chinese respirator-like products that include medical protective mask 95 percent efficiency (GB 19083-2010) and KN95 (GB2626-2006)

- As a Class I medical device, medical masks are subject to self-declaration, with the manufacturer obliged to have evidence to support claims of conformance to ASTM F2100. This evidence can be product clearance through the US FDA. Health Canada further references Type IIR masks of EN 14683

- Eye and face wear is certified by the CSA Group as meeting CSA Z94.3.1. The CSA Group is the certification arm of CSA

- Gowns are addressed similarly to medical masks in that manufacturers are able to make self-declarations of conformity but must have supporting evidence to back up such claims. Health Canada also references AAMI PB70 (US) as equivalent to CSA Z314 standard and cites EN 13795-1 for gowns and EN 14126 for coveralls

- Conformity assessment requirements for masks that are used in working environments or by the general community are usually specified in terms of guidelines for their general type issued by Health Canada and by various provincial organizations. Québec Province has established a document that specifies how claims for these products must be demonstrated.

All medical PPE manufacturers are subject to ISO 13485 quality management system requirements for medical devices. Manufacturers or suppliers of medical devices are also required to keep evidence of their compliance with the requirements.

37 https://buyandsell.gc.ca/specifications-for-COVID-19-products.

Class II medical devices require a license to be submitted to the TPD for approval. The application for a Class II medical device requires:

- A description of the medical conditions, purposes, and uses for which the device is manufactured, sold, or represented
- A list of the standards complied with in the manufacture of the device to satisfy the applicable general minimum safety and effectiveness requirements
- An attestation by a senior official of the manufacturer that the manufacturer has objective evidence to establish that the device meets the applicable general minimum safety and effectiveness requirements
- A copy of the device label
- A copy of the quality management system certificate certifying that the quality management system under which the device is manufactured meets the requirements set out in the National Standard of Canada CAN/CSA-ISO 13485 "Medical devices—quality management systems—requirements for regulatory purposes," as amended and valid.

If Class I devices are imported and not labelled as described above, the importer must obtain a Medical Device Establishment Licence (MDEL) through TPD before selling the device. Alternatively, specific for COVID-19, an importer can obtain an interim order authorization for importing and selling medical devices. Specific instructions for either obtaining an MDEL through an expedited process or through the interim order authorization are provided at:

https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/personal-protective-equipment/authorization.html

An MDEL is required for Class II medical devices (for example, medical gloves).

Authorized medical devices and license holders are listed in one of the following lists or databases:

- Database of Classes II, III, and IV medical devices licensed by Health Canada:

https://health-products.canada.ca/mdall-limh/index-eng.jsp

- Database of companies that have an MDEL:

https://health-products.canada.ca/mdel-leim/index-eng.jsp

In addition to these medical device databases, authorization lists related to COVID-19 medical devices have been created. This is a result of new mechanisms put in place for expedited access to COVID-19 medical devices:

https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized.html

Finally, it is noted that the Canadian accreditation body for conformity assessment activities is an independent arm of SCC, which is a signatory to the ILAC MRA for laboratory testing, as well as to the IAF MLA for product and management system certification, among others.

3.6 Colombia

3.6.1 Regulatory landscape for COVID-19-related PPE

Colombia is the third-largest medical device market in Latin America, after Brazil and Mexico. According to Article 124 of Law 0009 of January 24, 1979, Colombia's Ministry of Health and Social Protection is responsible for regulating the provision and use of both medical devices and health care-related PPE in the country.

Importers of medical devices and medical PPE are required to obtain sanitary registration from the National Institute for Food and Drug Surveillance (INVIMA), which is part of the Ministry of Health and Social Protection. INVIMA requires medical devices to be approved in a founding member country of the International Medical Device Regulators Forum, formerly known as the Global Harmonization Task Force, or from a country that has an existing regulatory agreement of mutual recognition with Colombia. The Forum founding members include Australia, Canada, the EU, Japan, and the United States. Foreign manufacturers have the option to have the INVIMA registration certificate issued to their company names and maintain control over their registrations in the Colombian medical device market, so they can change the importer of record listed in the certificate, if necessary.

3.6.2 Approach to standardization and key product standards for PPE

L'Instituto Colombiano de Normas Técnicas y Certificación (Colombian National Standards Body, or ICONTEC) is a private, non-profit organization that was founded on May 10, 1963, by representatives of the private sector. Since 1984, it has been recognized by the Colombian government as the national standardization body and representative of the country to the various international and regional standards organizations.

The main activity of ICONTEC is the study, adoption, and promotion of technical standards in the different economic and social activities related to the private and governmental sectors in Colombia. It operates in 42 different areas of standardization and has over 162 active technical committees.

In the COVID-19 context, although there are some older (pre-1990s) nationally developed Colombian standards, with a few exceptions (for example, head or shoe covers, community face coverings) most recent standards are national adoptions of regional (EN), international (ISO) or ANSI/ International Safety Equipment Association (ISEA)/ASTM standards. Further details are provided in Part 8 of this guide.

ICONTEC is also the largest body for certification of management systems and products in the country providing accredited certification to ISO 9001 and ISO 13485 quality management system standards, among many others. In addition, ICONTEC runs five metrology labs that provide calibration services to industry.

Table 3.8 provides an overview of the main product standards for PPE in the Colombian market and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 3.8: Overview of COVID-19-related PPE standards in the Colombian market

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

PPE	Main product standards	More details (link)
Respirators	**NTC 3852:2020** Respiratory protective devices—filtering half-masks to protect against particles-requirements, testing, marking. Identical to **EN 149:2001+A1:2009** **NTC 6486:2020** Respiratory protective devices. For N series respirators, adopts **42 CFR part 84** requirements	8.1.1
Medical face masks	**NTC 1733:2020** Medical face masks—requirements and test methods. Identical to **EN 14683:2019** **NTC 6436:2020** Standard specification for performance of materials used in medical face masks. Identical to **ASTM F2100-20**, since revised	8.1.2
Community face coverings	**NTC 6449:2020** Masks (face masks) for use in environments other than the health sector	8.1.3
Face shields	**NTC 6493:2020** Individual eye protection. Specifications. Identical to **EN 166:2001** **NTC 3610:2020** Eye and face personal protection devices at work and education. Identical to **ANSI/ISEA Z87.1: 2015**	8.2
Protective goggles	**NTC 6493:2020** Individual eye protection. Specifications. Identical to **EN 166:2001** **NTC 3610:2020** Eye and face personal protection devices at work and education. Identical to **ANSI/ISEA Z87.1: 2015**, since revised	8.2
Medical examination gloves	**NTC-ISO 11193-1:2020** Single-use medical examination—Part 1: Specification for gloves made from rubber latex or rubber solution. Identical to **ISO 11193-1: 2008** (since revised) **NTC-ISO 11193-2:2020** Single-use medical examination gloves. Part 2: Specification for gloves made from poly(vinyl chloride). Identical to **ISO 11193-2:2006**	8.3.1
Surgical gloves	n/a	8.3.2
Suits and coveralls	**NTC 6434:2020** Protective clothing. Requirements and test methods for clothing protection against biological agents. Identical to **EN 14126:2003** (current) **NTC-EN 14605:2020** Protective clothing against liquid chemicals. Requirements performance for clothing with liquid-tight seams (Type 3) or with spray-tight joints (Type 4), including garments that offer protection only to certain parts of the body (Types PB [3] and PB [4]). Identical to **EN 14605:2005+A1:2009** (current) **NTC-EN 13034:2020** Protective clothing against liquid chemicals. Requirements performance for chemical protective clothing that offers protection limited against liquid chemicals (Type 6 and PB [6] equipment). Identical to **EN 13034:2005+A1:2009** (current)	8.4.1
Aprons	**NTC 6434:2020** Protective clothing. Requirements and test methods for clothing protection against biological agents. Identical to **EN 14126:2003** (current) **NTC-EN 14605:2020** Protective clothing against liquid chemicals. Requirements performance for clothing with liquid-tight seams (Type 3) or with spray-tight joints (Type 4), including garments that offer protection only to certain parts of the body (Types PB [3] and PB [4]). Identical to **EN 14605:2005+A1:2009** (current) **NTC-EN 13034:2020** Protective clothing against liquid chemicals. Requirements performance for chemical protective clothing that offers protection limited against liquid chemicals (Types 6 and PB [6] equipment). Identical to **EN 13034:2005+A1:2009** (current)	8.4.1
Shoe and head covers	**NTC 6457:2020** Disposable hats/caps **NTC 6451:2020** Disposable foot covers	8.4.1
Gowns	**NTC 5623:2020** Surgical drapes and sheets. Requirements and test methods. Part 1: Surgical drapes and gowns. Identical to **EN 13795-1:2019**	8.4.2

3.6.3 Approach to conformity assessment

Under its Act No. 3 of March 24, 2020, INVIMA facilitated the supply of certain products related to the prevention, diagnosis, and treatment of COVID-19, due to the risk of shortages.

This includes the following products, which do not require health registration for as long as the state of national emergency is maintained:

- Protective glasses
- Latex and nitrile gloves
- Sterile gloves
- N95 masks and FFP2 or FFP3 respirators
- Filter masks
- Full or partial body protection: gowns, caps, sterile surgical clothing, surgical fields, operative field, sheets, covers, biohazard suits, leggings, and metatarsal protectors
- Facial protectors: masks or visors
- Disposable face masks
- Bioprotection suits (blouse and pants or coveralls)

INVIMA will grant authorization for the importation and manufacture of these products as long as the following requirements are met:

Import requirements

- A request is submitted to INVIMA with information of the manufacturer, country of origin of the product, and data of the authorized representative, if applicable
- List of products to be imported, including their date of manufacture
- Free sale certificate from the country of origin, or equivalent document or certification issued by the health authority. Interested parties may provide the link of the health entity so that INVIMA can verify their marketing authorization in that country.

Manufacturing requirements

- Submit the request to INVIMA along with the manufacturer's information (name, address, email, and telephone)
- Provide the list of products to be manufactured
- List the specific national or international technical standards that have been used in the manufacturing process
- Carry out a self-assessment of compliance with the requirements indicated in the technical annex of Resolution 522 of 2020, through the INVIMA's website.

The officially recognized accreditation body in Colombia is Organismo Nacional de Acreditación de Colombia (Colombian National Accreditation Body, or ONAC). ONAC is a non-profit corporation, constituted in 2007 under Colombian laws within the framework of the Civil Code. Its main objectives are to accredit the technical competence of conformity assessment bodies, to act as a monitoring authority in the Organisation for Economic Co-operation and Development's good laboratory practices, and to perform the functions of the national accreditation body in accordance with the designation contained in Chapter 26 of Decree 1074 of 2015.

ONAC is a signatory of the ILAC MRA for accreditation of ISO/IEC 17025 and ISO 15189 and the IAF MLA for product and management system certification.

3.7 India

3.7.1 Regulatory landscape for COVID-19-related PPE

In India, COVID-19-related PPE generally falls within the scope of the Medical Device Rules (2017). For the last few years, the medical devices sector in India has been transitioning from being largely unregulated to a regulated regime. Since the late 1980s, medical devices have been regulated by the Central Drug Standard Control Organization (CDSCO) by notifying them as "drugs" under the Drugs & Cosmetics Act (1940). An important recent development was the issue of the Medical Devices Rules (MDR) in 2017 which aligned more closely with international practices and classified medical devices based on risk, as follows:

- Low risk—Class A
- Low-moderate risk—Class B
- Moderate-high risk—Class C
- High risk—Class D

These rules have been effective from January 1, 2018, but are applied only to specific "notified" medical devices, still leaving a large number of devices unregulated. In order to allow for more general application and a transition time for industry, further notifications, issued on February 11, and September 3, 2020, laid out the timelines for phased implementation of regulation for specific device categories and provided a formal definition of "non-notified medical devices."[38] Included in Category 12 of this latter classification are various forms of PPE, among them:

- Face shields, particular respirator (*sic*), latex and non-latex medical examination gloves, gowns/coveralls (all considered as Class A medical devices)
- Nitrile gloves, latex, and non-latex surgical gloves (Class B)

The situation on medical PPE was clarified with a notice issued by CDSCO on September 13, 2021, "Classification of medical devices pertaining to PPE under the provisions of Medical Device Rules, 2017-Reg." which provides the following classification:

Table 3.9: Classification of PPE as per the Medical Devices Rules (2017)—India

Medical device name	Risk class
Face shield	A
Surgical gloves (latex or non-latex)	B
Medical examination gloves (latex or non-latex)	A
Surgical/isolation gowns (non-sterile), patient gowns, professional examination gowns	A
Surgical/isolation gowns (sterile)	B
Face masks and/or respirators (included in an overall "PPE" listing)	B

In the notice the intended use of the above medical device types is also provided.

The transition plan for the MDR currently requires all Class A and Class B medical devices to comply with the MDR 2017 by September 30, 2022, and Class C and D devices by September 30, 2023.

38 CDSCO (Medical Device Division) . September 3, 2020. File No 29/Misc/03/2020/DC(200).

3.7.2 Approach to standardization and key product standards for PPE

Historically, India's portfolio of standards was based largely on British Standards. Independent national standardization activity started in 1947 with the establishment of the Indian Standards Institution (ISI) and in 1952 an Act of Parliament also gave to ISI the responsibility of operating a certification marking scheme. The Bureau of Indian Standards (BIS) Act was approved in 1986 and ISI was superseded by BIS on April 1, 1987. The BIS Act has since been revised in 2016.

BIS standards have subsequently evolved to become closely aligned with the European and international standards published by CEN and ISO respectively, both in terms of product standards and test methods. The need for this approach was further reinforced in 1995, when India joined the WTO (see Part 1 of this guide.)

The Indian standards portfolio for PPE is mature and extensive. The process of adopting ISO or even EN test methods has been used extensively, although the links are often not obvious from the standards numbering process. The link is usually contained within the standard foreword and not reflected by adopting or prefixing the foreign standard number, as is common in many other economies.

BIS standards, other than those which are adoptions of ISO/IEC standards, are available as free downloads at https://standardsbis.bsbedge.com/

The EU standards are themselves largely moving to an ISO standard base for PPE within the next few years and work will be required by BIS to ensure that this alignment is maintained. According to a recent UK government report,[39] "to achieve alignment with the largest sector of global economies, the Indian standards landscape therefore needs to decide whether to align with the USA or to the rest of the ISO world. This may present some difficulties in the supply chain for materials, where ASTM standards are often used to qualify materials, which then require additional testing to ISO standards. ISO is the direction that the majority of economies are currently travelling in."

The report goes on to make the following recommendations:

- A more general adoption of current ISO-based headline product standards that are either in use in Europe or being introduced within the next few years
- To continue the process of adopting ISO test methods in support of the headline product standards
- To provide clearer definitions between protective and medical products and the relevant standards, ensuring that both single-approach (PPE or medical device) and dual-use product requirements are clearly defined
- The more extensive use of prefixing existing ISO standard numbers in order to make adopted standards more obvious to the whole supply chain. This may require additional agreements between BIS and other standard-issuing bodies.

The MDR prescribes the use of product standards as follows:

- **Sub-rule 1**The medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act (No. 63 of 1985) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time
- **Sub-rule 2** Where no relevant standard of any medical device has been laid down under Sub-rule 1, such device shall conform to the standard laid down by the International Organization for Standardization (ISO) or the International Electrotechnical Commission (IEC), or by any other pharmacopoeial standards
- **Sub-rule 3** In the case of standards which have not been specified under sub-rule (1) and sub-rule (2), the device shall conform to the validated manufacturer's standards.

The quality management systems required for medical device manufacturers are based on ISO 13485:2003 and not the latest (2016) version. This means that manufacturers have to seek certification to ISO 13485:2016 in order to achieve international recognition but also comply with the older (2003) version for compliance to MDR.

39 UK Foreign, Commonwealth and Development Office. March 2021. *Report on UK-India Ease of Doing Business Programme PPE Project*.

The overall situation was somewhat complicated at the beginning of the COVID-19 pandemic. In March 2020, emergency guidelines for PPE published by the Ministry of Health prescribed the use of foreign or international standards for PPE (and not BIS standards as prescribed in the MDR), but without defining how conformity to these standards should be demonstrated.

The Ministry of Textiles, which took the responsibility of ramping up production of many categories of PPE, also took the initiative of installing a system of certifying the quality of coveralls by testing in designated laboratories. It subsequently advised PPE manufacturers to obtain BIS certification which resulted in the implementation of BIS standards in the PPE industry (not all of which are aligned to international standards), despite Ministry of Health guidelines not referencing them. This situation continues (Q4 2021), and BIS certification is being required for public procurement.

Table 3.10 provides an overview of the main product standards for PPE in the Indian market and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 3.10: Overview of COVID-19-related PPE standards in the Indian market

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

PPE	Main product standards	More details (link)
Respirators	**IS 9473:2002** (reaffirmed 2019) Respiratory protective devices—filtering half- masks to protect against particles—specification. Based on **EN 149:1991 version** (since revised)	9.1.1
Medical face masks	**IS 16289:2014** (reaffirmed 2019) Medical textiles—surgical face masks—specification	9.1.2
Community face coverings	n/a	9.1.3
Face shields	**IS 5983:1980** (reaffirmed 2018) Specification for eye protectors. Based on **ISO 4849**, since replaced by **ISO 16321-1** **IS 8521-1:1977** (reaffirmed 2018) Specification for industrial face shields—Part 1—with plastic visor	9.2
Protective goggles	**IS 5983:1980** (reaffirmed 2018) Specification for eye protectors. Based on **ISO 4849**, since replaced by **ISO 16321-1**	9.2
Medical examination gloves	**IS 15354-1:2018** Single-use medical examination gloves—Part 1: Specification for gloves made from rubber latex or rubber solution. Identical to **ISO 11193-1: 2008** (since revised) **IS 15354-2:2018** Single-use medical examination gloves—Part 2: Specification for gloves made from poly(vinyl chloride). Identical to **ISO 11193-2: 2006** **IS 6994-7:2021** Protective gloves—general requirements and test methods. Identical to **ISO 21420:2020** **IS 6994-5: 2021** Protective gloves against dangerous chemicals and micro-organisms—requirements for micro-organisms risks. Identical to **ISO 374-5:2016**	9.3.1
Surgical gloves	**IS 13422:1992** (reaffirmed 2018) Disposable surgical gloves specification. Based on **ASTM D3577-88** (since revised) **IS 6994-7:2021** Protective gloves—general requirements and test methods. Identical to **ISO 21420:2020** **IS 6994-5: 2021** Protective gloves against dangerous chemicals and micro-organisms—requirements for micro-organisms risks. Identical to **ISO 374-5:2016**	9.3.2

Suits & coveralls	**IS 17423:2021** Medical textiles—bio-protective coveralls—specification	9.4.1
Aprons	n/a	9.4.1
Shoe and Head covers	n/a	9.4.1
Gowns	**IS 17334:2019** Medical textiles—surgical gowns and surgical drapes— specification	9.4.2

3.7.3 Approach to conformity assessment

Registration to provide products covered by the MDR—including the PPE mentioned in Category 12 of the CDSCO September 2020 Notice—is a temporary measure, as a step toward licensing. After the transition is complete this will require manufacturers to implement a quality management system as per its schedule 5 (based on old version of ISO 13485) and demonstrate compliance to product standards as specified in the MDR. It important to note that during this transition period neither compliance to the MDR nor to the product standards mentioned therein is legally mandated.

The officially recognized accreditation bodies in India for conformity assessment activities are the National Accreditation Board for Certification Bodies (NABCB) for product and management system certification, among others, and the National Accreditation Board for Testing and Calibration Laboratories (NABL). Both are entities under the Quality Council of India and signatories to the IAF MLA and ILAC MRA respectively. MDR prescribes audits by notified bodies for classes A and B devices and audits by the regulator for classes C and D devices. The notified bodies are required to be accredited by NABCB. The list of notified bodies can be seen on the website of the CDSCO.[40]

3.8 Jordan

3.8.1 Regulatory landscape for COVID-19-related PPE

The fundamental provisions for occupational safety and health matters in Jordan are defined in Chapter 9 of the 1996 Labour Law and its amendments. The Occupational Health and Safety Directorate[41] of the Ministry of Labour oversees its implementation, with attributions that include ensuring the provision of a healthy, safe, and decent work environment in all sectors and professions by raising awareness and compliance with standards and best practices related to occupational safety and health. However, its activities do not cover the regulation of medical-related PPE, most of which is regulated as medical devices by the Jordan Food and Drug Administration (JFDA) under the Ministry of Health and/or covered by "mandatory standards" issued by the Jordan Standards and Metrology Organization (JSMO).

The Drug and Pharmacy Law No 12 of 2013 and its associated regulations and directives, consider medical devices as part of "medical supplies," which are defined as being "all devices, means, substances, tools, items or reagents and calibrators, including the software required for their operation, whether used alone or in association with another, that are intended by the manufacturer for human use for achieving any of the following purposes: [...] diagnosis, prevention, supervision, treatment, or reduction of diseases [...]." All are administered by the Medical Devices & Supplies Directorate of the JFDA.

Most of the medical PPE in this guide is classed as low risk (Class I)[42] in a classification system that closely mirrors that of the EU.[43] Only surgical masks are considered as low-to-moderate risk (Class IIa).

While products falling under Classes I and IIa do not require registration, any products that are deemed as

40 https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/ListofNotifiedmd.pdf.

41 http://www.mol.gov.jo/EN/Pages/Occupational_Safety_and_Health_Directorate.

42 https://www.regdesk.co/resource-library/jordan/.

43 https://www.who.int/medical_devices/countries/regulations/jor.pdf?ua=1.

medical devices need to be approved for import by the JFDA and must comply with certain conditions that mainly pertain to the documents required for import purposes, as well as the information that must be included on labels and inner and outer packaging.

3.8.2 Approach to standardization and key product standards for PPE

The JSMO is the national standards body and was established as a public organization according to the Standards and Metrology Law (1994 and 2000).

The JSMO issues two types of standards:

- **Technical standards:** Mandatory standards that are based on international benchmarks and agreements. These standards cover products that effect consumers' health and safety, such as food products, chemical detergents, electrical equipment, and "personal safety equipment." Technical standards are published in the Jordan Official Gazette in hard copy only and are registered in the Jordan Quality Mark database.

- **Standard specifications**: Optional (voluntary) standards for manufacturers and importers. Examples include furniture products, clothes, textiles, and shoes. Some companies choose to set their own standard specification, adding special features or qualities.

In its role to strengthen the national quality infrastructure for products and services and align Jordanian national standards with international best practices, the JSMO is focusing on PPE as a priority sector and in response to an urgent national need.

In addition to its role in standardization, the JSMO also conducts the following activities:

- Supervision of the national system for metrology in Jordan aiming to maintain the national measurement standards and assure traceability to SI Units, in cooperation with the Jordan National Metrology Institute

- Certification, including product conformity certificates such as the Jordan Quality Mark Certificate, Local Conformity Certificate, Conformity Certificate for Export Purposes and others. The process to receive a quality mark is divided into four stages: application procedure, assessment procedure, certification procedure, and surveillance procedure

- Market surveillance to verify conformity of imported products and products placed on the market with mandatory technical regulations

- Managing the WTO/TBT Enquiry Point and providing information services to economic operators.

Table 3.11 provides an overview of the main product standards for PPE in the Jordanian market and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 3.11: Overview of COVID-19-related PPE standards in the Jordanian market

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

PPE	Main product standards	More details (link)
Respirators	**JS 1943:2011** Respiratory protective devices -filtering half-masks to protect against particles-requirements, testing, marking. Identical to **EN 149:2001** (since amended)	10.1.1
Medical face masks	**JS 1745:2007** Disposable surgical masks-requirement and test methods. Based on **EN 14683:2005** (since revised)	10.1.2
Community face coverings	n/a (under development)	10.1.3
Face shields	**JS 268:2008** Personal eye protection—specifications. Identical to **EN 166:2001**	10.2
Protective goggles	**JS 268:2008** Personal eye protection—specifications. Identical to **EN 166:2001**	10.2
Medical examination gloves	**JS 809 series** (Medical gloves for single use) **JS 809-1:2005** Requirements and testing for freedom from holes. Identical to **EN 455-1:2000** (since revised) **JS 809-2: 2014** Requirements and testing for physical properties. Identical to **EN 455-2:2009** (since revised) **JS 809-3: 2014** Requirements and testing for biological evaluation. Identical to **EN 455-3: 2006** (since revised) **JS 809-4: 2014** Requirements and testing for shelf-life determination. Identical to **EN 455-4: 2009**	10.3.1
Surgical gloves	**JS 809 series** (Medical gloves for single use) **JS 809-1:2005** Requirements and testing for freedom from holes. Identical to **EN 455-1:2000** (since revised) **JS 809-2: 2014** Requirements and testing for physical properties. Identical to **EN 455-2:2009** (since revised) **JS 809-3: 2014** Requirements and testing for biological evaluation. Identical to **EN 455-3: 2006** (since revised) **JS 809-4: 2014** Requirements and testing for shelf-life determination. Identical to **EN 455-4: 2009**	10.3.2
Suits and coveralls	**JS 1899:2009** Protective clothing for protection against chemicals—classification, labeling, and performance requirements. Identical to **ISO 16602:2007** (since amended)	10.4.1
Aprons	**JS 1899:2009** Protective clothing for protection against chemicals—classification, labeling, and performance requirements. Identical to **ISO 16602:2007** (since amended)	10.4.1
Shoe and head covers	n/a	10.4.1
Gowns	**JS 983-1:2007** Surgical drapes, gowns, and clean air suits, used as medical devices, for patients, clinical staff, and equipment—Part 1: General requirements for manufacturers, processors, and products. Equivalent to **EN 13795-1:2002** (since revised) **JS 983-2:2007** Surgical drapes, gowns, and clean air suits, used as medical devices, for patients, clinical staff, and equipment—Part 2: Test methods. Equivalent to **EN 13795-2:2002** (since revised) **JS 983-3:2008** Surgical drapes, gowns, and clean air suits, used as medical devices, for patients, clinical staff, and equipment—Part 3: Performance requirements and performance levels. Equivalent to **EN 13795-3:2006**, since merged with **EN 13795-1** and **EN 13795-2**	10.4.2

3.8.3 Approach to conformity assessment

All imported goods subject to mandatory standards require verification through laboratory testing in Jordan. The JSMO undertakes these responsibilities by cooperating with approved laboratories, including those at the JSMO, Ministry of Health, Greater Amman Municipality, Ministry of Agriculture and Royal Scientific Society, all of which perform inspection and testing.

The Ministry of Health sets technical rules and specifications applicable to all medical equipment to ensure that all such products being sold to Jordanian end users meet the requirements of safety and quality. Public sector tenders do not require regulatory review if the product has been authorized for marketing in the United States, Europe, or Japan. Other specifications are stipulated in the tender terms on a case-by-case basis.

Pre-market approval is mandatory for all medical devices; suppliers are required to:

- Appoint an authorized representative in Jordan to submit the application
- Fill out the application form and submit all required documents:
  - Certificate of free sale (CFS)
  - Quality system certification (standard not specified)
  - Declaration of conformity
  - Description of device and intended use.

If approved, the applicant will receive a registration certificate.

Medical equipment procured by the public sector is tested either by the beneficiary itself (that is, Ministry of Health, Royal Medical Services, and so on) or the Royal Scientific Society. This testing is not applicable to medical equipment procured by the private sector, which is not subject to any prescribed testing procedures.

The JFDA may prohibit the import of a product, cease its sale or distribution, ban its marketing, suspend or revoke its registration, or recall it if:

- The product is found to be toxic, of inferior quality, ineffective, or of less than the required efficacy, pursuant to a report from the WHO, the manufacturer or other entity accredited by the JFDA
- It proves that it is not permissible to market the product or that its marketing has been suspended in the country that was relied on for its registration
- It was registered based on incorrect information
- Certain variations on the product that require renewal of the registration were made without that renewal
- Certain variations on the product that require prior approval were made without obtaining that approval.

The officially recognized accreditation body for Jordan is the Accreditation Unit of the Jordanian Accreditation and Standardization System (JAS-AU) which is hosted by, but is independent from, the JSMO. All certificates of accreditation issued by the JAS-AU for testing laboratories, calibration laboratories, and medical laboratories are recognized and accepted worldwide as a result of its full membership of the Arab Accreditation Cooperation (ARAC) and ARAC's subsequent admission to the ILAC MRA in 2017.

The JAS-AU's scope that is covered by the ARAC multilateral arrangement includes the following:

- Calibration laboratories ISO/IEC 17025
- Testing laboratories ISO/IEC 17025
- Medical/clinical laboratories ISO 15189
- Inspection ISO/IEC 17020
- Product certification ISO/IEC 17065.

3.9 Kenya

3.9.1 Regulatory landscape for COVID-19-related PPE

General occupational safety and health legislation in Kenya can be traced back to the Factories' Ordinance Act (1950) which gradually evolved over time to become the Occupational Safety and Health Act (2007), still in force today. The Directorate of Occupational Safety and Health Services within the Ministry of Labour, Social Security and Services is responsible for the oversight and enforcement of the provisions of the act, which requires all government sectors to develop policies and guidelines to support it. The Ministry of Health is the lead health care policy-setting institution in Kenya and published its "Occupational safety and health policy guidelines for the health sector in Kenya" in July 2014. The Pharmacy and Poisons Board, an agency under the Department of Medical Services at the Ministry of Health, is the regulatory body for registration of medical devices, including PPE.

On February 28, 2020, President Uhuru Kenyatta established a new committee to guide the response to COVID-19. This committee, chaired by the Cabinet Secretary for Health, was tasked with coordinating the country's COVID-19 preparedness, prevention, and response. In particular, this committee is responsible for coordinating capacity building of medical professionals, enhanced surveillance at points of entry, preparation of isolation and treatment facilities, medical supplies, and PPE. Table 3.12 shows the various categories of PPE and their application that have been defined for healthcare workers in the fight against COVID-19.

Table 3.12: Risk categories for PPE to be provided to health care workers[44]

PROTECTION LEVEL	PROTECTIVE EQUIPMENT	SCOPE OF APPLICATION
LEVEL 1 PROTECTION	• Disposable surgical mask • Facility uniform • Gloves	• Triage • Outpatients' clinic • Private clinics
LEVEL 2 PROTECTION	• Facility uniform • N95 mask • Caps • Waterproof surgical gowns • Gloves • Eye protection e.g., face shield or goggles • Plastic apron	• COVID-19 clinics • Isolation wards and CCU • Radiology unit for confirmed COVID-19 patients • Decontamination and cleaning unit (public health) • Laboratory • Farewell home
LEVEL 3 PROTECTION	• Disposable scrubs • N95 mask • Waterproof surgical gowns • Plastic apron • Face shield or goggles if available • Caps • Gloves	• During suctioning • Intubation • Bronchoscopy • Surgery • Endoscopy or colonoscopy

3.9.2 Approach to standardization and key product standards for PPE

The Kenya Bureau of Standards (KEBS) is a statutory body established under the Laws of Kenya Standards Act (2012), Chapter 496. The aims and objectives of the Bureau include preparation of standards relating to products, measurements, materials, processes, and so on, and their promotion at national, regional, and international levels, certification of industrial products, assistance in the production of quality goods, improvement of measurement accuracy, and circulation of information relating to standards. KEBS is also mandated to offer quality inspection of imports based on Kenya Standards or other approved specifications.

KEBS has remained the premier government agency for the provision of standards, metrology, and conformity assessment services since its inception in 1974. Over that period, its main activities have grown from the development of standards and quality control for a limited number of locally made products in the 1970s to the provision of more comprehensive standards development, metrology, conformity assessment,

44 Republic of Kenya, Ministry of Health. 2021. *Guidelines on Case Management of COVID-19 in Kenya*.

training, and certification services. With the re-establishment of the East African Community and Common Market for Eastern and Southern Africa, KEBS activities now include participation in the development and implementation of standards, metrology, and conformity assessment activities at the regional level where it participates in the harmonization of standards, measurements and conformity assessment regimes for regional integration.

KEBS also operates the National Enquiry Point in support of the WTO/TBT Agreement.

Table 3.13 provides an overview of the main product standards for PPE in the Kenyan market and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 3.13: Overview of COVID-19-related PPE standards in the Kenyan market

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

PPE	Main product standards	More details (link)
Respirators	**KS 2409-6:2018** Health care wastes management commodities. Specification—Part 6: Filtering face masks to protect against particles. Based on (but not identical to) **EN 149:2001,** since amended	11.1.1
Medical face masks	**KS 2636:2021** Medical face masks—specification. Based on (but not identical to) **EN 14683:2019**	11.1.2
Community face coverings	**KS 2924:2020** Personal protective equipment—face masks—masks for public use—specification	11.1.3
Face shields	**KPAS 2919:2020** Personal protective equipment—face shield—specification	11.2
Protective goggles	**KS 2409-8:2018** Health care wastes management commodities. Specification—Part 8: Safety goggles. References **ISO 4849**, since replaced by **ISO 16321-1**	11.2
Medical examination gloves	**KS ISO 11193-1:2020** Single-use medical examination gloves —Part 1: Specification for gloves made from rubber latex or rubber solution. Identical to **ISO 11193-1:2008** with **AMD1: 2012,** since revised **KS ISO 11193-2:2006** Single-use medical examination gloves. Part 2: Specification for gloves made from poly(vinyl chloride). Identical to **ISO 11193-2:2006,** current	11.3.1
Surgical gloves	**KS ISO 10282:2014** Single-use sterile rubber surgical gloves. Identical to **ISO 10282:2014,** current	11.3.2
Suits and coveralls	**KS ISO 13688:2013** Protective clothing—general requirements. Identical to **ISO 13688:2013,** since amended. **KS 2409-07:2018** Health care wastes management commodities. Part 7: Overall clothing—specification	11.4.1
Aprons	**KS 2409-3:2018** Health care wastes management commodities. Specification—Part 3: Plastic apron	11.4.1
Shoe and head covers	n/a	11.4.1
Gowns	n/a	11.4.2

3.9.3 Approach to conformity assessment

Public procurement for both medical equipment (including PPE) and pharmaceuticals is performed by the Kenya Medical Supplies Agency (KEMSA), a state corporation and a specialized medical logistics provider for the Ministry of Health. KEMSA typically uses open international tenders, open national tenders limited to local Kenyan suppliers only, restricted tenders, or direct procurement from government agencies to source products. All public tenders are advertised on the KEMSA website and must follow the Public Procurement Act (2015).

All imported products require a certificate of conformity (CoC) for customs clearance at the border, applicable for each consignment, and importers are required to obtain the CoC for their goods before applying for import permits from the Pharmacy and Poisons Board through the Kenya National Single Window Electronic (KenTrade) System.

In September 2017, Kenya incorporated all medical devices, food supplements, medical cosmetics, herbal products, and other allied borderline health care products into the Pre-Export Verification of Conformity program. This is a conformity assessment program applied to products at the respective exporting countries, to ensure their compliance with the applicable Kenyan technical regulations and mandatory standards or approved specifications. Products must demonstrably meet requirements before they can be exported to Kenya. Non-compliant goods will be denied entry.

The program is operated by accredited third-party inspection companies in 19 different geographical regions on behalf of KEBS. The basis of certification is the relevant Kenya standards or approved specifications, and can include:

- Physical inspection prior to shipment
- Sampling, testing, and analysis in accredited laboratories
- Audit of production processes
- Documentary check of conformity to regulations
- Assessment of conformity to Kenyan Standards.

The officially recognized accreditation body for Kenya is the Kenya Accreditation Service (KENAS), established in 2009 to carry out accreditation of conformity of assessment services including calibration, product testing, medical testing (pathology) and proficiency testing laboratories, inspection, verification, and certification bodies in all economic sectors. It is a state corporation re-established by the Kenya Accreditation Service Act (No. 17 of 2019) as the sole national accreditation body for Kenya.

KENAS is responsible to the Ministry of Industry, Trade and Enterprise Development with a broad objective to strengthen the conformance to standards technical infrastructure and to build confidence in Kenyan products and services locally and globally. KENAS contributes to Kenya's development agenda by promoting the use of accreditation and the acceptance of equivalence of accredited bodies worldwide as means for facilitating trade, enhancing economic outcomes, managing and mitigating risks to quality, health, safety, environment, and consumer protection.

KENAS is also the designated member and representative for Kenya for regional and international accreditation. Since 2017, KENAS has been a full signatory to the mutual recognition arrangements (MRAs) with the African Accreditation Cooperation (AFRAC), the IAF and ILAC.

3.10 Malaysia

3.10.1 Regulatory landscape for COVID-19-related PPE

PPE intended for use in health care facilities or for the prevention of transmission of disease falls within the scope of the Medical Devices Act (2012) (Act 737) and is regulated as medical devices in Malaysia. The regulation of medical devices is carried out by the Medical Device Authority (MDA) of the Ministry of Health (www.mda.gov.my). The act has been further detailed by the Medical Device Regulations 2012 and other regulations issued later on specific topics. The MDA has issued several guidance documents available at https://www.mda.gov.my/doc-list/guidance-document.html.

PPE within the scope of this guide is considered as Class A (low risk) medical devices, therefore the involvement of a "registered conformity assessment body" (similar to a "notified body" in the EU) is not necessary.

It is also worth mentioning that PPE for non-medical uses (that is, industrial, construction, chemical protection, and so on) is regulated under the Occupational Safety and Health Act 1994 (Act 514) and regulations issued under it. Such PPE must be approved by the Department of Occupational Safety and Health (https://www.dosh.gov.my/index.php#) under the Ministry of Human Resources.

3.10.2 Approach to standardization and key product standards for PPE

The national standards body of Malaysia is the Department of Standards Malaysia (DSM), under the Ministry of International Trade and Industry, https://www.jsm.gov.my/. The DSM represents Malaysia in the ISO, IEC, and the regional organizations involved in standardization activities including the Asia-Pacific Economic Cooperation Sub-Committee on Standards and Conformance (APEC-SCSC) and the ASEAN (Association of Southeast Asian Nations) Consultative Committee for Standards & Quality.

Malaysian standards related to COVID-19 are freely available online at https://www.jsm.gov.my/relevant-standards-related-to-covid-19-pandemic and at the MySOL platform, launched in 2021 at https://msonline.jsm.gov.my/

The following MDA Guidance Documents are relevant to medical PPE:

- MDA/GD/0058 (September 2021)—personal protective equipment (PPE)—requirements
- MDA/GD/0033 (October 2021)—medical face mask and respirator

Table 3.14 provides an overview of the main product standards for PPE in the Malaysian market and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 3.14: Overview of COVID-19-related PPE standards in the Malaysian market

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

PPE	Main product standards	More details (link)
Respirators	**MS 2323:2010** Respiratory protective devices—filtering half-masks to protect against particles—requirements, testing, and marking. Identical to **EN 149:2001,** since amended	12.1.1
Medical face masks	**MS EN 14683:2021** Medical face masks—requirements and test methods. Identical to **EN 14683:2019**	12.1.2
Community face coverings	n/a	12.1.3
Face shields	n/a	12.2
Protective goggles	n/a	12.2
Medical examination gloves	**MS 2299-1:2010** Medical gloves for single use—Part 1: Requirements and testing for freedom from holes. Identical to **EN 455-1:2000**, since revised **MS 2299-3:2010** Medical gloves for single use—Part 3: Requirements and testing for biological evaluation. Identical to **EN 455-3:2006,** since revised	12.3.1
Surgical gloves	**MS 2299-1:2010** Medical gloves for single use—Part 1: Requirements and testing for freedom from holes. Identical to **EN 455-1:2000**, since revised **MS 2299-3:2010** Medical gloves for single use—Part 3: Requirements and testing for biological evaluation. Identical to **EN 455-3:2006,** since revised	12.3.2
Suits and coveralls	**MS ISO 13688:2020** Protective clothing —general requirements. Identical to **ISO 13688:2013**, since amended	12.4.1
Aprons	**MS ISO 13688:2020** Protective clothing—general requirements. Identical to **ISO 13688:2013**, since amended	12.4.1
Shoe and head covers	**MS ISO 13688:2020** Protective clothing—general requirements. Identical to **ISO 13688:2013**, since amended	12.4.1
Gowns	n/a	12.4.2

It can be seen from Table 3.14 that Malaysian standards exist for several, but not all, PPE types and these are adaptations of EN or ISO standards (not always aligned with the latest versions).

Even when they are available, the Malaysian standards are not always referred to in the MDA Guidance Documents. For the purpose of complying with medical device regulations, standards from the United States and the EU are generally accepted. Table 3.15 provides some specific examples.

Table 3.15: Other (non-Malaysian) PPE standards accepted by the MDA

PPE type	Accepted performance standards	Comments
Procedure mask/ respirators	EN 14683:2019 (type I or II) or ASTM F2100-19 (level 1) or YY/T 0969 (BFE ≥ 95%)	MDA accepts any equivalent standard giving comparable performance
Respiratory protection devices	---	Not medical devices, added for completeness
Surgical mask/respirators/fluid-resistant surgical masks	EN 14683:2019 (type IIR) or ASTM F2100-19 (level 2 or 3) or YY/T 0469 (BFE ≥ 98%)	MDA accepts any equivalent standard giving comparable performance
Community face coverings	---	Not medical devices; added for completeness. The Ministry of Domestic Trade and Consumers Affairs is in the process of regulating based on MS EN 14683 requirements
Face shield/goggles	EN 166 For irritation ISO 10993-10:2010 or ISO 10993-23:2021	
Medical examination gloves (non-sterile)	ISO 11193-1:2020 (rubber) or EN 455 series or (depending on material) ASTM D6319, ASTM D3578, ASTM D5250, AST D6977 or alternative equivalent set of standards	EN 455-2 and -4 have not been adopted as Malaysian standards.
Surgical gloves (sterile)	ISO 10282 or EN 455 series or ASTM D3577 For sterility EN ISO 11607-1:2019 or alternative equivalent set of standards	
Coveralls	EN 14126, ISO 16603, ISO 16604, ISO 22610 and ISO 22612	
Non-surgical gowns	ANSI/AAMI PB70, level 1 or 2 or EN 13795-1	
Surgical gowns/isolation gowns	ANSI/AAMI PB70, level 3 or 4 (recommended) or EN 13795-1 Also, if sterile, EN 556-1, or alternative equivalent set of standards	
Aprons	Standards as above for coveralls For tear resistance EN ISO 7765-1, EN ISO 6383-2 If biodegradable, EN 13432 or ASTM D6400	
Head/shoe covers	Standards as above for coveralls If biodegradable, EN 13432 or ASTM D6400	

3.10.3 Approach to conformity assessment

The manufacturer, or its authorized representative in Malaysia, must apply to the MDA in order to register their medical devices and must submit for review a declaration of conformity. The application must include a full test report for the product and (if it is to be supplied sterile) the sterilization process validation report—see Guideline Document MDA/GL/MD-01 (June 2014). Also, a technical documentation file must be prepared and made available on request. The file must be in the Common Submission Dossier Template (CSDT) format and contain evidence of conformity of the medical device to the relevant essential principles of safety and performance contained in the legislation—see Guidance Document MDA/GD/0008 (March 2014).

For Class A medical devices such as medical PPE, no involvement of an external conformity assessment body is required, although the manufacturer must establish a quality management system according to ISO 13485 and a post-market surveillance system (see Table 3.16).

Table 3.16: Conformity assessment requirements for Class A medical devices

Conformity assessment element	Manufacturer/representative responsibility	Conformity assessment requirement
Quality management system	a) Establish and maintain a full quality management system or may exclude design and development controls, process control and inspection and testing; and/or b) Keep evidence (validation report) on the aspect of manufacture concerned with securing and maintaining sterile condition if the medical device is to be supplied sterile	Pre-market and regulatory audit not required
Post-market surveillance system	a) Establish and maintain post-market surveillance system b) Record and evaluate reports of adverse events c) Document, maintain and implement: i. Complaint handling ii. Distribution records iii. Mandatory problem/adverse event reporting iv. Field corrective action v. Recall	Pre-market and regulatory audit not required Regulatory audits may be conducted as deemed necessary by the authority
Technical documentation	Prepare summary of technical documentations (refer to MDA/GD/0008: CSDT) and have available for review on request	Pre-market submission of CSDT not required. May be requested by the authority for the purpose of investigating specific safety or regulatory concerns
Declaration of conformity	Prepare declaration of conformity as per specified in MDA/GD/0025	Manufacturer/representative to submit during registration process, keep on file and present on request by the authority

From 1st June, 2021, PPE for applications such as respiratory protection (particulate filters) and body protection must obtain certification from an approved accredited conformity assessment body. Initially, the only body that is approved is SIRIM QAS International Sdn. Bhd (https://www.sirim-qas.com.my/our-services/product-certification/personal-protection-equipment-scheme/), but more are expected to be added to the list in the future. The same requirement will hold for personal eye protection and gloves after 1st June, 2022. Such certification typically involves a type examination (that is, examination of a prototype to confirm that it meets the requirements of the relevant product standard), followed by factory audits/product sampling and testing in order to verify ongoing conformity of the product.

The officially recognized accreditation body in Malaysia for conformity assessment activities is the national standards body DSM, which is a signatory to the ILAC MRA for laboratory testing, as well as to the IAF MLA for product and management system certification, among others.

3.11 South Africa

3.11.1 Regulatory landscape for COVID-19-related PPE

The overarching legislation for health- and safety-related matters in South Africa is the Occupational Health and Safety Act 85 (1993) which, together with its regulations and incorporated standards, requires employers to provide and maintain, as far as is reasonably practicable, a working environment that is safe and without risks to the health of workers. Employers are required to take such steps as may be reasonably practicable to eliminate or mitigate hazards or potential hazards.

The act further requires employers to ensure, as far as is reasonably practicable, that all persons who may be directly affected by their activities, such as customers, clients or contractors and their workers who enter their workplace or come into contact with their employees, are not exposed to hazards to their health or safety. In the context of the COVID-19 pandemic, it is important to emphasize that this obligation also applies to self-employed persons, for example, plumbers or electricians, whose working activities bring them into contact with members of the public.

With regard to PPE, any product that falls within the definition of a medical device, or that is indicated or intended for use in a medical or health care environment, is regulated as a medical device by the South African Health Products Regulatory Authority (SAHPRA) under the Medicines and Related Substances Act (No. 101 of 1965). SAHPRA was formed in 2018 to replace the existing Medicines Control Council and Directorate of Radiation Control. This includes all the products covered in this guide, with the exception of community face coverings and non-sterile face masks that are not used in a medical or health care environment.

Medical devices are classified according to their associated risk to the patient, user, or public health as follows:

- A—Low risk
- B—Low-moderate risk
- C—Moderate-high risk
- D—High risk

Details of classification criteria and associated standards can be found in the SAHPRA document "Classification of medical devices and IVDs"[45] and the 2020 Department of Health document "COVID-19 disease—personal protective equipment, body bags, disinfectants, alcohol-based hand rub, and digital thermometers—specification guidelines."[46]

A medical device may only be manufactured, imported, exported, distributed, or wholesaled by an organization that holds a valid medical device establishment license issued by SAHPRA, in terms of Section 22C(1)(b) of the Medicines and Related Substances Control Act 101 of 1965 after amendment by the Medicines and Related Substances Control Amendment Act (No. 90 of 1997). Some COVID-19-related PPE is also subject to regulation and authorization by the National Regulator for Compulsory Specifications. For example, face masks fall into different regulatory groups depending on the type of mask and its intended use, as shown in Figure 3.5.[47]

45 https://www.sahpra.org.za/wp-content/uploads/2020/01/Classification_Medical_Devices_IVDs_Nov19_v2.pdf.

46 https://www.nicd.ac.za/wp-content/uploads/2020/11/PPE-Specifications-21-Aug-2020-Signed.pdf.

47 SAHPRA. May 2020 (v2). "Joint SAHPRA/NRCS/SABS Communication to Stakeholders—Regulatory Status of Equipment Being Used to Help Prevent Coronavirus (COVID-19)."

Figure 3.5: Examples of the classification of masks according to the South African PPE or medical device regulations

	Cloth mask	Non-sterile medical (surgical) mask	Non-sterile medical (surgical) mask	Sterile medical (surgical) mask	Dust mask	Respirator mask	Respirator mask (particle filtering half mask
							
Examples		1-ply, 2-ply or 3-ply masks	3-ply masks	3-ply masks		N95, KN95	N95, KN95
Classification	Non-medical general	Non-medical general	Class A medical device	Class A medical device (sterile)	Non-medical general	Class B medical device	Non-medical e.g., mining industry
SAHPRA manufacturer, distributor, wholesaler license	No	No	No Exemption from licensing requirement for non-sterile Class A medical devices	Yes	No	Yes	No
NRCS sales permit/ authorization (LOA)	No	No	No	No	No	Yes	Yes
Specification/ Standards/ Other legislation	None Department of Health guideline on the "Use of cloth face masks by	None	Yes SANS 1866-1: 2018	Yes SANS 1866-1: 2018	None	Yes SANS 1866-2: 2018	Yes SANS 1866-2: 2018

Further requirements for employers regarding the use of COVID-19-related PPE are defined in the Disaster Management Act (2020) "Consolidated coronavirus COVID-19 direction on occupational health and safety measures in certain workplaces," but the Act does not include any specific requirements for PPE itself.

3.11.2 Approach to standardization and key product standards for PPE

The South African Bureau of Standards (SABS) is a statutory body that was originally established under the terms of the Standards Act (1945) and currently exists under the Executive Authority of the Minister of Trade, Industry and Competition. The SABS was a founder member of ISO. The legislation concerning the SABS has been modified several times to cater for changing circumstances and to amend the scope of activities of the body. The latest edition is the Standards Act (2008), promulgated "to provide for the development, promotion, and maintenance of standardization and quality in connection with commodities and the rendering of related conformity assessment services."

As the national standardization authority, SABS is responsible for maintaining South Africa's database of more than 6,500 national standards, as well as developing new standards and revising, amending, or withdrawing existing standards as required.

Internationally, SABS experts represent South Africa's interests in the development of international standards through their engagement with bodies such as the ISO and IEC and, at a regional level, the SADC Cooperation in Standards (SADCSTAN), the standardization body for the Southern African Development Community (SADC) of 14 nations.

SABS Commercial (Pty) Ltd. is a self-financing division within the SABS, offering certification, testing, consignment inspection, and other services, mostly to industry. Apart from offering systems certification

and product testing against the requirements of South African National Standards (SANS), SABS Commercial also operates its proprietary product certification scheme—the SABS Mark of Approval, assuring buyers that products are safe, fit for purpose, and offer redress.

Historically, the SABS also undertook certain regulatory functions on behalf of South Africa. However, in keeping with best international practice, this regulatory function was separated from the organization's standardization and certification activities in 2008 via the promulgation of the new Standards Act (2008) and the National Regulator for Compulsory Specifications Act (2008). Under these new laws, the former SABS Regulatory division separated to form the National Regulator for Compulsory Specifications, also residing under the Department of Trade and Industry.

SABS has played a significant role in the development of a standards, quality assurance, accreditation, and metrology infrastructure in the South African Development Community (SADC). It hosts the secretariat of the regional standard coordination forum, SADCSTAN and the legal metrology group, the SADC Cooperation in Legal Metrology (SADCMEL). SABS also operates the National Enquiry Point in support of the WTO/TBT Agreement.

Table 3.17 provides an overview of the main product standards for PPE in the South African market and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 3.17: Overview of COVID-19-related PPE standards in the South African market

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

PPE	Main product standards	More details (link)
Respirators	**SANS 50149:2003** Respiratory protective devices—filtering half-masks to protect against particle—requirements, testing, and marking. Identical to **EN 149:2001,** since amended **SANS 50143:2003** Respiratory protective devices—particle filters—Requirements, testing, marking. Identical to **EN 143:2000**, since revised	13.1.1
Medical face masks	**SANS 1866-1:2018** Medical devices. Part 1: Medical face masks. Based on **ASTM F2100**, most recently revised in 2021 **SANS 1866-2:2018** Medical devices. Part 2: Medical respirators based on **ASTM F2100** and **42 CFR part 84**	13.1.2
Community face coverings	n/a (under development)	13.1.3
Face shields	**SANS 50166:2002** Personal eye protection—specifications. Identical to **EN 166:2001** **SANS 1404:2009 Eye protectors for industrial and non-industrial use**	13.2
Protective goggles	**SANS 50166:2002** Personal eye protection—specifications. Identical to **EN 166:2001** **SANS 1404:2009 Eye protectors for industrial and non-industrial use**	13.2
Medical examination gloves	**SANS 11193-1:2010**, Single-use medical examination gloves—Part 1: Specification for gloves made from rubber latex or rubber solution). Identical to **ISO 11193-1: 2008,** since revised	13.3.1
Surgical gloves	**SANS 68:2003** Single-use sterile rubber surgical gloves. Identical to **ISO 10282:2002**, since revised	13.3.2
Suits and coveralls	n/a	13.4.1
Aprons	n/a	13.4.1
Shoe and head covers	n/a	13.4.1

Gowns	**SANS 53795:2015** Surgical drapes, gowns, and clean air suits, used as medical devices for patients, clinical staff, and equipment—general requirements for manufacturers, processors, and products, test methods, performance requirements, and performance levels. Identical to **EN 13795**, since replaced by **EN 13795-1** and **EN 13795-2**	13.4.2

3.11.3 Approach to conformity assessment

All new requests to place medical devices on the South African market require the following documents to be submitted to SAHPRA to obtain a medical device establishment license:

- Cover letter on company letterhead indicating intention to apply for a new SAHPRA license
- License application
- Proof of payment
- Curriculum vitae of the authorized representative
- Quality manual
- Supportive evidence for each Class C and D PPE listed, including evidence of pre-market approval/ registration/evidence of emergency use authorization for each listed PPE from at least one of the six jurisdictions recognized by SAHPRA (Australia, United States, EU, Brazil, Canada, and Japan)
- Certificate of free sale confirming evidence that each listed PPE is legally sold or distributed
- Evidence of ISO 13485:2016 certification of the original manufacturer for each listed PPE
- Copy of instructions for use for each listed PPE
- Copy of labeling and packaging of each listed PPE
- Supportive evidence for each Class A (measuring and/or sterile), B, C and/or Class D PPE listed, including evidence of compliance against the minimum requirements and/or certification against relevant standards and specifications as determined by the SABS and/or the National Regulator for Compulsory Specifications.

SAHPRA license holders must, as specified in regulation 17 of the regulations relating to medical devices and IVDs and in accordance with the "8.04 Recall, Adverse Event and Post-Marketing Vigilance Reporting of Medical Devices and IVDs", also:

- Report any adverse event or product quality incidents to the authority
- Conduct post-marketing vigilance and monitoring of the quality of the PPE.

The officially recognized accreditation body for South Africa is the South African National Accreditation System (SANAS). SANAS is responsible for carrying out all accreditations in respect of conformity assessments mandated through the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act (No. 19 of 2006). It is directed and legally represented by a board of directors whose members are appointed by the Minister of Trade and Industry.

SANAS is a signatory of the relevant IAF MLA and ILAC MRAs, which include the following scopes in the context of COVID-19:

- Management systems (ISO/IEC 17021-1)
- Product certification (ISO/IEC 17065)
- Calibration (ISO/IEC 17025)
- Testing (ISO/IEC 17025)
- Medical testing (ISO 15189)
- Inspection (ISO/IEC 17020)

3.12 United Kingdom

3.12.1 Regulatory landscape for COVID-19-related PPE

Since the UK left the European Union, it must be considered as a separate market with its own regulations for PPE and medical devices. UK Conformity Assessed (UKCA) marking indicates conformity with the applicable requirements for products sold within Great Britain. UKCA marking became mandatory following the end of the Brexit transition period although, until an extended deadline of January 1, 2023, for PPE and June 30, 2023, for medical devices, the CE mark is accepted as a valid alternative. Due to its geographical position, Northern Ireland requires manufacturers to follow a distinct UK Northern Ireland (UKNI) marking approval process.

	Type of goods	Accepted markings or combination of markings
Placing goods on the market in Great Britain	Manufactured goods being placed on the Great Britain market until the end of 2022 (June 2023 for medical devices)	UKCA or CE
	Manufactured goods placed on the Great Britain market from January 1, 2023 (July 1, 2023, for medical devices)	UKCA
Placing qualifying Northern Ireland goods on the market in Great Britain	Qualifying Northern Ireland goods being placed on the Great Britain market under unfettered access	CE or CE and UKNI

Currently (early 2022) the processes for CE and the UKCA marking are identical, but over time these are expected to diverge as both the EU and UK potentially establish different requirements.

The PPE regulation in the UK is now known as the "Regulation 2016/425 on personal protective equipment as brought into UK law and amended" and is enforced by the UK's Health and Safety Executive.

Regarding medical devices, such as surgical gowns and medical gloves for single use, the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) referred to as "UK MDR 2002" apply. These have transposed into UK law, among others, the Directive 93/42/EEC on medical devices (EU Medical Devices Directive), which since May 2021 has been superseded in the EU by the Medical Device Regulation (EU) 2017/745. Under the EU exit transitional arrangements, until June 30, 2023, either the UK MDR 2002 or the EU MDR can be used. After that date, only the UK MDR will be applicable. The regulations on medical devices are enforced by the Medicines and Healthcare Products Regulatory Agency.

3.12.2 Approach to standardization and key product standards for PPE

The British Standards Institution (BSI) is a non-profit distributing organization recognized by the UK government as the national standards body. BSI produces British Standards and is also responsible for the adoption of international and European standards in the UK. There are currently several designations for British Standards as they relate to PPE, as follows:

- "BS" indicates a standalone British Standard
- "BS EN" indicates that the standard is an adoption of the applicable EN standard
- "BS EN ISO" indicates that the standard is an adoption of the applicable EN standard, which in turn is an adoption of the applicable ISO standard
- "BS ISO" indicates that the standard is a direct adoption of the applicable ISO standard.

Following the UK's exit from the EU, BSI continues its membership of CEN—CENELEC and is therefore still active in the development of and providing inputs into European (EN) standards. The UK now uses the term "designated standards"[48] rather than the EU's "harmonized standards" to bestow presumption of conformity to the UK's PPE regulation. These standards currently mirror each other, but once again they could diverge over time.

48 https://www.gov.uk/government/publications/designated-standards-ppe.

Table 3.18 provides an overview of the main product standards for PPE in the UK market and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 3.18: Overview of COVID-19-related PPE standards in the UK market

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

PPE	Main product standards	More details (link)
Respirators	**BS EN 149:2001 +A1:2009** RPD—filtering half-masks to protect against particles—requirements, testing, marking **BS EN 143:2021** Respiratory protective devices—particle filters— requirements, testing, marking	14.1.1
Medical face masks	**BS EN 14683:2019** Medical face masks—requirements and test methods	14.1.2
Community face coverings	**BSI Flex 5555:2021** Community face coverings—specification	14.1.3
Face shields	**BS EN 166:2002** Personal eye protection—specifications	14.2
Protective goggles	**BS EN 166:2002** Personal eye protection—specifications	14.2
Medical examination gloves	**BS EN 455 series** (Medical gloves for single use) **BS EN 455-1: 2020** Requirements and testing for freedom from holes **BS EN 455-2: 2015** Requirements and testing for physical properties **BS EN 455-3: 2015** Requirements and testing for biological evaluation **BS EN 455-4: 2009** Requirements and testing for shelf-life determination	14.3.1
	BS EN ISO 21420:2020 Protective gloves—general requirements and test methods **BS EN ISO 374-5: 2016** Protective gloves against dangerous chemicals and micro-organisms—requirements for micro-organisms risks	
Surgical gloves	**BS EN 455 series** (Medical gloves for single use) **BS EN 455-1: 2020** Requirements and testing for freedom from holes **BS EN 455-2: 2015** Requirements and testing for physical properties **BS EN 455-3: 2015** Requirements and testing for biological evaluation **BS EN 455-4: 2009** Requirements and testing for shelf-life determination	14.3.2
	BS EN ISO 21420:2020 Protective gloves—general requirements and test methods **BS EN ISO 374-5: 2016** Protective gloves against dangerous chemicals and micro-organisms—requirements for micro-organisms risks	
Suits and coveralls	**BS EN ISO 13688:2013+A1:2021** Protective clothing—general requirements	14.4.1
	BS EN 14126:2003 Protective clothing—performance requirements and tests methods for protective clothing against infective agents **BS EN 13034:2005+A1:2009** Protective clothing against liquid chemicals—performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment) **BS EN 14605:2005+A1:2009** Protective clothing against liquid chemicals—performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])	

Aprons	**BS EN ISO 13688:2013+A1:2021** Protective clothing—general requirements **BS EN 14126:2003** Protective clothing—performance requirements and tests methods for protective clothing against infective agents **BS EN 13034:2005+A1:2009** Protective clothing against liquid chemicals—performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment) **BS EN 14605:2005 +A1:2009** Protective clothing against liquid chemicals—performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])	14.4.1
Shoe and head covers	**BS EN ISO 13688:2013+A1:2021** Protective clothing—general requirements **BS EN 14126:2003** Protective clothing—performance requirements and tests methods for protective clothing against infective agents **BS EN 13034:2005+A1:2009** Protective clothing against liquid chemicals—Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment) **BS EN 14605:2005 +A1:2009** Protective clothing against liquid chemicals—performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])	14.4.1
Gowns	**BS EN 13795-1:2019** Surgical clothing and drapes—requirements and test methods—Part 1: Surgical drapes and gowns	14.4.2

3.12.3 Approach to conformity assessment

The UK is currently following a process similar to that of Europe, meaning that all PPE and medical devices must comply with the associated regulation, but with the use of the UKCA mark instead of the CE marking. The UKCA marking on a product indicates that the manufacturer or importer of that product affirms its compliance with the relevant UK legislation and the product may be sold in the United Kingdom. It is a criminal offence to affix UKCA marking to a product that is not compliant or to offer it for sale.

Both the PPE Regulation (EU 2016/425) and the MDR (EU 2017/745) are based on the existing European "New Approach Directives." This means that manufacturers, or their authorized representative in the UK, must demonstrate compliance with the essential health and safety requirements of the applicable regulation either directly or by demonstrating conformity to the associated designated standards (presumption of conformity to the regulation). Because the regulations are often very generic and performance-based in their requirements (which in some cases can apply to broad families of products), demonstration of conformity to the designated standards is often the preferred way of demonstrating conformity to the regulation.

Depending on the risk classification, certain categories of PPE and medical devices are subject to conformity assessment by an "approved body". The approved body status is bestowed by the relevant UK government department—the Department for Business, Energy & Industrial Strategy in the case of PPE, and the Medicines and Healthcare Products Regulatory Agency for medical devices. Full details of approved bodies can be found on the UK government's website.[49] Medical devices under the scope of this guide are Class I. The intervention of an approved body is only necessary for sterile products and only in relation to sterilization process.

The officially recognized accreditation body in the UK for conformity assessment activities is the United Kingdom Accreditation Service (UKAS) which is a signatory to the ILAC MRA for laboratory testing, as well as to the IAF MLA for product and management system certification, among others.

49 https://www.gov.uk/government/publications/medical-devices-uk-approved-bodies/uk-approved-bodies-for-medical-devices.

3.13 Vietnam

3.13.1 Regulatory landscape for COVID-19-related PPE

The first Occupational Safety and Health (OSH) Law was passed by the National Assembly of Vietnam in June 2015. The Ministry of Health is in charge of managing the OSH Law for activities, equipment and chemicals used in the medical/pharmacy sector. Article 23 of the OSH Law requires that, when providing PPE, employers must ensure that the correct types of PPE are available with the quality as prescribed by national technical standards and regulations.

The government's response to COVID-19 was spearheaded by the multi-sectoral National Steering Committee for the Prevention and Control of COVID-19, chaired by the Vice Prime Minister and comprising members from 23 ministries. This structure was replicated throughout provincial and local levels and all public and private organizations. The following technical regulations were issued in the early stages of the pandemic:

Decision 870/QD-BYT dated March 12, 2020: Temporary technical guidance for splash-resistant and antibacterial fabric masks. This decision addresses technical specifications for washable (reusable) cloth masks which have a bactericide material (nano silver, activated carbon, or equivalent). It encompasses requirements and test methods from standards TCVN 8389-1:2010 and TCVN 8389-2:2010 on medical face masks.

Decision 1444/QD-BYT dated March 29, 2020: Temporary guidance on the selection and use of

masks in prevention and control of COVID-19 epidemic. This decision specifies three types of face masks offering different protection levels (from highest to lowest):

- FFP2, according to the EU classification (or US N95)
- Masks complying with Vietnamese standards TCVN 8389-1 to -3
- "870 masks" complying with the decision above

It also recommends mask types for use in specific situations (that is, hospital rooms with confirmed COVID-19 cases, screening areas, and so on).

Decision 1616/QD-BYT dated April 8, 2020: Temporary guidance on techniques, classification,

and selection of COVID-19 pandemic prevention clothing. The objectives of this decision are to provide:

- Guidance on technical standards for COVID-19 prevention clothing
- Guidance on classification of suits to prevent the spread of COVID-19
- Instructions for choosing the appropriate protective clothing in professional work.

This document is based on the US standard ANSI/AAMI PB 70:2012 describing liquid barrier performance levels (1-4; 1 being the lowest) and classification of surgical and isolation gowns for use in health care settings.

With respect to medical devices, registration and monitoring is performed by the Department of Medical Equipment and Construction (DMEC), under the Ministry of Health. The basic regulation consists of Decree No. 36/2016/ND-CP, which has been subsequently modified by Decrees No. 169/2018/ND-CP and No. 03/2020/ND-CP. Medical devices are split into two groups which are classified into four categories based on the level of potential risks related to their technical design and manufacture: Group 1 includes Class A (low risk) while Group 2 includes Categories B (medium to low risk), C (medium to high risk) and D (high risk). The classification rules are compliant with international treaties on classification of medical devices of the Association of Southeast Asian Nations (ASEAN) of which Vietnam is a member. The classification must be made by qualified entities in Vietnam (previously, classification by foreign entities was accepted).

3.13.2 Approach to standardization and key product standards for PPE

The national standardization body of Vietnam is the Directorate for Standards, Metrology and Quality (STAMEQ) (https://tcvn.gov.vn/?lang=en), a governmental body under the Ministry of Science and Technology. It has the responsibility of advising the government on issues in the fields of standardization, metrology, productivity, and quality management in the country and it represents Vietnam in the ISO, IEC and regional standardization organizations. The function, duties, and organizational structure of STAMEQ are stipulated in the Prime Ministerial Decision 27/2014/QD-TTg.

The overall approach to standards in Vietnam is as follows (in line with the findings of a recent United Nations Development Programme Vietnam study on PPE carried out in 2020–21):[50]

- There are some Vietnamese standards (TCVN) for PPE related to medical/health care applications, but they do not cover all products (that is, medical gowns, respiratory protection equipment)
- In most instances, these are adaptations of ISO standards but are not always aligned with the latest versions
- A review is currently underway on the range of available standards and to promote their alignment with international best practices.

Table 3.19 provides an overview of the main product standards for PPE in the Vietnamese market and an indication about whether these are based on or are similar to versions of other national, regional, or international standards.

Users are advised to use caution with these comparisons and to consult the more detailed information in other parts of the guide by following the links provided.

Table 3.19: Overview of COVID-19-related PPE standards in the Vietnamese market

Color coding:

- Green: Based on or similar to ISO standard
- Yellow: Based on or similar to EN standard
- Blue: Based on or similar to a US standard
- Red: Standalone national standard
- Blank: No applicable national standard

PPE	Main product standards	More details (link)
Respirators	n/a	15.1.1
Medical face masks	**TCVN 8389-1: 2010** Medical face mask—Part 1: Normal medical face mask **TCVN 8389-2:2010** Medical face mask—Part 2: Medical face mask preventing bacteria	15.1.2
Community face coverings	n/a	15.1.3
Face shields	n/a	15.2
Protective goggles	n/a	15.2
Medical examination gloves	**TCVN 6343-1:2007** Single-use medical examination gloves—Part 1: Specification for gloves made from rubber latex or rubber solution). Identical to **ISO 11193-1: 2002** with **AMD 1: 2007** (since revised) **TCVN 6343-2:2007** Single-use medical examination gloves. Part 2: Specification for gloves made from poly(vinyl chloride) Identical to **ISO 11193-2:2006** (current) **TCVN 12326-5:2018** Protective gloves against dangerous chemicals and micro-organisms—Part 5: Terminology and performance requirements for micro-organisms risks. Identical to **ISO 374-5:2016** (current)	15.3.1

50 https://www.undp.org/vietnaml.

Surgical gloves	**TCVN 6344:2007** Single-use sterile rubber surgical gloves. Identical to **ISO 10282:2002** (since revised)	15.3.2
Suits and coveralls	**TCVN 6689:2021** Protective clothing—general requirements. Identical to **ISO 13688:2013 + AMD1:2021**	15.4.1
Aprons	**TCVN 6689:2021** Protective clothing—general requirements. Identical to **ISO 13688:2013 + AMD1:2021**	15.4.1
Shoe and head covers	**TCVN 6689:2021** Protective clothing—general requirements. Identical to **ISO 13688:2013 + AMD1:2021**	15.4.1
Gowns	n/a	

Regarding PPE for the COVID-19 pandemic, temporary guidance has also been provided in the Decision 1616/QD-BYT dated April 8, 2020, which directly defines the essential requirements and/or standards to be applied. This is a temporary guidance, subject to updates. Table 3.20 provides a summary.

Table 3.20: Essential requirements defined directly in Decision 1616/QD-BYT dated 08/04/2020

PPE type	Requirements	Comments
All	If PPE is to be sterilized, bioburden per EN ISO 11737-1 ≤ 30 CFU/g	
"High-filtration efficiency masks"	Comply with EN 149:2001 + A1: 2009 or EN 14683:2019 or 42 CFR part 84	EU: type FFP2 NR (respirators) EU: type I, II or IIR (medical masks) US: type N95 (respirator) Equivalent types complying with standards from other countries are also accepted
Medical masks	Comply with TCVN 8389-1:2010 or TCVN 8389-2:2010	Standard medical masks or medical masks to prevent infection
Anti-droplet and antibacterial cloth masks	According to Decision 870/QD-BYT	
Face shields	Listed in Decision 1616/QD-BYT	
Safety goggles	Comply with TCVN 5039:1990, EN 166:2002 ANSI Z87.1:2015	
Disposable medical examination gloves	Comply with TCVN 6343-1:2007 or 6343-2:2007	Made from rubber or PVC. Decision does not include requirements for surgical gloves
Medical gowns	—	In the decision, EN 13795-1 is mentioned but no explicit requirements for medical gowns are defined
Protective clothing	Classified as level 1-4 per ANSI/AAMI PB 70 or Class 1 to 6 per EN 14126, clause 4.1.4.1	In the US, the testing standard ASTM F1671 is used for level 4. This is very similar to the international standard ISO 16604 used in the EU

3.13.3 Approach to conformity assessment

Simplified approval procedures ("quick registration") apply for products already circulating in at least two countries from within the EU member states, Japan, Canada, Australia, and the United States. A proposed revision will add the UK and Switzerland to the list and reduce the need for circulation to only one country. The ASEAN Common Submission Technical Dossier (CSTD) has been applied from January 1, 2022.

Manufacturers of medical devices, which includes most the aforementioned PPE, have been required to apply a quality management system per TCVN ISO 13485:2017 since January 1, 2020. Conformity assessment bodies must register and fulfil the relevant requirements for the appropriate areas of activity according to Decree 107/2016/ND-CP. They must be accredited by an accreditation body signatory to the IAF MLA for certification bodies or the corresponding ILAC MRA for inspection bodies or laboratories.

In Vietnam, there are two such accreditation bodies, the Bureau of Accreditation (http://www.boa.gov.vn/en) and the Accreditation Office for Standards Conformity Assessment Capacity. The Bureau of Accreditation is a signatory of the relevant ILAC MRA for laboratory testing as well as the IAF MLA for product and management system certification, while the Accreditation Office is a member of the ILAC MRA for laboratories (https://www.aosc.vn/).

PART 4
PRODUCT-SPECIFIC COMPARISONS OF EU AND US MARKETS

4.1 Masks

This section is divided into sub-sections corresponding to the three main categories of masks (see product overview in section 2.1):

- Respirators (also known as respiratory protective equipment, respiratory protective devices [RPD], or filtering face piece respirators)
- Medical face masks
- Community face coverings

4.1.1 Respirators

4.1.1.1 EU market requirements

Respirators are covered by the EU PPE Regulation (EU) 2016/425, which superseded the PPE Directive 89/686/EEC. The regulation is based on the "new approach" aligned to the "new legislative framework" policy, under which manufacturers, or their authorized representatives in the EU, must demonstrate compliance with the essential health and safety requirements of the PPE Regulation, directly or by using harmonized European standards. The latter confers presumption of conformity to the regulatory requirements. The harmonized standard in the case of respirators is EN 149[51] and they are Category III PPE according to the regulation.

Note: A transition process has been outlined in Article 47 of the PPE Regulation which states "without prejudice, member states shall not impede the making available on the market of products covered by Directive 89/686/EEC which are in conformity with that directive and which were placed on the market before 21 April 2019 and also EC type-examination certificates and approval decisions issued under Directive 89/686/EEC shall remain valid until 21 April 2023 unless they expire before that date."

Particle-filtering half-masks are classified according to their penetration of filter material and their maximum total inward leakage. Penetration of filter material is tested per EN 13274-7, using both sodium chloride (NaCl) and paraffin oil aerosols. "Filtering efficiency", defined as 100 percent minus "penetration of filter material", is a commonly used term. There are three classes of devices: FFP1, FFP2, and FFP3 with filtering efficiencies of minimum 80 percent, 94 percent, and 99 percent respectively (FFP1 is not recommended by WHO). The total inward leakage is tested using a panel of 10 human subjects and only NaCl aerosol. The limits are expressed as percentage leakage (both as individual values and arithmetic means) and they are stricter the higher the respirator class is. Other important characteristics include:

- Breathing resistance, measured both for inhalation (less strict limits, that is, more difficulty in breathing, for increasing filtering efficiency) and exhalation (same limits for all respirator classes)

51 EN 149:2001+A1:2009. "Respiratory protective devices— filtering half-masks to protect against particles—requirements, testing, marking."

- Carbon dioxide (CO_2) content in the "dead space" of the respirator (average ≤1 percent for all classes)
- Practical performance, tested by two subjects carrying out specified tasks.

In addition to their filtering efficiency class, respirators:

- Can be single-shift, that is, non-reusable (marked NR)—or reusable (marked R), though the latter is not recommended for a medical environment
- Can exhibit clogging resistance (marked D)—not required in a medical environment
- Can have an exhalation valve—not indicated in a medical environment.

4.1.1.2 US market requirements

Respirators typically used in US health care and related functions include:

- Filtering face piece respirators (disposable)
- Elastomeric half face piece air-purifying respirators, or APR (reusable face piece, disposable filters)
- Powered air-purifying respirators, or PAPR (reusable blower, other reusable components, disposable filters)

Respirators are PPE subject to the National Institute for Occupational Safety and Health (NIOSH) 42 CFR Part 84 (Approval of Respiratory Protective Devices)—available for free download from the US Code of Federal Regulations, at https://ecfr.federalregister.gov/. This includes the following main topics:

- 84.170 Air-purifying particulate respirators; description
- 84.171 Required components and attributes
- 84.172 Airflow resistance test
- 84.173 Exhalation valve leakage test
- 84.174 Filter efficiency level determination test—non-powered series N, R, and P filtration

Subpart K of 42 CFR Part 84 specifies the requirements for "air-purifying particulate respirators" as follows:

- Non-powered air-purifying particulate respirators (series N, R, and P). These utilize the wearer's negative inhalation pressure to draw the ambient air through the air-purifying filter elements (filters) to remove particulates from the ambient air. They are designed for respiratory protection against atmospheres with particulate contaminants at concentrations that are not immediately dangerous to life or health and that contain adequate oxygen to support life
- N-series filters are restricted for use in workplaces free of oil aerosols (which is the case for COVID-19 applications) and are further subdivided according to the efficiency level of the filter(s) as follows:
  1. N100 filters, min. 99.97 percent efficiency
  2. N99 filters, min. 99 percent
  3. N95 filters, min. 95 percent

Other relevant subparts of CFR Part 84 include:

- Subpart A—General provisions
- Subpart B—Application for approval
- Subpart C—Fees
- Subpart D—Approval and disapproval
- Subpart E—Quality control

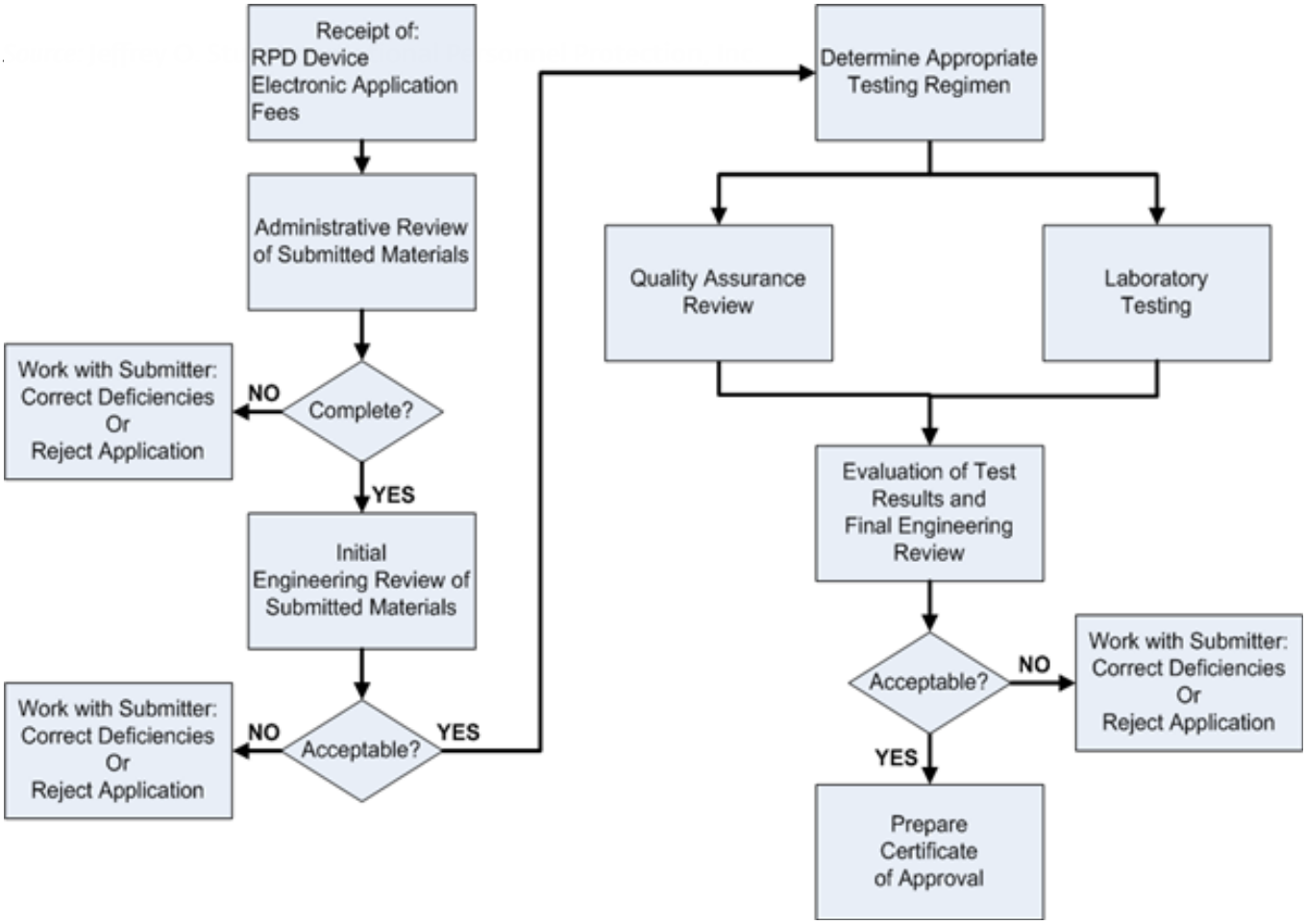
In addition to specifying requirements and conformity assessment criteria, 42 CFR Part 84 also specifies the testing methods to be used. These are based on the NIOSH procedures as follows:

Characteristic	NIOSH procedure for test method[52]
Filtration efficiency	TEB-APR-STP-0059 (for N95)
Airflow resistance for inhalation	TEB-APR-STP-0007
Airflow resistance for exhalation	TEB-APR-STP-0003
Exhalation valve leakage	TEB-APR-STP-0004

There are no requirements for measuring the build-up of carbon dioxide in the respirator or the amount of total inward leakage. The latter property is addressed in separate Occupational and Safety Health Administration (OSHA) regulations, covered in 29 CFR Part 1910.134, where employees must be subject to quantitative fit testing and achieve a fit factor of at least 100 for the specific respirator.

The approval process for respirators is shown in Figure 4.1.

Figure 4.1: NIOSH process for approval of respirators in the US market[53]



4.1.1.3 Comparison between EU, US, and ISO criteria

A summary of the main differences between EN 149 and 42 CFR Part 84 Subpart K is as follows. Further details can be found in Table 4.1.

- There is an ***approximate*** equivalence as follows:

52 For details related to N95 respirators and other filtering face piece respirators used in health care, see the CDC website at https://www.cdc.gov/niosh/npptl/resources/certpgmspt/pdfs/APR-FFR-03122018-508.pdf.

53 For further details, see the CDC website at https://www.cdc.gov/niosh/npptl/respmanuf.html.

  - FFP2 ➔ N 95
  - FFP3 ➔ N 99
- Filter efficiency is calculated differently
- Testing for the United States is restricted to the National Personal Protective Technology Laboratory
- Breathing resistance flow and pressure limits differ because of the different flow rates specified by the various standards for the inhalation and exhalation resistance tests. Although this appears to suggest that the standards' requirements for breathing resistance differ from each other, it is important to understand that pressure drop across any filter will naturally be higher at higher flow rates. Given typical pressure curves for respirator filters, the standards' various pressure drop requirements are actually quite similar[54]
- In the United States, carbon dioxide content of inhalation air and total inward leakage are not specified.

It is also noted that ISO technical committee TC 45/SC 15 is in the process of developing a comprehensive range of RPD standards covering the following areas:

- ISO 16900 series: Methods of test and test equipment (14 parts)
- ISO 16972: Vocabulary and graphical symbols
- ISO 16973: Classification
- ISO 16975 series: Selection, use and maintenance (four parts, among them—under development—Part 4: Selection and usage guideline for RPD under pandemic/epidemic/outbreak of infectious respiratory disease)
- ISO 16976 series: Human factors (eight parts)
- ISO 17420 series: Performance requirements for various types of respiratory products (nine parts; most relevant to the scope of this guide are Part 1: General and Part 2: Requirements for filtering RPD, both published in 2021).

Due to the difference in approaches between EN and ISO standards (product versus wearer-related requirements) and the strong interplay between RPD standards and the PPE Regulation in the EU, the above standards are not envisioned to be adopted as EN ISO in the foreseeable future. The only ISO standard adopted by the relevant standardization committee in Europe (CEN TC 79) is ISO 16972.

54 3M. 2020. "Comparison of P2, FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes." Technical bulletin. https://multimedia.3m.com/mws/media/1793275O/3m-anz-2020-comparison-of-ffp2-kn95-and-n95-and-other-filtering-facepiece-respirator-classes.pdf.

Table 4.1: Comparison of standards for respirators in the EU and US markets and applicable ISO testing standards

Color code for EU/US comparisons:

- **Green:** Same requirement and same (or similar) test methods
- **Yellow:** Similar requirement but with different test methods
- **Red:** Requirements are more stringent
- **Blue:** Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 149:2001+A1:2009, Classes FFP2 and FFP3**		**US 42 CFR Part 84, Series/Levels N95 and N99**		**COMPARISON/COMMENTS**	**ISO**
Characteristic/ property	**Testing method**	**Requirement**	**Requirement**	**Testing method**		**Testing method**
Practical performance		Pass	Pass	Fit testing before use (required by OSHA, not NIOSH) ASTM F3387-19 "A qualitative or quantitative respirator fit test shall be used to determine the ability of the individual respirator wearer to obtain a satisfactory fit with a tight-fitting respirator"		ISO 16975-3:2017 Respiratory protective devices—selection, use and maintenance—Part 3: Fit-testing procedures
Total inward leakage		**FFP2** ≤ 11% leakage (individual values) ≤ 8% leakage (arithmetic mean)	**N95** n/a		Not required in the US	ISO 16900-1:2019 Respiratory protective devices—methods of test and test equipment—Part 1: Determination of inward leakage
		FFP3 ≤ 5% leakage (individual values) ≤ 2% leakage (arithmetic mean)	**N99** n/a		As above	

(Market) standard	EU EN 149:2001+A1:2009, Classes FFP2 and FFP3		US 42 CFR Part 84, Series/Levels N95 and N99		COMPARISON/COMMENTS	ISO
Characteristic/ property	**Testing method**	**Requirement**	**Requirement**	**Testing method**		**Testing method**
Filtering efficiency	EN 13274-7. Mechanical strength conditioning per EN 143. Particle size distribution measurement according to ISO 15900:2020	**FFP2** ≥ 94% (@ 95 L/min)—specified as max penetration of 6%	**N95** ≥ 95%	TEB-APR-STP-0059 (NIOSH)	In the EU, testing with both NaCl and paraffin oil aerosols is required, while in the US only testing with NaCl is required	ISO 16900-3:2012 Respiratory protective devices—methods of test and test equipment—Part 3: Determination of particle filter penetration
		FFP3 ≥ 99% (@ 95 L/min)—specified as max penetration of 1%	**N99** ≥ 99%			
Compatibility with skin		Pass	n/a		Not required in the US	
Flammability	Burner to ISO 6941	Pass	n/a		Not required in the US	
Carbon dioxide content		Average ≤ 1% by volume in "dead space"	n/a		Not required in the US	
Field of vision		Pass	Pass	(OSHA requirement, not NIOSH)		
Breathing resistance (inhalation)		**FFP2** ≤ 70 Pa (@ 30 L/min) ≤ 240 Pa (@ 95 L/min)	**N95** ≤ 343 Pa (@ 85 L/min)—specified as 35 mm H_2O	(NIOSH) TEB-APR-STP-0007 (inhalation)		ISO 16900-2:2017 Respiratory protective devices—methods of test and test equipment—Part 2: Determination of breathing resistance
		FFP3 ≤ 100 Pa (@ 30 L/min) ≤ 300 Pa (@ 95 L/min)	**N99** ≤ 343 Pa (@ 85 L/min)—specified as 35 mm H_2O			
Breathing resistance (exhalation)		**FFP2 and FFP3** ≤ 300 Pa (@160 L/min)	**N95 and N99** ≤ 245 Pa (@ 85 L/min)—specified as 25 mm H_2O	(NIOSH) TEB-APR-STP-0003 (exhalation)		

4.1.2 Medical face masks

4.1.2.1 EU market requirements

These are considered as Class I medical devices according to the European Union Medical Device Regulation (EU) 2017/745 (EU MDR).

The performance/testing standard is EN 14683:2019,[55] "Medical face masks—requirements and test methods." The standard defines three types of masks: I, II, and IIR. They differ on two important characteristics regarding infective agents:

- Type I has bacterial filtration efficiency (BFE) of min. 95 percent
- Types II and IIR have a BFE of min. 98 percent
- Type IIR is the only "splash-resistant" type; it can withstand spurts of synthetic blood under conditions and methods specified in ISO 22609.

Another important characteristic is breathability (same limit for Types I and II, higher for Type IIR, that is, worse breathability, justified by its increased resistance to penetration). Other characteristics are bioburden (same limits for all types) and biocompatibility (passes evaluation per EN ISO 10993-1). As it is stated in the standard, "Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by health care professionals in an operating room or in other medical settings with similar requirements."

Conformity assessment:

- As a Class I medical device, for products not delivered sterile: assemble technical documentation, issue EU declaration of conformity and operate a quality management system to ISO 13485 for production as well as a post-market surveillance system for any adverse effects
- For terminally sterilized packages, in addition to the above, involvement of a notified body is needed to evaluate the quality assurance of the sterilization process.

4.1.2.2 US market requirements

The main technical standard is ASTM F2100-21, "Standard specification for performance of materials used in medical face masks," which covers both surgical masks (with head ties) and isolation masks (sometimes called procedure masks) having ear loops (see also section 2.1.2). The ASTM standard defines three barrier levels: Level 1, having BFE of min. 95 percent, while Levels 2 and 3 have min. 98 percent. Unlike, however, in the EN standard, all three barrier levels exhibit:

- Splash resistance (higher as the level increases)
- Sub-micron particulate filtration efficiency (not required in EN 14683)
- Flammability characteristics (measured according to 16 CFR Part 1610).

As with the corresponding EN, breathability of the mask is specified (same increased limit for Levels 2 and 3 compared to Level 1, that is, worse breathability due to the higher filtering efficiency and splash resistance).

Surgical masks are Class II medical devices, subject to the US Food and Drug Administration (FDA) Regulations, Part 878—General and Plastic Surgery Devices, Subpart E—Surgical Devices; 21 CFR 878.4040 (see also section 3.2.3).

55 *Note*: This is recognized as a "harmonized standard" in the EU, with a presumption of conformity to the essential requirements of the previous Directive 93/42/EEC (but, as of 31 December, 2021, not yet for [EU] 2017/745).

4.1.2.3 Comparison between EU and US criteria

The main similarities/differences regarding the test methods are:

- BFE—the method referenced in ASTM F2100 is ASTM F2101 which is very similar to the methodology of EN 14683 (Annex B)
- Differential pressure—both ASTM F2100 and EN 14683 refer to Annex C of EN 14683
- Particle filtration efficiency according to ASTM F2299 is not required by EN 14683. ASTM F2299 uses aerosols with latex spheres for materials (unlike EN 149/EN 13274-7 which use NaCl or paraffin oil aerosols on final products)
- ASTM F2100 requires the resistance to penetration by synthetic blood to be measured according to ASTM F1862 (very similar to ISO 22609:2014)
- ASTM F2100 requires flammability testing according to 16 CFR Part 1610
- Biocompatibility requirements which were not explicitly addressed in ASTM F2100-20 are now included in the current edition (ASTM F2100-21), similar to the EN standard.

A comparison of the key requirements is provided in Table 4.2.

Table 4.2: Comparison between EU and US standards for medical face masks

Color code for EU/US comparisons:

- Green: Same requirement and same (or similar) test methods
- Yellow: Similar requirement but with different test methods
- Red: Requirements are more stringent
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 14683:2019, Types I, II, and IIR**		**US ASTM F2100-21, Levels 1, 2, and 3**		**COMPARISON/COMMENTS**
Characteristic/ property	**Testing method**	**Requirement**	**Requirement**	**Testing method**	
Bacterial filtration efficiency (BFE)		≥95% (Type I) ≥98% (Type II, IIR)	≥95% (Level 1) ≥98% (Level 2, 3)	ASTM F2101	Limits essentially same (for corresponding types); testing methods essentially same
Particulate filtration efficiency (PFE)	n/a	n/a	≥95% at 0.1 micron (Level 1) ≥98% at 0.1 micron (Level 2, 3)		Only a US requirement
Pressure drop		<40 Pa/cm² (Type I, II) <60 Pa/cm² (Type IIR)	<49 Pa/cm² (Level 1)—specified as < 5 mm H_2O/cm² <58.8 Pa/cm²) (Level 2 & 3)—specified as < 6 mm H_2O/cm²	EN 14683	Limits for Types I, II are 20% lower than for Level 1 (better breathability in the EU); limits for Type IIR about same as for Levels 2,3; identical testing methods

Synthetic blood penetration	ISO 22609:2004	≥16 kPa (Type IIR only)	≥ 10.67 kPa (Level 1)— specified as ≥ 80 mm Hg ≥ 16 kPa (Level 2)— specified as ≥ 120 mm Hg ≥ 21.33 kPa) (Level 3)— specified as ≥ 160 mm Hg	ASTM F1862	Limit same for Type IIR and Level 2; limits not set for Types I, II. For Level 1 (3) lower (higher) limits than Level 2; essentially same methods in EU/US
Microbial cleanliness	EN ISO 11737-1:2018	≤30 (CFU/g)	n/a		Only an EU requirement
Biocompatibility	EN ISO 10993 series	Passes evaluation	Passes evaluation	ISO 10993 series	Masks are considered in the EU as surface devices in contact with intact skin with limited exposure, while in the US with long-term exposure
Flammability		n/a	Class 1 according to 16 CFR Part 1610.		Only a US requirement

4.1.3 Community face coverings

4.1.3.1 EU market requirements

Community face coverings are not subject to any specific EU regulations, but nevertheless are covered by Directive 2001/95/EC on general product safety. Under this directive, a product is considered safe if it meets all statutory safety requirements under European or national law.

As of December 2021, there is no European standard for community face coverings, although criteria have been defined in the CEN Workshop Agreement (CWA) 17553:2020 ("Community face coverings— guide to minimum requirements, methods of testing, and use").

CWA 17553 prescribes requirements for reusable or disposable community face coverings intended for the general public, including the following:

- The mask must cover the nose, mouth, and chin, with no valves, made of one or multiple fabric layers (woven, knitted, non-woven, and so on) with or without film. It can have an attachment for either the head or ears
- Must be able to withstand handling and wear throughout the indicated lifetime; need to consider breathability, moisture absorption, and biocompatibility
- Filtration efficiency of the material: two levels according to filtration efficiency to particles around 3 (± 0.5) µm:
  - ≥ 90%
  - ≥ 70%

  Filtration efficiency can be either for particles (PFE—by one of three options) or bacterial (BFE—by EN 14683)
- Three options for demonstrating breathing resistance and air permeability (EN 14683; EN 13274-3; EN ISO 9237)
  - Differential pressure of the material ≤ 70 Pa/cm²

  - Inhalation resistance ≤ 2.4 mbar and exhalation resistance ≤ 3 mbar
  - Air permeability ≥ 96 l/s/m² for a vacuum pressure of 100 Pa
- Reusable masks must be capable of withstanding at least five cleaning cycles with minimum washing temperature of 60°C according to EN ISO 6330 or producer instructions
- Recommended to use recyclable or compostable material to reduce the environmental impact.

In the relevant European Standardization Committee (CEN TC 248 "textiles and textile products"), a technical specification is under development (as of December 2021), to be published as CEN/TS 17553: "Textiles and textile products—community face coverings—minimum requirements, methods of testing and use." This deals with the following aspects of textiles, textile products, and textile components of products:

- Test methods (including relevant testing equipment)
- Terms and definitions
- Specifications and, if necessary, classifications in terms of their expected behavior.

It will also address the use of multi material textile-based face coverings, and textile-based face coverings incorporating transparent elements to allow for lip reading.

4.1.3.2 US market requirements

Requirements for community face coverings are currently provided in ASTM F3502-21 "Standard specification for barrier face coverings."[56]

The objective of a face covering to ASTM F3502 is twofold:

- Source control (to protect the public)
- Offer protective capability (protect the wearer).

The standard includes the following requirements:

- Design: Minimum criteria are specified that entail fully covering the mouth and nose of the wearer; the use of non-toxic, non-irritating materials, providing a means of retention on the head; the availability of sizes
- Protection:
  - Measurement of sub-micron particulate filtration efficiency and airflow resistance (based on 42 CFR Part 84 Subpart K) applied to single-use and reusable products (reusable products are evaluated before and after maximum number of laundering or cleaning cycles specified by manufacturer). The use of a fixture for supporting samples is also permitted if the product does not seal directly onto the test stand.
  - Seals to the face and to prevent particles going around the perimeter of the mask. Manufacturer has to report a product design analysis self-declaration; optional to use a modified version of ASTM Test Method F3407 ("Standard test method for respirator fit capability for negative-pressure half-face piece particulate respirators")
- Comfort: The face coverings must be comfortable enough for people to wear for long periods of time
- The potential that products could be used over again.

  Two levels of filtration and breathability performance are defined in the standard, as follows:

56 Prior to the publication of ASTM F3502, guidance was available from the American Association of Textile Chemists and Colorists' standard AATCC M14 ("Guidance and considerations for general purpose textile face coverings"). Although this was referenced in the Interim WHO guidance (December 2020), for the purposes of this benchmarking guide only the ASTM specification is considered.

Property	Level 1 (lower performance)	Level 2 (higher performance)
Filtration efficiency	≥20%	≥50%
Airflow resistance (breathability)	≤15 mm H_2O	≤5 mm H_2O

Each performance property is classified separately, which is why there are four possible sets of classifications for a community face covering.

Conformity assessment of the product is based on a supplier's declaration of conformity with a requirement for testing laboratories to be accredited to ISO/IEC 17025 for the specific tests.

4.1.3.3 Comparison between EU and US criteria

CWA 17553 and ASTM F3502 are written in different styles and format, making direct comparison difficult. ASTM F3502 uses whole-product filtration and air-resistance tests compared to CWA 17553. A summary of some key characteristics is nevertheless provided in Table 4.3, but users are encouraged to consult the actual standards for definitive criteria.

Table 4.3: Comparison between EU and US standards for community face coverings

Color code for EU/US comparisons:

- Green: Same requirement and same (or similar) test methods
- Yellow: Similar requirement but with different test methods
- Red: Requirements are more stringent
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	EU CWA 17553:2020		US ASTM F3502-21		COMPARISON/ COMMENTS
Characteristic/ property	Testing method	Requirement	Requirement	Testing method	
Breathing resistance	EN 14683:2019, Annex C or EN 13274-3	≤ 70 Pa/cm² or Inhalation resistance of 2.4 mbar Exhalation resistance 3 mbar	Level 1 ≤ 15 mm H_2O Level 2 ≤ 5 mm H_2O	Subpart K of 42 CFR Part 84, modified as per § 8.2	1. Alternate characteristic to breathing resistance in the EU is air permeability, see below 2. In the US the breathing resistance of the entire mask is measured (not per unit area)
Air permeability	EN ISO 9237	≥ 96 l/s/m² @ 100 Pa	n/a		
Particle filtration efficiency (PFE)	EN 13274-7 or EN ISO 16890-2 or EN ISO 21083-1:2018	Level 90% ≥ 90% Level 70% ≥ 70% Particle size 3 (± 0.5) µm	Level 1 ≥20% Level 2 ≥ 50% Sub-micron particle size	Subpart K of 42 CFR Part 84, modified as per § 8.1	Alternate characteristic to PFE in the EU is BFE test (see below)

Bacterial filtration efficiency (BFE)	EN 14683:2019, Annex B	Level 90% ≥ 90% Level 70% ≥ 70%	Manufacturer may choose to provide the BFE results (as per ASTM F 2101) along with PFE		
Inward leakage		n/a	Results to be reported (no criteria are set)	Determined through a design analysis or optional application of a modified form of ASTM F3407 (quantitative leakage testing)	

4.2 Eye and face protection

This section covers the requirements for both glasses/goggles and face protection, all of which are covered by standards with similar scopes in both markets. A useful reference is ISO 4007:2018 "Personal protective equipment—eye and face protection—vocabulary," which can be browsed freely on the ISO website.

4.2.1 EU market and ISO requirements

In the EU, the standard EN 166:2001, "Personal eye protections—specifications," covers all safety eyewear (including spectacles, goggles, and face shields). The EN 166 standard includes requirements for lenses (which are called "oculars" in the standard and can be prescription or not, mounted or unmounted) and complete eye protectors and frames. The standard is a generic one covering several fields of use. For the purposes of this guide, only the fields of "basic use" and "droplets and splashes of liquids" are considered. The requirements of the standard are split into the categories:

- Basic (applicable for all eye protectors)
- Particular (depending on the field of use)
- Optional requirements

Among those, a selection of the categories most relevant to medical PPE is made in this guide. Lastly, the standard makes reference to the following testing method standards:

- EN 167 (for optical test methods)
- EN 168 (for non-optical test methods)

EN 166 is likely to be replaced by the recently published ISO 16321-1:2021 standard, "Eye and face protection for occupational use—Part 1: General requirements," which additionally covers face protection. It has already been adopted as a European standard but has not yet become a harmonized standard (see 3.1.2). ISO 16321-1 supersedes ISO 4849:1981, ISO 4851:1979, ISO 4852:1978, and ISO 4856:1982. Requirements in the ISO 16321-1 standard are split into:

- General
- Geometrical optical (testing methods in ISO 18526-1)
- Physical optical (testing methods in ISO 18526-2)
- Physical and mechanical (testing methods in ISO 18526-3)

They are also separated as mandatory and optional requirements (depending on the intended use, some optional may become mandatory).

ISO 16321-1 uses test methods from the ISO 18526 series of standards (four parts, as above, plus ISO 18526-4 about head forms used in testing). ISO 18526-1 and -2 cancel and replace ISO 4854:1981 while ISO 18526-3 supersedes and replaces ISO 4855:1981. The ISO 18526 series of standards is also expected to replace the relevant testing method standards EN 167 and EN 168.

In the EU, PPE for either eye or face protection will fall under the PPE Regulation and be classified as Category II products (see PPE Regulation guidelines mentioned in 3.1.2).

4.2.2 US market requirements

ANSI/ISEA Z87.1:2020: The "American national standard for occupational and educational personal eye and face protection devices" is also a generic standard, covering all types of eye and face protection in the United States. Requirements in the standard are split into:

- Fundamental design requirements for all protectors (includes optical and physical requirements)
- Optional design requirements (includes anti-fog properties)
- Optional hazard-specific requirements (includes droplet and splash-protector requirements).

Test methods are included in Chapter 9 of the standard.

In July 2021, another standard was published: ANSI/ISEA Z87.62-2021, "American national standard for occupational and educational personal eye and face protection devices for preventing exposures caused by sprays or spurts of blood or body fluids." This standard addresses protection from the risk posed by the presence of spray and spurt of biological hazards. However, it does not yet address the risk from aerosolized pathogens, which may be considered in future editions.

In the Z87.62 standard, three product protection categories are defined: C1 (for eyes only), C2 (for nose and mouth only), and C3 (for all three). A main requirement of this standard is the experimental validation of the effective coverage area (for the protection categories claimed) by employing a spray and spurt test using a biofluid simulant. It should be noted that the test measures the exposure to the physical hazard (blood or other body fluid) and not the transmission of pathogens that it may carry.

In the United States, eye and face protection equipment used in health care settings are both considered as Class I medical devices, and therefore, are exempt from FDA 510(k) submissions (see 3.2.3).

4.2.3 Comparison between EU, US, and ISO criteria

A comparison of relevant characteristics between the EU, the United States, and ISO can be seen in Table 4.4.

Table 4.4: Comparison between EU, US, and ISO standards for eye and face protection

Color code for EU/US comparisons:

- Green: Same requirement and same (or similar) test methods
- Yellow: Similar requirement but with different test methods
- Red: Requirements are more stringent
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Notes:

- For EN 166, only requirements and tests for frames and complete eye protectors have been included (see Table 9 of EN 166), that is, not for mounted or unmounted oculars (lenses), with the exception of transmittance and fogging resistance. Optional requirements for frames/complete eye protectors are generally not included.
- For the US and ISO standards, in general, requirements for lenses (only) and optional requirements for frames/complete eye protectors have also not been included.

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 166:2001**		**US ANSI/ISEA Z87.1:2020**		**(ISO) ISO 16321-1:2021**		**COMPARISON/COMMENTS**
Characteristic/property	**Testing method**	**Requirement**	**Requirement**	**Testing method**	**Testing method**	**Requirement**	
Construction and materials		Pass	Pass	Section 9.1 and ANSI Z80.1	ISO 18526-3, clause 6.1	Pass	EU-US test methods comparable. ISO comparable to EN; includes adjustment features
Headband		Pass	n/a		ISO 18526-3, clause 6.5	Pass	Different than in EU
Basic/"fundamental" requirements							EU refers to "basic" requirements; US refers to "fundamental design requirements"
Field of vision	EN 168 (clause 18)	Pass	n/a		ISO 18526-3, clause 6.2	±30° horizontally and vertically	Different than in EU
Minimum coverage area		Not a requirement except for special uses	An ellipse with axes ≥40 mm and ≥ 33mm		ISO 18526-3, clauses 6.3 & 6.4	Pass (both frontal and lateral directions)	Called "area to be protected" in ISO
Transmittance of oculars without filtering action	EN 167 (clause 6)	> 74.4%	≥ 85% (or ≥ 78% if relaxed optics)	Section 9.2 (use of a spectrophotometer and weighing factors in Annex C)	ISO 18526-2, clause 7.1 or 7.3	≥80% ≥75% (for face shields)	EU-US similar methods; more stringent requirement in the US; similar ISO requirements/test method as in EN

(Market) standard	EU EN 166:2001		US ANSI/ISEA Z87.1:2020		(ISO) ISO 16321-1:2021		COMPARISON/COMMENTS
Characteristic/property	**Testing method**	**Requirement**	**Requirement**	**Testing method**	**Testing method**	**Requirement**	
Haze	n/a	n/a	≤3%	Section 9.3 and ASTM D1003-13	ISO 18526-2, clause 14.1	≤3%	Called "scattered light" in ISO; similar to the US
Increased robustness	EN 168 (clause 3.2)	Pass	Pass	Section 9.6	ISO 18526-3, clause 7.3.1	Pass	EU-US comparable test methods. Characteristic in the US is called "drop-ball impact resistance" Called "basic impact level" in ISO; similar to method in EU
Thermal stability	EN 168 (clause 5)	Pass	n/a		ISO 18526-3, clause 6.7	Pass	Called "resistance to thermal exposure" in ISO; similar to EU
Resistance to corrosion	EN 168 (clause 8)	Pass	Pass	Section 9.8	ISO 18526-3, clause 6.9	Pass	EU, US, and ISO very similar methods
Resistance to ignition	EN 168 (clause 7)	Pass	Pass	Section 9.7	ISO 18526-3, clause 6.10	Pass	EU, US, and ISO very similar methods
"Particular requirements" (per EU)				**Called "optional hazard-specific requirements" in the US**			
Droplets and splashes of liquid	EN 168 (clause 12)	No color present for goggles Face shields pass the area coverage test	No color present for goggles Face shields pass the area coverage test	Section 9.17.1 goggles (droplets) Section 9.17.2 face shields (splashes)	ISO 18526-3, clause 6.12 (droplets) Clause 6.13 (streams of liquids)	No color present for droplets No wetness for streams of liquids	In the US, same head forms as in EN 168 are used in all tests; EU-US similar test methods Same method in ISO as in the EU (for droplets only); stricter method in ISO than in EU for splashes
Lateral protection (optional)	EN 168 (clause 19)	Pass	Pass	Section 9.10, Annex D			Similar test methods in the EU and US; in the US, only for impact-rated protectors In ISO, covered by property "area to be protected" mentioned earlier
Optional requirements (per EU)							
Resistance to fogging (only for oculars; not complete eye protectors)	EN 168	Time without fogging ≥8 s	Time without fogging ≥8 s	Section 9.20		ISO 18526-3, clause 6.11	Same requirements/method in EU/US/ISO

4.3 Gloves

4.3.1 Medical examination gloves

4.3.1.1 EU market and ISO standards requirements

Standards for medical gloves for single use in the EU currently[57] harmonized under the Medical Devices Directive are:

- EN 455-1:2000, "Medical gloves for single use—Part 1: Requirements and testing for freedom from holes" (not the latest version)
- EN 455-2:2009+A2:2013, "Medical gloves for single use—Part 2: Requirements and testing for physical properties "(not the latest version)
- EN 455-3:2006, "Medical gloves for single use—Part 3: Requirements and testing for biological evaluation" (not the latest version)
- EN 455-4:2009, "Medical gloves for single use—Part 4: Requirements and testing for shelf-life determination"

The following highlights are pointed out for the above standards:

- EN 455 contains a watertightness test for checking for freedom of holes. In the 2020 version the acceptable quality limit (AQL) for surgical gloves (only) has been reduced from 1.5 to 0.65 (that is, a stricter limit)
- EN 455-2 contains dimensional measurements and tensile properties (force at break before and after ageing). The 2015 version removed an exception for nitriles in the force at break limits
- EN 455-3 covers biocompatibility requirements, restrictions on chemicals present in the gloves, test for endotoxins (if the gloves are sterile and are additionally labeled with "low endotoxin content"), test for powder residue, test for leachable proteins (associated with the allergenic potential of natural rubber latex products), and immunological methods for the measurement of natural rubber latex allergens (optional). The 2015 version restated the restrictions on chemicals, among others, removing the requirements to achieve levels "as low as reasonably practicable" (ALARP)
- EN 455-4 requires manufacturers to test the properties that are reasonably expected to alter over the shelf life of the product (for example, force at break, freedom from holes, and in the case of sterile gloves, pack integrity). Test methods for real-time/accelerated shelf-life determination are provided.

Medical gloves are considered medical devices in the EU. Thus, they fall under the scope of the newly applicable (since May 2021) Medical Device Regulation (MDR). For administrative reasons, the above harmonized standards under the previous directive have not yet become harmonized under the new regulation. Therefore, for the time being, they should be used with caution and as an aid in showing conformity to the essential safety and performance requirements of the MDR.

It is evident from the above that distinct European standards (parts of the EN 455 series) exist for different characteristics of medical gloves for single use, while in ASTM and ISO standards a single document contains requirements for all characteristics. It is also noted that the EN 455 series includes both surgical and medical examination gloves, with no separate standards for the different materials from which they can be made. However, because this distinction is made in the ASTM (US) and ISO standards, the standard comparison in subsequent sections is done separately for examination and for surgical gloves.

While surgical gloves are typically supplied sterile, examination gloves are supplied typically non-sterile. However, there are sterile examination gloves available on the market being used in non-surgical applications where additional protection against the transfer of infective agents is necessary.

All medical gloves are Self-declaration Class I in the MDR. However, where sterile, there is a requirement for

57 As of December 31, 2021.

a notified body to certify the sterilization process.

The ISO standards for medical examination gloves are ISO 11193-1:2020, "Single-use medical examination gloves—Part 1: Specification for gloves made from rubber latex or rubber solution," and ISO 11193-2:2006, "Single-use medical examination gloves—Part 2: Specification for gloves made from poly(vinyl chloride)."

ISO 11193-1:2020 is a relatively recent edition, while many national adoptions of it or standards based on it, are still using the previous edition (2008). In the standard, two types of gloves are defined: Type 1, made primarily from natural rubber latex and Type 2, made from various synthetic rubber latexes, emulsions or solutions. Watertightness requirements and method are similar to the EN/US standards while tensile properties (for which different limits apply for Types 1 and 2 gloves) are an amalgam of the requirements in the EU and US standards (see next section). Lastly, from the characteristics regarding biological evaluation (see EN 455-3), only powder residue content has been specified (for the first time) in the 2020 edition of the ISO standard.

ISO 11193-2:2006 has similar requirements and testing methods to ISO 11193-1, with the limits of the tensile properties differing somewhat due to the different material of construction (PVC versus rubber). Biocompatibility evaluation to the relevant parts of ISO 10993 is specified but no other biological evaluation is specified (for example, powder residue, extractable plasticizers). It is also noted that PVC does not have the allergenic properties of natural rubber latex.

Any of these gloves may be PPE if they claim to protect the wearer and are labeled accordingly. Being a medical glove and a PPE glove are not mutually exclusive, but they must be treated as two separate approvals.

The following two standards for protective gloves are used in conjunction with each other. They will not be analyzed in detail but are mentioned here for completeness:

- EN ISO 21420:2020, "Protective gloves—general requirements and test methods," is the new European standard containing general requirements for protective gloves (not yet a harmonized standard under the PPE Regulation, where the superseded EN 420:2003+A1:2009 is listed instead).

- EN ISO 374-5:2016, "Protective gloves against dangerous chemicals and micro-organisms: Part 5: Terminology and performance requirements for micro-organism risks." This standard, in addition to the watertightness test of EN 455-1, provides also for an air leak test and a test for resistance to bloodborne pathogens penetration using ISO 16604.

4.3.1.2 US market requirements

The requirements for medical examination gloves in the US market are covered by multiple standards, depending on the material used, as follows:

- ASTM D3578 (latex exam gloves)

- ASTM D5250 (PVC exam gloves)

- ASTM D6319 (nitrile exam gloves)

- ASTM D6977 (polychloroprene exam gloves)

The existence of different standards for different materials of construction is somewhat mirrored in the ISO standards (see 4.3.1.1) and in this respect is not the same as in the EU. Regarding tensile properties, in the ASTM standards tensile strength is specified (in units of pressure, as opposed to the force at break in the EN/ISO standards), as well as percentage elongation at break, both properties being measured before and after ageing. For rubber gloves, limits for stress (again in pressure units) at a 500 percent elongation are also specified (only before ageing). Lastly, in the ASTM standards references to other ASTM standards containing testing methods are made.

Examination gloves are considered by the FDA to be Class I medical devices subject to general controls only (see 21 CFR § 880.6250 as amended). Nevertheless, the FDA requires that examination gloves be subject to a clearance through a 510(k) process except when exemptions are applied during public health emergencies, as has been the case for COVID-19. Also, as of January 2017, the FDA banned powdered examination gloves

(see 81 FR 91730[58]).

As in the EU/ISO, there are also standards pertaining to gloves which claim to be or are labeled as PPE. Main standards, which will not be analyzed but are mentioned for completeness, are:

- ANSI/ISEA 105-2016, "American national standard for hand protection classification," addresses the classification and testing of hand protection for specific performance properties related to mechanical protection (for example, puncture resistance, including a needlestick puncture test which may happen in a health care environment), chemical protection (for example, permeation resistance), and so on.

- NFPA 1999:2018, "Standard on protective clothing and ensembles for emergency medical operations," which covers requirements for, among others, emergency medical examination gloves (both single-use and multiple-use). Requirements are specified for dexterity, puncture resistance, resistance to bloodborne pathogens penetration, and so on.

58 https://www.federalregister.gov/documents/2016/12/19/2016-30382/banned-devices-powdered-surgeons-gloves-powdered-patient-examination-gloves-and-absorbable-powder.

4.3.1.3 Comparison of EU, US, and ISO criteria

Table 4.5 compares the requirements for medical examination gloves in the EU and US standards as well as similarities/differences with ISO standards.

Table 4.5: Comparison between EU, US, and ISO standards for medical examination gloves

Color code for EU/US comparisons:

- Green: Same requirement and same (or similar) test methods
- Yellow: Similar requirement but with different test methods
- Red: Requirements are more stringent
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: The most recent versions of EN 455 series standards have been used (not all yet harmonized under the PPE Regulation or MDR).

Note: Testing standard is only mentioned if it is not defined in the product specification

(Market) standard	**EU EN 455 series**		**US ASTM—material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)**		**Comments**	**(ISO) Material specific— ISO 11193-1:2020 (rubber) ISO 11193-2:2006 (PVC)**		**COMPARISON/COMMENTS**
Characteristic/ property	**Testing method**	**Requirement**	**Requirement**	**Testing method**		**Requirement**	**Testing method**	
Freedom from holes	EN 455-1:2020	AQL =1.5	AQL =2.5	ASTM D5151	EU has stricter requirements than the US/ISO standards; same test method	AQL =2.5		

(Market) standard	**EU EN 455 series**		**US ASTM—material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)**		**Comments**	**(ISO) Material specific— ISO 11193-1:2020 (rubber) ISO 11193-2:2006 (PVC)**		**COMPARISON/COMMENTS**
Characteristic/ property	**Testing method**	**Requirement**	**Requirement**	**Testing method**		**Requirement**	**Testing method**	
Force at break (N) / Tensile strength (MPa), elongation at break (%) (Also, after ageing/ challenge)	EN 455-2 :2015, method A of ISO 23529:2010	(Median of 13 samples) Non-thermoplastic materials ≥ 6.0N Thermoplastic materials (PVC, PE) ≥ 3.6N	AQL = 4.0 Nitrile ≥ 14MPa/ elongation ≥400% Latex (natural) ≥ 14MPa / Elongation ≥ 500% Polychloroprene ≥ 14MPa/ elongation ≥ 400% PVC ≥ 11MPa/ elongation ≥ 300%	ASTM D412, ASTM D573 (ageing)	The US values are after accelerated ageing (higher tensile strength/ elongation limits generally apply before ageing for all materials) EU standards specify minimum absolute force (N) for samples taken from the glove (varies with thickness); ASTM specifies in terms of tensile strength (MPa – force per unit area)	AQL = 4.0 For rubber ≥ 6.0 N Elongation ≥ 500% (Type 1), 400% (Type 2) For PVC ≥ 7.0 N Elongation ≥ 350% (limit for force has been lowered by about 50% in the EU)	ISO 37, ISO 188	ISO 11193-1 Types 1 and 2 roughly correspond Types I and II in ASTM D3578. ISO rubber limit same as in EU (but elongation at break is also specified) In general, the tensile properties and their limits specified in the ISO standards are an amalgam of the EU/US ones
Biocompatibility	EN ISO 10993-5 and -10	Pass	Pass	Per FDA regulations	Generally similar methodology	Pass	ISO 10993 series	
Powder residue content	EN 455-3, EN ISO 21171:2006	≤ 2.0mg/glove	≤ 2.0mg/glove (powder free gloves) ≤ 10 mg/dm² (powdered gloves)	ASTM D6124	Limits and method same (for powder-free gloves); powdered gloves have been disallowed in the US by the FDA	Only for rubber gloves ≤ 2.0mg/glove (powder free gloves) ≤ 10 mg/dm² (powdered gloves)	ISO	Limits have first been specified in the 2020 edition of ISO 11193-1
Aqueous soluble protein content	EN 455-3	"Manufacturer shall monitor the content in natural rubber latex (NRL) gloves and shall try to minimize it"	≤ 200 µg/dm² (only for rubber gloves)	ASTM D5712	Unlike the US, the EU does not mention specific limits; methods are essentially the same	n/a (may be specified in future edition)		

(Market) standard	**EU EN 455 series**		**US ASTM—material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)**		**Comments**	**(ISO) Material specific— ISO 11193-1:2020 (rubber) ISO 11193-2:2006 (PVC)**		**COMPARISON/COMMENTS**
Characteristic/ property	**Testing method**	**Requirement**	**Requirement**	**Testing method**		**Requirement**	**Testing method**	
Extractable antigenic protein content	EN 455-3, Annex B	Optional	≤ 10 µg/dm² (only for rubber gloves)	ASTM D6499	In the EU, measuring this characteristic is optional; (immunological) method essentially same	n/a (may be specified in future edition)		
Sterility		EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	Pass	US Pharmacopeia		If gloves are sterilized, the nature of the sterilization process shall be disclosed on request		

4.3.2 Surgical gloves

4.3.2.1 EU market and ISO standard requirements

The same basic standards of the EN 455 series that apply to medical examination gloves also cover surgical gloves. Further details can be found in 4.3.1.1.

The relevant ISO standard is ISO 10282:2014. In the standard two types of gloves are defined: Type 1, made primarily from natural rubber latex and Type 2, made from various synthetic rubber latexes, emulsions, or solutions. Watertightness requirements and methods are similar to the EN/US standards while tensile properties (for which different limits apply for Types 1 and 2 gloves) are an amalgam of the requirements in the EU and US standards (see below section).

If claimed or labeled as PPE, surgical gloves fall within the scope of the EN ISO standards for "protective gloves" mentioned in 4.3.1.1.

4.3.2.2 US market requirements

The main standard used in the US market is ASTM D3577-19 "Standard specification for rubber surgical gloves." In the standard, Type 1 gloves (made from natural rubber latex) and Type 2 (made from a rubber cement or from synthetic rubber latex) are defined. Otherwise, the requirements and test methods are similar to those for the medical examination gloves (see 4.3.1.2). Another useful standard is ASTM 7103-19 "Standard guide for assessment of medical gloves" covering both medical examination and surgical gloves.

Surgical gloves are considered by the FDA to be Class I medical devices, subject to general controls only (see 21 CFR § 878.4460 as amended). Also, as of January 2017, FDA banned powdered surgical gloves (see 81 FR 91730).

4.3.2.3 Comparison of EU, US, and ISO criteria

Table 4.6 compares the requirements for surgical gloves in the EU and US markets as well as similarities/differences with ISO standards.

Table 4.6: Comparison between EU, US, and ISO standards for surgical gloves

Color code for EU/US comparisons:

Green – Same requirement and same (or similar) test methods
Yellow – Similar requirement but with different test methods
Red – Requirements are more stringent
Blue – Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: The most recent versions of EN 455 series standards have been used (not yet harmonized under the PPE Regulation or MDR).

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 455 series**		**US ASTM D3577-19 Type 1: Natural rubber Type 2: Synthetic rubber**		**Comments**	**(ISO) ISO 10282:2014 Type 1: Natural rubber Type 2: Synthetic rubber**		**COMPARISON/ COMMENTS** *Note*: Similar types defined in ISO as in the US (EU does not differentiate)
Characteristic/ property	**Testing method**	**Requirement**	**Requirement**	**Testing method**		**Requirement**	**Testing method**	
Freedom from holes	EN 455-1:2020	AQL = 0.65	AQL = 1.5	ASTM D5151	Latest version of EN 455-1 is stricter than before	AQL = 1.5		
Force at break (N) / Tensile strength (MPa), elongation (%) (Also, after ageing/challenge)	EN 455-2 :2015, method A of ISO 23529:2010	(Median of 13 samples) All materials ≥ 9.0N	AQL = 4.0 Type 1: Latex (natural) ≥18MPa/ elongation ≥560% Type 2: Synthetic rubber ≥12Mpa/ elongation ≥490%	ASTM D412, ASTM D573 (ageing)	The US values are after accelerated ageing (higher tensile strength/ elongation limits generally apply before ageing for all materials) EU standards specify minimum absolute force (N) for samples taken from the glove (varies with thickness); ASTM specifies in terms of tensile strength (MPa—force per unit area)	AQL = 4.0 Type 1: Latex (natural) ≥9.5 N/elongation ≥550% Type 2: synthetic rubber ≥9.0N/elongation ≥500%	ISO 37, ISO 188	The ISO values are after accelerated ageing (higher limits apply before ageing) ISO tensile properties specified and their limits are an amalgam of the ones in the EU/US
Biocompatibility	EN ISO 10993-5 and -10	Pass	Pass	Per FDA regulations	Generally similar methodology	Passes (generally similar methodology with EU/US)	ISO 10993-1	
Powder residue content	EN 455-3, EN ISO 21171:2006	≤ 2.0 mg/glove	≤ 2.0mg/glove	ASTM D6124	Limits and method same; surgical gloves can only be powder free	n/a (may be specified in future edition)		
Aqueous soluble protein content	EN 455-3, Annex A	"Manufacturer shall monitor the content in NRL gloves and shall try to minimize it"	≤ 200 µg/dm²	ASTM D5712	Unlike the US, the EU does not give specific limits; method essentially same	n/a (may be specified in future edition)		

(Market) standard	**EU EN 455 series**		**US ASTM D3577-19 Type 1: Natural rubber Type 2: Synthetic rubber**		**Comments**	**(ISO) ISO 10282:2014 Type 1: Natural rubber Type 2: Synthetic rubber**		**COMPARISON/ COMMENTS** *Note*: Similar types defined in ISO as in the US (EU does not differentiate)
Characteristic/ property	**Testing method**	**Requirement**	**Requirement**	**Testing method**		**Requirement**	**Testing method**	
Extractable antigenic protein content	EN 455-3, Annex B	Optional	≤ 10 µg/dm²	ASTM D6499	In the EU, measuring this characteristic is optional; (immunological) method essentially same	n/a (may be specified in future edition)		
Sterility		EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	Pass	US Pharmacopeia		Gloves shall be sterilized; the nature of the sterilization process shall be disclosed on request.	No specific method provided	

4.4 Clothing

This section covers the requirements for all the categories of protective clothing described in, which are subject to similar core requirements regardless of their specific application. However, it is important to differentiate between protective clothing (under the PPE Regulation) and surgical or isolation gowns (under the MDR). Because of this differentiation, 4.4 is split into sections 4.4.1 for protective clothing (PPE for full- or partial-body protection) and 4.4.2 for gowns (medical devices). The reader is reminded that, as mentioned in 1.4.1, depending on the claims made by the manufacturer, a product may need to cover both sets of requirements.

4.4.1 Full-body and partial-body garments (other than surgical/isolation gowns)

4.4.1.1 EU market requirements

The core standard is EN 14126:2003, "Protective clothing against infective agents," which includes the following infective agent seam and material tests:

- ISO 16603:2004, "Clothing for protection against contact with blood and body fluids— determination of the resistance of protective clothing materials to penetration by blood and body fluids—test method using synthetic blood" (indicator test for ISO 16604), Classes 1–6, 0 to 20 kPa (barrier test)
- ISO 16604:2002 "Resistance of protective clothing materials to penetration by bloodborne pathogens using Phi-X174 bacteriophage," Classes 1–6, 0 to 20 kPa (barrier test)
- EN ISO 22610:2006, "Surgical gowns, resistance to wet bacterial penetration," Classes 1–6 (breakthrough times)
- ISO/DIS 22611 (never published), "Resistance to penetration by contaminated liquid aerosols," Classes 1–3 (quantitative breakthrough)
- EN ISO 22612:2005, "Clothing, resistance to dry microbial penetration," Classes 1–3 (quantitative breakthrough).

Other relevant standards, harmonized under the PPE Regulation, include:

- EN 14605:2005+A1:2009, "Protective clothing against liquid chemicals—performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])"
- EN 13034:2005+A1:2009, "Protective clothing against liquid chemicals—performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)"
- EN ISO 13688:2013+A1:2021,[59] "Protective clothing—general requirements."

EN 14126 provides requirements for protection from infectious agents (including COVID-19) for both full- and partial-body garments. EN 14126 calls up in clause 4.3 the relevant general protective clothing requirements from EN 340 (now EN ISO 13688) and the requirements from the chemical protective clothing types in Table 4.7.

59 As of December 31, 2021, the amendment had not yet been harmonized under the PPE Regulation.

Table 4.7: Types of chemical protection clothing

Type of clothing	Common suit name	PB option	Relevant current standard
Type 1a, 1b, 1c, 2	Gas tight for Types 1 Ventilated gas tight for Type 2	No	EN 943-1:2015+A1:2019 (Type 1) EN 943-1:2002 (Type 2) EN 943-2:2019 (Type 1 ET)
Type 3	Jet or splash tight	Yes	EN 14605:2005+A1:2009
Type 4	Spray or light splash tight	Yes	EN 14605:2005+A1:2009
Type 5	Dust tight	No	EN 13982-1:2004+A1:2010
Type 6	Light spray tight	Yes	EN 13034:2005+A1:2009

It is pointed out that EN 14126:2003 (the standard for protective clothing against infective agents) must be associated with a chemical suit "type" standard for material mechanical performance, regardless of whether or not chemical protection is claimed. Partial-body protection (PB), for example, aprons or head/shoe covers, is only available with "Types" 3, 4 and 6. Suit "Types" 3, 4, 6, PB [3], PB [4] and PB [6] refer to test methods from EN 14325:2004 (this is the version referenced by the harmonized EN 14126—a 2018 version of EN 14325 has also been issued).

In combination, the above standards provide for tests regarding:

- Innocuousness and design/comfort
- Properties of materials (mechanical, flammability, chemical resistance, and resistance to penetration by infective agents)
- Properties for seams (parts of the construction of integral parts of the garment), joins (between integral parts of the garment) and assemblages (of different garments or of garments and accessories, detachable or not)
- Whole-suit requirements
- Accessories (for example, visors).

As already mentioned, aprons and head/shoe covers, if they claim to offer partial-body protection, are considered PPE. As such, they should comply with the requirements above applicable for innocuousness, design/comfort and materials only. (See also table in 4.4.1.3, where all sets of requirements are included.)

Additionally, it is noted the international standard ISO 16602:2007+A1:2012, "Protective clothing for protection against chemicals—classification, labeling and performance requirements," does not address protection against infective agents and is only relevant for mechanical/chemical properties of materials and suit integrity as relates to COVID-19 protection. Of course, other ISO standards (ISO 16603, ISO 16604, ISO 22610, and ISO 22612 mentioned previously in this section) constitute the basic suite of testing methods for resistance to infective agents.

Lastly, for single-use aprons and head/shoe covers, the following standard is optionally applicable (for biodegradable products): EN 13432:2000, "Packaging—requirements for packaging recoverable through composting and biodegradation—test scheme and evaluation criteria for the final acceptance of packaging" (currently under revision). The standard includes references to appropriate test methods.

4.4.1.2 US market requirements

Requirements for protective garments in the United States in the scope of this guide are addressed mainly by NFPA 1999:2018, "Standard on protective clothing and ensembles for emergency medical operations."[60] The

60 Another standard for chemical protection is NFPA 1992 "Standard on liquid splash-protective ensembles and clothing for hazardous materials emergencies."

scope of the standard is quite broad, encompassing emergency medical garments and related accessories (that is, eye/face protection, gloves, helmets, and footwear), both single- and multiple-use. The standard contains design and performance requirements, as well as some test methods (for other tests, reference is made to established ASTM or other standards). Examples of requirements include:

- Mechanical properties of materials (for example, tear resistance, tensile strength, but not abrasion and flex cracking resistance included in EN 14126)
- Liquid integrity test (per ASTM F1359)
- Bio-penetration resistance (per ASTM F1671, on which ISO 16604—used in the EU—was based), but not dry/wet bacterial penetration resistance provided for in EN 14126.

It is noted that in the United States gowns used in health care settings typically are not covered by NFPA 1999—which is more suited to emergency response situations— but comply to a different set of standards (see 4.4.2.2).

Conformity assessment of products within the scope of NFPA 1999 must be provided by third-party product certification bodies.

Lastly, for single-use aprons and head/shoe covers, the following standard is optionally applicable (for biodegradable products): ASTM D6400-19, "Standard specification for labeling of plastics designed to be aerobically composted in municipal or industrial facilities."

4.4.1.3 Comparison between EU, US market, and ISO requirements

Table 4.8 compares the requirements for protective clothing in the EU and US markets as well as similarities/differences with ISO standards.

Table 4.8: Comparison between EU, US, and ISO standards for protective clothing

Color code for EU/US comparisons:

- Green: Same requirement and same (or similar) test methods
- Yellow: Similar requirement but with different test methods
- Red: Requirements are more stringent
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Notes:

- For simplicity, only requirements for materials and whole suits are included (that is, requirements for seams, joins, assemblages, and integral components such as visors are not included).
- For protection against infective agents, only the following protection types, as defined in the standards, are considered here: Type 4 (spray-tight), Type PB [4] (partial-body protection—Type 4), Type 6 (limited protection against liquid chemicals), and Type PB [6] (partial-body protection—Type 6).

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU**		**US**		**ISO**		**COMPARISON/ COMMENTS**
Characteristic/ property	**Testing method**	**Requirement**	**Requirement**	**Testing method**	**Requirement**	**Testing method**	
I. General requirements	**Standard**	**EN ISO 13688:2013+ A1:2021**		**NFPA 1999:2018**	**ISO 13688:2013+AMD 1:2021**		
Innocuousness	General assessment methodology in Annex B. Azo dyes according to EN ISO 14362-1 *Note*: Also cl. 4.3 of EN 14126	No harmful substances present No azo dyes present	No specific requirements		No harmful substances present No azo dyes present	General assessment methodology in Annex B Azo dyes according to ISO 14362-1 and ISO 14362-3	ISO/EU: Same limits/ methods

(Market) standard	EU		US		ISO		COMPARISON/ COMMENTS
Characteristic/ property	**Testing method**	**Requirement**	**Requirement**	**Testing method**	**Requirement**	**Testing method**	
Design and comfort	Assessment in Annex C	Acceptable	Acceptable *Note*: Design requirements only ≥650 g/(m²24 h) *Note*: In the US for single-use garments/ ensembles "moisture vapor transmission rate" is specified ≥450 W/m² *Note*: In the US for multiple-use garments/ensembles "total heat loss test" is specified	Section 6.1 Section 8.28 and ASTM E96 Section 8.32 and ASTM F1868	Assessment in Annex C	Acceptable	Same requirements; similar methodology as in EU/ISO/US
II. Protection against infective agents	**Standard**	**EN 14126:2003 and EN 14605:2005+A1:2009 (for Type 4 and PB [4]) or EN 13034:2005+A1:2009 (for Type 6 and PB [6])**		**NFPA 1999:2018**	**ISO 16602:2007+AMD1:2012**		ISO 16602 is really about protective clothing against chemicals— not against infective agents; requirements on mechanical properties and chemical resistance of materials are included, as well as whole-suit requirements
1.Materials requirements							
a) Mechanical properties							
Abrasion resistance	cl. 4.4 of EN 14325 & EN ISO 12947-2 *Note*: Reference in this column to EN 14325 without a year, means the current edition (2018) *Note*: In EN 14325:2004, instead use EN 530	Class 1 to 6 (highest)	Abrasion resistance is considered as a precondition to barrier performance of materials	ASTM D4157	Class 1 to 6 (highest)	ISO 12947-2	EU/ISO: Same limits/ essentially same method

(Market) standard	EU		US		ISO		COMPARISON/ COMMENTS
Characteristic/ property	**Testing method**	**Requirement**	**Requirement**	**Testing method**	**Requirement**	**Testing method**	
Flex cracking resistance	cl. 4.5, 4.6 of EN 14325 and EN ISO 7854, method B	Class 1 to 6 (highest)	Flex fatigue is considered as a precondition to barrier performance of materials	ASTM F392	Class 1 to 6 (highest)	ISO 7854, method B	EU/ISO: Same limits/ essentially same method
Trapezoidal tear resistance	cl. 4.7 of EN 14325 and EN ISO 9073-4:1997	Class 1 to 6 (highest)	Single-use: "Tear resistance test two" ≥17 N Multiple-use: "Tear resistance test one" ≥36 N	Section 8.38 and ASTM D5733 (non-woven) Section 8.7 & ASTM D5587 (woven)	Class 1 to 6 (highest)	ISO 9073-4	EU/ISO: Same limits/ essentially same method
Tensile strength	cl. 4.9 of EN 14325 and EN ISO 13934-1 *Note*: Additionally bursting strength, cl. 4.8 of EN 14325:2004 and EN ISO 13938-1	Class 1 to 6 (highest)	≥50 N ≥66N (single-use) ≥222.5N (multiple-use)	Section 8.4 and ASTM D5034 Section 8.5 and ASTM D3787	Class 1 to 6 (highest) Class 1 to 6 (highest)	ISO 13934-1 ISO 13938-1	For tensile strength ASTM limits/method not directly comparable to EU/ISO (which are same) Burst strength is an additional US/ISO requirement (was eliminated in the EU)
Puncture resistance	cl. 4.10 of EN 14325 and EN 863	Class 1 to 6 (highest)	≥12N (single-use) ≥25N (multiple-use)	Section 8.6 and ASTM D2572	Class 1 to 6 (highest)	ISO 13996	ASTM limits/method not directly comparable to EU or ISO
b) Chemical resistance							
Permeation by chemicals (Applicable for Types 4 and PB[4])	EN ISO 6529, method A (liquids) *Note*: In EN 14325:2004 also EN 374-3	Class 1 to 6 (highest)			Class 1 to 6 (highest)	ISO 6529, method A	EU/ISO: Same limits/ essentially same method in ISO 16602. Alternatively, resistance to penetration by liquids under pressure (per ISO 13994:2005, Procedure D) is applied
Repellency to liquids (Applicable to Types 6 and PB[6])	ISO 6530	Class 1 to 3 (highest)	≤30%	Section 8.31	Class 1 to 3 (highest)	ISO 6530	*Note*: In the US it is called "water absorption resistance test." It applies only to multiple-use garments/ensembles EU/ISO: Same limits/ essentially same method

(Market) standard	EU		US		ISO		COMPARISON/ COMMENTS
Characteristic/ property	**Testing method**	**Requirement**	**Requirement**	**Testing method**	**Requirement**	**Testing method**	
Penetration by liquids (Applicable to Types 6 and PB[6])	ISO 6530	Class 1 to 3 (highest)			Class 1 to 3 (highest)	ISO 6530	EU/ISO: Same limits/ essentially same method
c) Flammability							
Resistance to ignition or flame (more stringent)	cl. 4.14 of EN 14325 & EN 13274-4, method 3	Pass or min. class 1	Flame spread time: ≥3.5 s	Section 8.39 & ASTM D1230	n/a		Requirement eliminated by ISO 16602 AMD 1:2012
d) Penetration by infective agents					No relevant requirements in ISO 16602		
Contaminated liquids under hydrostatic pressure	Clause 4.1.4.1 of EN 14126, ISO 16603 and ISO 16604	Class 1 to 6 (highest)	Pass *Note*: In the US the "bio-penetration test one" applies	Section 8.3 & ASTM F1671	Requirement does not apply in ISO 16602 (ISO 16603 and 16604 are only laboratory method standards)		ASTM method and ISO 16604 are very similar
Mechanical contact with contaminated liquids (wet bacterial penetration)	Clause 4.1.4.2 of EN 14126 and EN ISO 22610	Class 1 to 6 (highest)	n/a		n/a		
(Biologically) contaminated liquid aerosols	Clause 4.1.4.3 of EN 14126 and ISO/DIS 22611 *(withdrawn)*	Class 1 to 3 (highest)	n/a		n/a		
Contaminated solid particles (dry microbial penetration)	Clause 4.1.4.4 of EN 14126 and ISO 22612	Class 1 to 3 (highest)	n/a		n/a		
2. Whole-suit requirements							
Mist test (Type 6)	EN ISO 17491-4 (method A) as modified by cl. 5.2 of EN 13034	Pass	Pass *Note*: In the US the "liquid tight integrity test one" applies	Section 8.2	Pass	ISO 17491-4 (method A)	EU/ISO: Same limits/ essentially same method

(Market) standard	EU		US		ISO		COMPARISON/ COMMENTS
Characteristic/ property	**Testing method**	**Requirement**	**Requirement**	**Testing method**	**Requirement**	**Testing method**	
Liquid spray test (Type 4)	Clause 4.3.4.2 etc. of EN 14605 and EN ISO 17491-4 (method B)	Pass	Pass	Section 8.2	Pass	ISO 17491-4 (method B)	EU/ISO: Same limits/ essentially same method
Practical performance	Per EN 14605/ EN 13034 ("seven movements" sequence while wearing the suit)	Pass	Demonstration of garment functionality is included as part of the liquid integrity testing applied to garments	ASTM F1154	Pass	ISO 16602, Annex A	EU/ISO: Same limits/ essentially same method

4.4.2 Gowns

4.4.2.1 EU market requirements

Requirements for gowns used in health care settings are included in EN 13795-1:2019, "Surgical clothing and drapes—requirements and test methods— Part 1: Surgical drapes and gowns." It is noted that, unlike in the United States, only a standard for *surgical* gowns exists. Therefore, in this subsection, by "gown" a "surgical gown" is meant. The standard covers both single-use and reusable gowns.

Requirements in the standard include:

- Mechanical properties (for example, liquid penetration, tensile strength, bursting strength)
- Resistance to wet bacterial penetration (due to a combination of wetness, pressure and rubbing) and dry microbial penetration (due to a combination of air movement and mechanical action by vibration)
- Microbial burden (it also possible that gowns are provided sterile).

The standard recognizes two levels of performance: "standard" and "high" and also differentiates between "critical product areas" of the garment and "less critical product areas." Critical product areas are defined as those with a greater probability to be involved in the transfer of infective agents to or from the wound, for example, the front and sleeves of surgical gowns. The applicable requirements depend on both the performance level and the critical/less critical areas.

The conformity assessment of gowns is done under the requirements of the EU Medical Devices Regulation (MDR) (EU) 2017/745. In fact, EN 13795-1 is harmonized under the previously valid EU Medical Devices Directive, but, as of 31 December 2021, not yet under the new regulation. Additionally, EN 13795-1 is not harmonized under the PPE Regulation, which means that if claims for PPE are made for a product, compliance to the requirements of EN 14126 (see 4.4.1.1) has to be checked.

4.4.2.2 US market requirements

For the definition and an overview of isolation and surgical gowns, the reader is referred to 2.4.2 of the guide. The key standard is ANSI/AAMI PB70:2012, "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities." The scope of the standard encompasses single- and multiple-use gowns, sleeve protectors and aprons but not surgical caps or foot covers.

The standard defines four levels of barrier performance: 1 to 4 (highest). Regarding barrier properties: Level 1 meets a water impact test; Levels 2 and 3 both meet water impact and hydrostatic pressure tests (higher limit for the latter for Level 3); and Level 4 must meet a resistance to bloodborne pathogens test (per ASTM F 1671), similar to ISO 16604.

All levels must also meet other requirements specified in ASTM F2407-20 for surgical gowns and ASTM F3352-19 for isolation gowns, respectively. For isolation gowns, properties such as tensile and seam strength are tested for, while, optionally, lint generation, comfort properties (for example, water vapor transmission rate or evaporative resistance), and physical properties (for example, abrasion resistance, flex durability) are also measured. Tests for surgical gowns are very similar, but some differences exist. Finally, for surgical gowns, when provided sterile, the selected sterilization process shall have a sterility assurance level of at least 10^{-6}.

Gowns used in health care settings are regulated as medical devices by the FDA. Both isolation and surgical gowns are Class II products (when Levels 3 or 4) subject to a pre-market (510(k)) notification. The simpler examination gowns are Class I products, subject only to general controls.

4.4.2.3 Comparison between EU and US market requirements

Table 4.9 compares the requirements for protective clothing in the EU and US markets.

Table 4.9: Comparison between EU and US standards for gowns

Color code for EU/US comparisons:

- Green: Same requirement and same (or similar) test methods
- Yellow: Similar requirement but with different test methods
- Red: Requirements are more stringent
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Notes:

- In the EU, specifications are defined for four situations: critical/less critical areas and standard/high performance. Unless otherwise specified, all areas and/or performances are implied.
- Both in the EU and the United States, single- and multiple-use surgical gowns are permitted. Multiple-use isolation gowns are also permitted in the US.
- Isolation gowns differ from surgical gowns based on their intended use and the expectation that the isolation gown provides 360° protection to the health care worker.
- For isolation gowns, the critical zone comprises the entire gown and must have a barrier performance of at least Level 1.

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 13795-1:2019, Surgical gowns**		**US ANSI/AAMI PB70:2012: All gowns ASTM F3352-19: Isolation gowns ASTM F2407-20: Surgical gowns**		**COMPARISON/COMMENTS**
Characteristic/ property	**Testing method**	**Requirement**	**Requirement**	**Testing method**	
Resistance to dry microbial penetration	EN ISO 22612:2005	≤ 300 CFU (less critical areas) *Note*: For critical product areas, wet bacterial penetration limits apply instead	n/a		AAMI PB 70 standard specifically excludes dry microbial penetration from its scope
Resistance to wet bacterial penetration	EN ISO 22610:2006	I_B ≥ 2.8 (critical areas, standard performance) I_B = 6.0 (critical areas, high performance)	n/a		US requires (only for Level 4) a stricter characteristic (viral penetration; see next row in table)
Viral penetration		n/a	Pass (AQL 4%, RQL=20%) (AAMI Level 4)	ASTM F1671	
Cleanliness microbial/ bioburden	EN ISO 11737-1:2018	≤ 300 CFU/100 cm²	n/a		

(Market) standard	**EU EN 13795-1:2019, Surgical gowns**		**US ANSI/AAMI PB70:2012: All gowns ASTM F3352-19: Isolation gowns ASTM F2407-20: Surgical gowns**		**COMPARISON/COMMENTS**
Characteristic/ property	**Testing method**	**Requirement**	**Requirement**	**Testing method**	
Particle release	EN ISO 9073-10:2004	Log_{10} (lint count) ≤ 4.0			Optional in the US
Water resistance (hydrostatic pressure)	EN ISO 811:2018	≥ 20 cm H_2O (critical areas, std. performance) ≥ 100 cm H_2O (critical areas, high performance) ≥ 10 cm H_2O (less critical areas)	≥ 20 cm H_2O (AAMI Level 2) ≥ 50 cm H_2O (AAMI Level 3) (AQL 4%, RQL=20%)	AATC 127	For critical areas/zones, US limits are same as EU ones (for standard performance) or lower (for high performance) Limits in the US apply only to critical zone components (akin to critical areas in the EU); EU and US methods are similar
Water resistance (impact penetration)		n/a	≤ 4.5 g (AAMI Level 1) ≤ 1.0 g (AAMI Levels 2, 3) (AQL 4%, RQL=20%)	AATC 42 or NWSP 80.3 NWSP 80.3 has replaced WSP 80.3 mentioned in AAMI PB 70 std.	Limits in the US apply only to critical zone components (akin to critical areas in the EU)
Bursting strength (dry) (wet)	EN ISO 13938:1:1999 *Note*: Newer version of the standard exists but is not referenced in EN 13795-1	≥ 40 kPa ≥ 40 kPa (critical areas)			
Tensile strength (dry) (wet)	EN 29073-3:1992	≥ 20 N ≥ 20 N (critical areas)	≥ 30 N	ASTM D5034	Higher limit in the US compared to the EU. Additionally, limits are set for tear strength (≥ 10 N per ASTM D5587 or D5733) and seam strength (≥ 30 N per ASTM D1683/D1683M). Physical property limits are same for all barrier levels per AAMI
Biocompatibility	EN ISO 10993-1:2009	Pass	Pass	ANSI/AAMI BE78 or ISO 10993-10	
Sterility		Packaging for terminally sterilized medical devices is recommended according to EN ISO 11607 series	Assurance level of sterilization process: at least 10^{-6}		
Flammability		Manufacturer to provide fire risk information	Class 1	16 CFR 1610	
Other criteria to consider		Comfort (depends on a variety of properties)	Optional: - Water vapor transmission Rate (ASTM D6701) - Evaporative resistance (ASTM F1868, Part B) - etc.		

PART 5
PRODUCT-SPECIFIC COMPARISONS (AUSTRALIA)

5.1 Masks

5.1.1 Respirators

The Australian standard on respirators is the Joint Australian/New Zealand Standard (AS/NZS) 1716:2012, "Respiratory protective devices." The standard covers many types of respirators (for example, against chemicals, particles, and so on). In this guide only Types P2 and P3 are included, with filtration efficiencies similar to the National Institute for Occupational Safety and Health (NIOSH) N95 and N99, other types being unsuitable for use in the COVID-19 context. The applicable sections of the standard are:

- Design and construction of assembled respirators
- Face pieces head coverings and harnesses
- Particulate filter respirators
- Marking and instructions

Test methods are included in appendices of the standard. A good overview of the applicable requirements and test methods is provided the informative Appendix P "Summary of conditioning and testing requirements."

It is envisioned that the AS/NZS will be replaced in future by the AS/NZ adoptions of the ISO 17420 series (specific performance requirements) and ISO 16900 series (test methods).[61]

Table 5.1 shows the requirements for respirators in the Australian market compared to those of the EU and US markets.

61 https://www.standards.org.au/news/new-guidance-for-respiratory-protective-equipment-released.

Table 5.1: Comparison between EU, US, and Australian standards for respirators

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.1 of this guide.

Color code:

- Green: Products made to the Australian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Australian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Australian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 149:2001 +A1:2009, Classes FFP 2 and FFP 3**	**Australia AS/NZS 1716:2012, Classes P2 and P3**	**US 42 CFR Part 84, Series/Levels N95 and N99**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Practical performance	Pass (based on 2 subjects performing various tasks)	Facial fit is determined during Total inward leakage test (cl. 2.2 of AZ/NZS)	Fit testing before use (required by OSHA, not NIOSH)	
Total inward leakage	**FFP2** ≤ 11% (individual) ≤ 8% (mean)	**P2** ≤ 8% (individual) ≤ 8% (mean)	n/a	Stricter limits in AS/NZS; method (using NaCl aerosol only) similar to EU test method
	FFP3 ≤ 5% (individual) ≤ 2 % (mean)	**P3** ≤ 5% (individual) ≤ 5% (mean) (Appendix D of AZ/NZS 1712)	n/a	
Filtering efficiency	**FFP2** ≥ 94% @ 95 L/min (NaCl and paraffin oil, (EN 13274-7)	**P2** ≥ 94% @ 95 L/min (NaCl) (Appendix I of AS/NZS 1712)	**N95** ≥ 95% @ 85 L/min (NaCl only)	Specified as max penetration of 6% in the EU and Australia
	FFP3 ≥ 99% @ 95 L/min (NaCl and paraffin oil, (EN 13274-7)	**P3** ≥ 99.95% @ 95 L/min (NaCl) (Appendix I of AS/NZS 1712)	**N99** ≥ 99% @ 85 L/min (NaCl only)	Specified as max penetration of 1% (EU) or 0.05% (AU), respectively Test methods of AS/NZS are somewhat different from EU criteria but performance criteria are similar (like US, Australia tests with NaCl only)
Compatibility with skin	Pass	Pass (Cl. 2.1.2 of AS/NZS 1712)	n/a	
Flammability	Pass	Only when a relevant claim is made Pass (Appendix C of AS/NZS 1712)	n/a	Test method similar to the EU one
Carbon dioxide content	Average ≤ 1% by volume in 'dead space'	Average ≤ 1% by volume in "dead space" (Appendix E 5.3 of AS/NZS 1712)	n/a	Test method similar to the EU one
Field of vision	Pass (in the practical performance test)	No explicit requirement	Pass	

(Market) standard	**EU EN 149:2001 +A1:2009, Classes FFP 2 and FFP 3**	**Australia AS/NZS 1716:2012, Classes P2 and P3**	**US 42 CFR Part 84, Series/Levels N95 and N99**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Breathing resistance (inhalation)	**FFP2** ≤ 70 Pa @ 30 L/min; ≤ 240 Pa @ 95 L/min	**P2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min (Appendix G of AS/NZS 1712)	**N95** ≤ 343 Pa @ 85 L/min	Limits same; test method similar to the EU one
	FFP 3 ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min	**P3** ≤ 120 Pa @ 30 L/min ≤ 420 Pa @ 95 L/min (Appendix G of AS/NZS 1712)	**N99** ≤ 343 Pa @ 85 L/min	Test method similar to the EU one, but limits are less strict. This is justified because P3 has a higher filtration efficiency requirement than FFP3
Breathing resistance (exhalation)	≤ 300 Pa @160 L/min	**P2** ≤ 120 Pa @85 L/min **P3** ≤ 300 Pa @85 L/min (when full face) (Appendix G of AS/NZS 1712)	≤ 245 Pa @ 85 L/min	Test method similar to the EU one but limits cannot be compared; a stricter requirement applies in the US
Security of attachments	n/a	Strap withstands a force of 10N (150N) for 10s for **P2** (**P3**-when full face) masks (Clause 3.2.6 of AS/NZS 1712)	n/a	Only a requirement in Australia

Respirators claimed for use in health care settings in Australia are regulated as medical devices (Class I); see 3.3.1.

5.1.2 Medical face masks

The relevant standard, AS 4381:2015, "Single-use face masks for use in health care," has requirements from the product standard EN 14683 (2014 edition) and also refers to test methods in that standard or to ASTM testing standards (previous editions). It defines Levels 1, 2 and 3, approximately corresponding to the same levels of barrier protection in the United States (standard ASTM F2100; see 4.1.2.2). As with in the United States, all levels exhibit splash resistance (with identical limits to the US standards) but, unlike in the United States, particulate filtration efficiency is not specified. Finally, as in the US standard, bioburden and biocompatibility are not explicit requirements.

Table 5.2 shows the requirements for medical face masks in the Australian market compared to those of the EU and US markets.

Table 5.2: Comparison between EU, US, and Australian standards for medical face masks

Note: For a detailed comparison of EU and US standards (including test methods), see 4.1.2.

Color code:

- Green: Products made to the Australian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Australian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Australian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	EU EN 14683:2019, Type I, II and IIR	Australia AS 4381:2015, Levels 1, 2 and 3	US ASTM F2100 – 21, Levels 1, 2 and 3	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Bacterial filtration efficiency (BFE)	≥ 95% (Type I) ≥ 98% (Types II, IIR)	≥ 95% (Level 1) ≥ 98% (Level 2, 3) Using ASTM F2101-14 or Appendix B of EN 14683:2014	≥ 95% (Level 1) ≥ 98% (Level 2, 3) Using ASTM F2101	Appendix B of EN 14683 has been updated in the 2019 edition
Differential pressure	< 40 Pa/cm² (Types I, II) < 60 Pa/cm² (Types IIR) (Tested at 8L/min flowrate)	<39.2 Pa/cm² (Level 1) <49.0 Pa/cm² (Level 2 and 3) *Note* 1: Using EN 14683:2014, Appendix C	<49 Pa/cm² (Level 1) <58.8 Pa/cm² (Level 2, 3) Using EN 14683	Limits in AU are stricter than the EU/US ones (for corresponding types/levels) *Note* 1: Specified as 4.0 mm and 5.0 mm H_2O/cm^2, respectively EN 14683:2019 Appendix C has been completely revised compared to the 2014 version
Sub-micron particulate filtration efficiency	n/a	n/a	≥ 95 (Level 1) ≥ 98 (Level 2,3) Both at 0.1 micron, using ASTM F2299	
Splash-resistance pressure	Not required Types I, II) ≥ 16.0 kPa (Type IIR) Using ISO 22609:2004	≥ 10.7 kPa (Level 1) ≥16 kPa (Level 2) ≥21.4 kPa (Level 3) *Note* 2 Using ASTM F1862/ F1862M-13 or ISO 22609	≥ 10.7 kPa (Level 1) ≥16 kPa (Level 2) ≥21.4 kPa (Level 3) Using ASTM F1862	Same limits/method as in US *Note* 2: Specified as ≥ 80, ≥120 and ≥160 mm Hg, respectively
Microbial cleanliness	≤ 30 CFU/g Using EN ISO 11737-1:2018	No explicit requirement	n/a	
Biocompatibility	Pass Using ISO EN 10993-1:2009	No explicit requirement	Pass Using ISO 10993-1	
Flame spread	n/a	n/a	Class 1 Using 16 CFR Part 1610	

Medical face masks used in health care settings in Australia are regulated as medical devices (Class I or, if sterile, Class Is; see 3.3.1.)

5.1.3 Community face coverings

According to the Australian Commission on Safety and Quality in Healthcare,[62] "you can use a cloth mask or a single-use surgical mask. Both types of masks are suitable for use to prevent the spread of COVID-19. Masks do not need to be surgical quality to be effective.

Cloth masks are any nose and mouth covering made of washable fabric that you can breathe through. Surgical masks are single-use, so can't be washed and used again."

However, since there is no relevant Australian Standard, no comparison to EU/US standards is made.

5.2 Eye and face protection

The relevant standard is AS/NZS 1337.1:2010+A1:2012+A2:2018, "Personal eye protection—Part 1: eye and face protectors for occupational applications." The standard is based on (but not identical to) EN 166. The standard specifies requirements for non-prescription oculars (lenses) and assembled eye and face protectors (requirements for prescription eye protectors against low and medium impact are given in another standard of the series, AS/NZS 1337.6). Testing methods are included as appendices in the standard.

Table 5.3 shows the requirements for eye and face protection in the Australian market compared to those of the EU and US markets.

Table 5.3: Comparison between EU, US, and Australian standards for eye and face protection

Notes:

For a more detailed comparison of EU and US standards (including test methods), see 4.2.3.

- In general, requirements for lenses (only) have not been included.
- Only low-impact resistance is included for the AS/NZS.

Color code:

- Green: Products made to the Australian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Australian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Australian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 166:2001**	**Australia AS/NZS 1337.1:2010+A1+A2**	**US ANSI/ISEA Z87.1-2020**	**COMPARISON/ COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/testing method**	
Construction and materials	Pass	Pass, clause 3.2.1 (finish), 3.2.2 (materials)	Pass (ANSI Z80.1)	Comparable to EU
Headband	Pass	n/a	n/a	
Basic/"fundamental" requirements				

62 https://www.safetyandquality.gov.au/covid-19-resources/faqs-community-use-face-masks.

(Market) standard	**EU EN 166:2001**	**Australia AS/NZS 1337.1:2010+A1+A2**	**US ANSI/ISEA Z87.1-2020**	**COMPARISON/ COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/testing method**	
Field of vision	Pass (EN 168)	Pass		Called "viewing area" in the AS/NZS
Min. coverage area	Not a requirement, except for special uses	Min. dimensions given in the standard for spectacles/goggles/ face shields Clauses 2.2.3, 2.2.4; (for small heads) 3.2.5.	Ellipse with axes ≥40 mm and ≥ 33 mm	Not directly comparable to US
Transmittance of oculars without filtering action	> 74.4% (EN 167)	≥80% (ocular category o), (Annex A)	≥ 85% (or ≥ 78% if relaxed optics)	Similar limits/test method as in EN
Haze	n/a	≤3% (Annex H)	≤3% (ASTM D1003-13)	Called "scattered light" in AS/NZS, similar to US
Increased robustness	Pass (EN 168)	Pass (Annex K, drop ball test, definitive test) Pass (Annex L (ballistic test; if in doubt, use Annex K)	Pass	Called "low-impact resistance" in AS/NZS, similar to EU/US
Penetration resistance (for plastic oculars/ visors)	n/a	Pass, Annex P (projectile test)	n/a	
Thermal stability	Pass (EN 168)	Pass (Annex T)	n/a	More stringent testing than in EN
resistance to corrosion	Pass (EN 168)	Pass (Annex U)	Pass	Same method as in EU
Resistance to ignition	Pass (EN 168)	Pass (Annex Q)	Pass	Very similar method to EU/US
Particular requirements (per EU)				
Droplets and splashes of liquid	No color present for goggles Face shields pass the area coverage test (EN 168)	No color present for all protectors (Annex V)	No color present for goggles Face shields pass the area coverage test	Same limit/method as in the EU (for droplets only) Different method for splashes
Lateral protection (optional)	Pass (EN 168)	Pass Clause 3.2.6	Pass (Annex D)	Applies only to eye protectors claiming impact resistance greater than low impact resistance; similar method to EU/US
Optional requirements (per EU)				
Resistance to fogging (only for oculars; not complete eye protectors)	Time without fogging ≥ 8 s (to EN 168)	n/a	Time without fogging ≥ 8 s	In AS/NZS, ventilation openings only for goggles that are not splash resistant

5.3 Gloves

5.3.1 Medical examination gloves

The relevant standard on rubber examination gloves, AS/NZS 4011.1, is a modified ISO 11193-1:2008 (there is now a 2020 version of the ISO standard). Variations are listed in Appendix ZZ of the AS/NZS standard. The same situation applies to AS/NZS 4011.2 on PVC gloves versus ISO 11193-2:2006 (current). The main variations of interest in this guide (common for both standards) are:

- Small modifications in the watertightness test
- Modifications in the tensile properties limits and methods
- Addition of non-mandatory glove cuff rupture resistance test to be used in cases of dispute.

In addition to Types 1 and 2 (with the same meaning as in ASTM/ISO standards), in AS/NZS 4011.1 Type 1a is defined for just "synthetic polyisoprene" gloves.

For completeness, the standard AS/NZS 2161.10.1:2005, "Protective gloves against dangerous chemicals and micro-organisms—Part 1: Terminology and performance requirements," is mentioned. This standard is identical to EN 374-1:2003, now superseded by EN ISO 374-1. As mentioned in 4.3.1.1 on EU requirements for medical examination gloves, standards on "protective gloves" (as opposed to "medical gloves") will not be further detailed.

Table 5.4 shows the requirements for medical examination gloves in the Australian market compared to those of the EU and US markets.

Table 5.4: Comparison between EU, US, and Australian standards for medical examination gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.1 of this guide.

Color code:

- Green: Products made to the Australian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Australian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Australian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	EU EN 455 series	Australia Material specific AS/NZS 4011.1:2014 for rubber AS/NZS 4011.2:2014 for PVC	US ASTM—material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	There are no Australian standards for exam gloves from materials other than rubber or PVC
Freedom from holes	AQL =1.5 (EN 455-1:2020)	AQL =1.5	AQL =2.5 (ASTM D5151)	Test method slightly modified from that of the EU/US

(Market) standard	EU EN 455 series	Australia Material specific AS/NZS 4011.1:2014 for rubber AS/NZS 4011.2:2014 for PVC	US ASTM—material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	There are no Australian standards for exam gloves from materials other than rubber or PVC
Force at break (N) / Tensile strength (MPa), elongation at break (%) (Also, after ageing/challenge)	Non-thermoplastic materials ≥6.0N Thermoplastic materials (PVC, PE) ≥ 3.6N (EN 455-2 :2015, method A of ISO 23529:2010)	AQL = 4.0 For rubber, ≥ 6.0 N Elongation ≥ 500% (Types 1 and 1a); ≥400% (Type 2) For PVC ≥ 7.0 N Elongation ≥ 350%	AQL = 4.0 Nitrile ≥ 14MPa/elongation ≥400% Latex (natural) ≥ 14MPa/elongation ≥ 500% Polychloroprene ≥ 14MPa/elongation ≥ 400% PVC ≥ 11MPa/elongation ≥ 300% (ASTM D412, ASTM D573 (ageing))	In the EU, instead of AQL the median of 13 samples is used In general, the tensile properties and their limits specified in the Australian/ISO standards are an amalgam of the EU/US ones Australian and EU standards specify minimum absolute force (N) for samples taken from the glove (varies with thickness); ASTM specifies in terms of tensile strength (MPa—force per unit area) Test method for Australia is slightly modified from that of the EU/US and ISO 23529
Biocompatibility	Pass (EN ISO 10993-5 and -10)	Pass (Relevant part(s) of ISO 10993)	Pass (FDA regulations)	
Powder residue content	≤ 2.0 mg/glove (EN 455-3, EN ISO 21171:2006)	n/a	≤ 2.0 mg/glove (powder-free gloves) ≤ 10 mg/dm² (powdered gloves) (ASTM D6124)	
Aqueous soluble protein content	"Manufacturer shall monitor the content in natural rubber latex gloves and shall try to minimize it" (EN 455-3)	n/a	≤ 200 µg/dm² Only for rubber gloves (ASTM D5712)	
Extractable antigenic protein content	Optional	n/a	≤ 10 µg/dm² Only for rubber gloves (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	"If gloves are sterilized, the nature of the sterilization process shall be disclosed ON THE PRODUCT in accordance with appropriate local regulatory requirements"	Pass (US Pharmacopeia)	
Cuff rupture resistance test	n/a	Force ≥5N	n/a	A non-mandatory test (only in case of dispute); method given in Appendix ZA of AS/NZS 4011

Medical examination gloves are regulated as medical devices in Australia, see 3.3.1.

5.3.2 Surgical gloves

The relevant standard, AS/NZS 4179:2014, "Single-use sterile surgical globes-specification," is a modified version of ISO 10282:2014 (current) with variations contained in Appendix ZZ of AS/NZS 4179. The main variations of interest in this guide are:

- Synthetic polyisoprene gloves have been moved from Type 2 (synthetic rubbers) to Type 1a, as their material properties are more closely related to natural rubber latex
- Small modifications in the watertightness test
- Modifications in the tensile properties limits and methods
- Addition of non-mandatory glove cuff rupture resistance test to be used in cases of dispute.

Table 5.5 shows the requirements for surgical gloves in the Australian market compared to those of the EU and US markets.

Table 5.5: Comparison between EU, US, and Australian standards for surgical gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.2 of this guide.

Color code:

- Green: Products made to the Australian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Australian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Australian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) Standard	**EU EN 455 series**	**Australia AS/NZS 4179:2014 (Types 1, 1a and 2)**	**US ASTM D3577-19, Type 1: Natural rubber Type 2: Synthetic rubber**	**COMPARISON/COMMENTS**
Characteristic/ Property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/ testing method**	
Freedom from holes	AQL = 0.65 (EN 455-1:2020)	AQL = 1.0	AQL = 1.5 (ASTM D5151)	Test method slightly different from that of EU/US

(Market) Standard	**EU EN 455 series**	**Australia AS/NZS 4179:2014 (Types 1, 1a and 2)**	**US ASTM D3577-19, Type 1: Natural rubber Type 2: Synthetic rubber**	**COMPARISON/COMMENTS**
Characteristic/ Property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/ testing method**	
Force at break (N) / Tensile strength (MPa), elongation (%) (Also, after ageing/ challenge)	All materials ≥ 9.0N (EN 455-2 :2015, method A of ISO 23529:2010)	AQL = 4.0 Types 1, 1a— latex (natural rubber and synthetic polyisoprene) ≥9.5 N/elongation ≥550% Type 2—synthetic rubber (except polyisoprene) ≥9.0N/elongation ≥500%	AQL = 4.0 Type 1l—latex (natural) ≥18MPa/elongation ≥560% Type 2—synthetic rubber ≥12Mpa/ elongation ≥490% (ASTM D412, ASTM D573 [ageing])	In the EU, instead of AQL the median of 13 samples is used In general, the tensile properties and their limits specified in the Australian standards are an amalgam of the EU/ US ones EU and AS/NZS standards specify minimum absolute force (N) for samples taken from the glove (varies with thickness); ASTM specifies in terms of tensile strength (MPa—force per unit area) The AS/NZS values are after accelerated ageing (higher limits apply before ageing) Test method slightly different from that of EU/US
Biocompatibility	Pass (EN ISO 10993-5 and -10)	"Shall comply with the relevant part(s) of ISO 10993"	Pass (FDA regulations)	
Powder residue content	≤ 2.0 mg/glove (EN 455-3, EN ISO 21171:2006)	No explicit requirements	≤ 2.0 mg/glove (ASTM D6124)	
Aqueous soluble protein content	"Manufacturer shall monitor the content in NRL gloves and shall try to minimize it" (EN 455-3, Annex A)	n/a	≤ 200 µg/dm² (ASTM D5712)	
Extractable antigenic protein content	Optional (EN 455-3, Annex B)	n/a	≤ 10 µg/dm² (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	Sterilized in accordance with ISO 11135 (ethylene oxide) or ISO 11137 (radiation)	Pass (US Pharmacopeia)	
Cuff rupture resistance test	n/a	Force ≥5N	n/a	Non-mandatory test (only in case of dispute); method given in Appendix ZA of AS/ NZS 4179

Surgical gloves are regulated as medical devices in Australia, see 3.3.1.

5.4 Clothing

5.4.1 Full-body and partial-body garments (other than surgical/isolation gowns)

The only relevant standard identified in Australia is AS/NZS 4501.2:2006, "Occupational protective clothing—Part 2: General requirements," an identical adoption of EN 340:2003 (since replaced by EN ISO 13688:2013+A1:2021) that addresses only general requirements for protective clothing. This standard does not address either chemical protection or protection against infective agents. Table 5.6 shows the requirements for protective clothing in the Australian market compared to those of the EU and US markets.

Table 5.6: Comparison between EU, US, and Australian standards for protective clothing

Notes:

For a more detailed comparison of EU and US standards (including test methods), see 4.4.1 of this guide.

For simplicity, only requirements for materials and whole suits are included (that is, requirements for seams, joins, assemblages, and integral components, such as visors, are *not* included).

For protection against infective agents only the following protection types, as defined in the standards, are considered here: Type 4 (spray-tight), Type PB [4] (partial-body protection—Type 4), Type 6 (limited protection against liquid chemicals) and Type PB [6] (partial-body protection—Type 6).

Color code:

- Green: Products made to the Australian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Australian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Australian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

Market	**EU**	**Australia**	**US**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/ testing method**	**Requirement/testing method**	
I. General requirements	**EN ISO 13688:2013+A1:2021**	**AS/NZS 4501.2:2006**	**NFPA 1999:2018**	The AS/NZS only specifies general requirements about (any type of) protective clothing and it supplements standards with requirements for specific protection. No AS could be identified similar to EN 14126 (protection against infective agents) but EN 14126 seems to be accepted in Australia, as well
Innocuousness	No harmful substances present No azo dyes present	No harmful substances present No azo dyes present	No specific requirements	AS/NZS is similar to EN ISO 13688 (contains fewer requirements than it, and some methods have since been revised)

Market	**EU**	**Australia**	**US**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/ testing method**	**Requirement/testing method**	
Design and comfort	Acceptable (Annex C)	Acceptable; assessment in Annex C	Acceptable (section 6.1) *Note*: Design requirements only ≥650 g/(m²24 h) *Note*: In the US for single-use garments/ ensembles "moisture vapor transmission rate" is specified (section 8.28 and ASTM E96) ≥450 W/m² *Note*: In the US for multiple-use garments/ ensembles "total heat loss test" is specified (section 8.32 and ASTM F1868)	Similar to EN ISO 13688
II. Protection against infective agents	**EN 14126:2003 & EN 14605:2005+A1:2009 (for Types 4 and PB [4]) or EN 13034:2005+A1:2009 (for Types 6 and PB [6])**	**No requirements in AS/NZS**	**NFPA 1999:2018**	
1. Materials requirements				
a) Mechanical		**No requirements for mechanical properties**		
Abrasion resistance	Class 1 to 6 (highest) (cl. 4.4 of EN 14325 & EN ISO 12947-2)	n/a	Abrasion resistance is considered as a precondition to barrier performance of materials (ASTM D4157)	
Flex cracking resistance	Class 1 to 6 (highest) (cl. 4.5, 4.6 EN 14325 and EN ISO 7854, method B)	n/a	Flex fatigue is considered as a precondition to barrier performance of materials (ASTM F392)	
Trapezoidal tear resistance	Class 1 to 6 (highest) (EN 14325 & EN ISO 9073-4:1997)	n/a	Single-use: "Tear-resistance test two" ≥17 N (section 8.38 and ASTM D5733 for non-woven) Multiple-use: "Tear-resistance test one" ≥36 N (section 8.7 and ASTM D5587 for woven)	
Tensile strength	Class 1 to 6 (highest) (cl. 4.9 of EN 14325 & EN ISO 13934-1)	n/a	≥50 N (section 8.4 and ASTM D5034) Also bursting strength: ≥66N (single-use) ≥222.5N (multiple-use) (section 8.5 and ASTM D3787)	Bursting strength was eliminated in EU
Puncture resistance	Class 1 to 6 (highest) (cl. 4.10 of EN 14325 & EN 863)	n/a	≥12N (single-use) ≥25N (multiple-use) (section 8.6 and ASTM D2572)	

Market	EU	Australia	US	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/ testing method**	**Requirement/testing method**	
b) Chemical resistance		**No requirements for chemical resistance properties**		
Permeation by chemicals (applicable to Types 4 and PB[4])	Class 1 to 6 (highest) (EN ISO 6529, method A for liquids)	n/a		
Repellency to liquids (applicable to Types 6 and PB[6])	Class 1 to 3 (highest) (ISO 6530)	n/a	≤30% (section 8.31)	In the US this is called "water-absorption resistance test"; applies only to multiple-use garments/ ensembles
Penetration by liquids (applicable to Types 6 and PB[6])	Class 1 to 3 (highest) (ISO 6530)	n/a		
c) flammability		**No requirements for flammability**		
Resistance to ignition or flame (more stringent)	Pass or Min. class 1 (cl. 4.14 EN 14325 and EN 13274-4, method 3)	n/a	Flame spread time ≥3.5 s (section 8.39 and ASTM D1230)	
d) Penetration by infective agents		**No requirements for infective agents**		
Contaminated liquids under hydrostatic pressure	Class 1 to 6 (highest) (cl. 4.1.4.1 of EN 14126, ISO 16603 and ISO 16604)	n/a	Pass *Note*: In the US the "bio-penetration test one" applies (section 8.3 and ASTM F1671)	
Mechanical contact with contaminated liquids (wet bacterial penetration)	Class 1 to 6 (highest) (cl. 4.1.4.2 of EN 14126 and EN ISO 22610)	n/a	n/a	
(Biologically) contaminated liquid aerosols	Class 1 to 3 (highest) (cl. 4.1.4.3 of EN 14126)	n/a	n/a	
Contaminated solid particles (dry microbial penetration)	As above (cl. 4.1.4.4 of EN 14126 and ISO 22612)	n/a	n/a	
2. Whole-suit requirements		**No requirements for whole suits**		
Mist test (Type 6)	Pass (EN ISO 17491-4 (method A) as modified by cl. 5.2 of EN 13034)	n/a	Pass (section 8.2) *Note*: In the US the "liquid tight integrity test one" applies	
Liquid spray test (Type 4)	Pass (cl. 4.3.4.2 etc. of EN 14605 and EN ISO 17491-4 [method B])	n/a	Pass (section 8.2)	
Practical performance	Pass (EN 14605/EN 13034—"seven movements" sequence while wearing the suit)	n/a	Demonstration of garment functionality is included as part of the liquid integrity testing applied to garments (ASTM F1154)	

5.4.2 Gowns

On the Standards Australia website, there is a reference to standards relating to key PPE for medical applications and environments. These are listed at https://www.standards.org.au/getmedia/4d7449e3-ee13-4b54-8f01-43476380106e6/D_1588-Standards-and-COVID-19-(002).aspx

The standard mentioned for gowns is AS 3789.2–1991, "Textiles for health care facilities and institutions—theatre linen and pre-packs." In the standard, among others, requirements are specified for "(operating) theatre gowns". However, these pertain only to dimensions, fabric types and so on, and not to barrier or mechanical properties.

On the Therapeutic Goods Administration (TGA) website, on the other hand, no specific Australian standard is mentioned for gowns, while reference is made to the standards in the EU and the United States, which are accepted for regulatory purposes, see https://www.tga.gov.au/behind-news/regulation-personal-protective-equipment-and-covid-19

As a result, no comparison to the EU-US standards can be provided.

PART 6
PRODUCT-SPECIFIC COMPARISONS (BRAZIL)

6.1 Masks

6.1.1 Respirators

The Brazilian standard ABNT NBR 13698:2011 is based on EN 149:1992 (which has since been substantially revised in a new 2001 edition and an amendment in 2009). Respirator classes PFF2 and PFF3, corresponding to FFP2 and FFP3 in the European standard, are considered in this guide. Table 6.1 shows the requirements for respirators in the Brazilian market compared to those of the EU and US markets.

Table 6.1: Comparison between EU, US, and Brazilian standards for respirators

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.1 of this guide.

Color code:

- Green: Products made to the Brazilian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Brazilian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Brazilian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU** **EN 149:2001 +A1:2009, Classes FFP2 and FFP3**	**Brazil** **ABNT NBR 13698:2011, Classes PFF2 and PFF3**	**US** **42 CFR Part 84, Series/Levels N95 and N99**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	Note that other classes of respirators are not included—not suitable for COVID-19 context
Practical performance	Pass (based on two subjects performing various tasks)	Pass (based on two subjects performing various tasks)	Fit testing before use (required by OSHA, not NIOSH)	
Total inward leakage	**FFP2** ≤ 11% (individual) ≤ 8% (mean)	**PFF2** ≤ 11% (individual) ≤ 8% (mean)	n/a	
	FFP3 ≤ 5% (individual) ≤ 2 % (mean)	**PFF3** ≤ 5% (individual) ≤ 2 % (mean)	n/a	

(Market) standard	**EU EN 149:2001 +A1:2009, Classes FFP2 and FFP3**	**Brazil ABNT NBR 13698:2011, Classes PFF2 and PFF3**	**US 42 CFR Part 84, Series/Levels N95 and N99**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	Note that other classes of respirators are not included—not suitable for COVID-19 context
Filtering efficiency	**FFP2** ≥ 94% @ 95 L/min (NaCl and paraffin oil, (EN 13274-7)	**PFF2** ≥ 94% @ 95 L/min (NaCl and paraffin oil)	**N95** ≥ 95% @ 85 L/min (NaCl only)	Specified as 6% max. penetration in Brazilian and EU standards; limits in Brazil and EU are same, but method differs
	FFP3 ≥ 99% @ 95 L/min (NaCl and paraffin oil, EN 13274-7)	**PFF3** ≥ 99% @ 95 L/min (NaCl and paraffin oil)	**N99** ≥ 99% @ 85 L/min (NaCl only)	Specified as 1% max. penetration in Brazilian and EU standards; limits in Brazil and EU are same, but method differs
Compatibility with skin	Pass	Pass	n/a	
Flammability	Pass	Pass	n/a	
Carbon dioxide content	Average ≤ 1% by volume in "dead space"	Average ≤ 1% by volume in "dead space"	n/a	
Field of vision	Pass (in the practical performance test)	Pass (in the practical performance test)	Pass	
Breathing resistance (inhalation)	**FFP2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min	**PFF 2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min	**N95** ≤ 343 Pa @ 85 L/min	
	FFP 3 ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min	**PFF 3** ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min	**N99** ≤ 343 Pa @ 85 L/min	
Breathing resistance (exhalation)	**FFP2 and FFP3** ≤ 300 Pa @160 L/min	**PFF 2 and PFF 3** ≤ 300 Pa @160 L/min	**N95 and N99** ≤ 245 Pa @ 85 L/min	

6.1.2 Medical face masks

The relevant standard, NBR 15052:2004, is the version referred to by the regulator, the Brazilian Health Regulatory Agency (ANVISA), and is based on the Australian Standard AS 4381:2015 (see 5.1.2). It defines Levels 1, 2 and 3, approximately corresponding to the same levels of barrier protection in the US (standard ASTM F2100). A newer version (NBR 15052:2021) was published in August 2021.

Table 6.2 shows the requirements for medical face masks in the Brazilian market compared to those of the EU and US markets.

Table 6.2: Comparison between EU, US, and Brazilian standards for medical face masks

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.2 of this guide.

Color code:

- Green: Products made to the Brazilian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Brazilian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Brazilian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	EU EN 14683:2019, Types I, II and IIR	Brazil NBR 15052:2004, Levels 1, 2 and 3	US ASTM F2100–21, Levels 1, 2 and 3	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/ testing method**	**Requirement/ testing method**	This table is based on NBR 15052:2004, and changes introduced in the new (2021) version have been noted
Bacterial filtration efficiency (BFE)	≥ 95% (Type I) ≥ 98% (Types II, IIR)	≥ 95% (Levels 0 and 1) ≥ 98% (Levels 2 and 3) Using ASTM F2101-14 or Appendix B of EN 14683:2014	≥ 95% (Levels 1) ≥ 98% (Levels 2,3) Using ASTM F2101	Essentially the same (for corresponding types) (NBR 15052:2021 now refers to EN14683:2019)
Differential pressure	< 40 Pa/cm² (Types I, II) < 60 Pa/cm² (Type IIR) (Tested at 8L/min flowrate)	<39.2 Pa/cm² (Level 1) <49.0 Pa/cm² (Levels 2 and 3) (Specified as 4.0 mm and 5.0 mm H_2O/cm² respectively) Using EN 14683:2014, Appendix C	<49 Pa/cm² (Level 1) <58.8 Pa/cm² (Levels 2 and 3) Using EN 14683	Brazilian standards are same or stricter than EU/US equivalents for different categories Brazilian standards are same or stricter than EU/US equivalents for different categories The 2021 version of NBR 15502 has relaxed the requirements for differential pressure, now aligned with ASTM F2100. This will mean that masks made to NBR 15052:2021 will not automatically meet the requirement of the EU market
Sub-micron particulate filtration efficiency	n/a	n/a	≥ 95 (Level 1) ≥ 98 (Levels 2,3) Both at 0.1 micron, using ASTM F2299	The 2021 version of NBR 15052 now includes identical requirements to those of ASTM F2100, so the color code will change to green once this is fully adopted

(Market) standard	EU EN 14683:2019, Types I, II and IIR	Brazil NBR 15052:2004, Levels 1, 2 and 3	US ASTM F2100–21, Levels 1, 2 and 3	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/ testing method**	**Requirement/ testing method**	This table is based on NBR 15052:2004, and changes introduced in the new (2021) version have been noted
Splash-resistance pressure	Not required (Types I, II) ≥ 16.0 kPa (Type IIR) Using ISO 22609:2004	≥ 10.7 kPa (Level 1) ≥16 kPa (Level 2) ≥21.4 kPa (Level 3) *Note 2* Using ASTM F1862	≥ 10.7 kPa (Level 1) ≥16 kPa (Level 2) ≥21.4 kPa (Level 3) Using ASTM F1862	Brazilian requirements identical to ASTM *Note 2*: Specified as ≥ 80, ≥120 and ≥160 mm Hg respectively
Microbial cleanliness	≤ 30 CFU/g Using EN ISO 11737-1:2018	No explicit requirement	n/a	
Biocompatibility	Pass Using ISO EN 10993-1:2009	Mentioned in NBR 15052 and required by ANVISA regulations (Using ISO EN 10993-1:2009)	Pass Using ISO 10993-1	
Flame spread	n/a	n/a	Class 1 Using 16 CFR Part 1610	The 2021 version of NBR 15052 now specifies requirements identical to those of ASTM F2100 (Class 1 using 16CFR Part 1610), so the color code will change to green once this is fully adopted

6.1.3 Community face coverings

ABNT PR 002:2020, "Masks for non-professional respiratory protection—guide with basic requirements for testing, manufacture, and use," is based on AFNOR SPEC S76-001. Table 6.3 shows the requirements for community face coverings in the Brazilian market compared to those of the EU and US markets.

Table 6.3: Comparison between EU, US, and Brazilian standards for community face coverings

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.3 of this guide.

Color code:

- Green: Products made to the Brazilian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Brazilian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Brazilian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU CWA 17553:2020**	**Brazil ABNT recommended practice PR 002:2020**	**US ASTM F3502-21**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Breathing resistance	EN 14683:2019, Annex C (≤ 70 Pa/cm²) EN 13274-3 (inhalation resistance of 2.4 mbar; exhalation resistance 3 mbar)	Inhalation resistance of 2.4 mbar; exhalation resistance of 3 mbar (breathing machine at a sinusoidal flow of 30 l/min or constant flow of 160 l/min)	Subpart K of 42 CFR Part 84, modified by § 8.2 (Level 1 ≤ 15 mm H_2O Level 2 ≤ 5 mm H_2O)	In the EU, either breathing resistance or air permeability (below) is measured
Air permeability	EN ISO 9237 (≥ 96 l/s/m² @ 100 Pa)	n/a	n/a	
Particle filtration efficiency (PFE)	EN 13274-7 EN ISO 16890-2 EN ISO 21083-1:2018, (Level 90% ≥ 90%; Level 70% ≥ 70%) Particle size 3 (± 0.5) µm	≥ 70%—particle size 3 (± 0.5) µm EN 13274-7	Subpart K of 42 CFR Part 84, modified by § 8.1 (Level 1 ≥20%; Level 2 ≥ 50%)	In the EU, either PFE or BFE (below) is measured
Bacterial filtration efficiency (BFE)	EN 14683:2019+AC:2019 (Level 90% ≥ 90%; Level 70% ≥ 70%)	n/a	Manufacturer may choose to provide the BFE results (as per ASTM F 2101) along with PFE	

6.2 Eye and face protection

There is no Brazilian national standard for eye and face protection—Brazilian PPE regulations refer to the "latest version of ANSI Z87.1." The recently published recommended practice for health care-related face protection (ABNT PR1009:2021) also draws heavily on ANSI/ISEA Z87.1, but is not referred to in the Brazilian PPE regulations. Table 6.4 shows the requirements for eye and face protection in the Brazilian market compared to those of the EU and US markets.

Table 6.4: Comparison between EU, US, and Brazilian standards for eye and face protection

Notes:

- In general, requirements for lenses (only) have not been included.
- For a more detailed comparison of EU and US standards (including test methods), see 4.2 of this guide.

Color code:

- Green: Products made to the Brazilian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Brazilian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Brazilian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 166:2001**	**Brazil ABNT PR1009:2021**	**US ANSI/ISEA Z87.1:2020**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Construction and materials	Pass	Pass (ANSI Z80.1)	Pass (ANSI Z80.1)	
Headband	Pass	n/a	n/a	
Basic (EU)/ fundamental (US) requirements				
Field of vision	Pass (EN 168)	n/a	n/a	
Min. coverage area	n/a	Ellipse with axes ≥40 mm and ≥ 33 mm	Ellipse with axes ≥40 mm and ≥ 33 mm	
Transmittance of oculars without filtering action	> 74.4% (EN 167)	≥ 85% (or ≥ 78% if relaxed optics)	≥ 85% (or ≥ 78% if relaxed optics)	
Haze	n/a	≤3% (ASTM D1003-13)	≤3% (ASTM D1003-13)	
Increased robustness	Pass (EN 168)	Pass	Pass	
Thermal stability	Pass (EN 168)	n/a	n/a	
Resistance to corrosion	Pass (EN 168)	Pass	Pass	
Resistance to ignition	Pass (EN 168)	Pass	Pass	
"Particular requirements" (per EU)				

(Market) standard	EU EN 166:2001	Brazil ABNT PR1009:2021	US ANSI/ISEA Z87.1:2020	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Droplets and splashes of liquid	No color present for goggles Face shields pass the area coverage test (EN 168)	No color present for goggles Face shields pass the area coverage test	No color present for goggles Face shields pass the area coverage test	
Lateral protection (optional)	Pass (EN 168)	Pass (Annex D)	Pass (Annex D)	Only for impact-rated protectors in US/Brazil
Resistance to fogging (only for oculars; not complete eye protectors)	Time without fogging ≥ 8 s (EN 168)	Time without fogging ≥ 8 s	Time without fogging ≥ 8 s	Requirement did not exist in 2015 edition of US standard; added in 2020 edition

6.3 Gloves

6.3.1 Medical examination gloves

Medical examination gloves are regulated as medical devices in Brazil (see 3.4.1). Brazilian standards are material specific. NBR ISO 11193-1:2015 (for gloves made of rubber/ latex) and NBR ISO 11193-2:2013 (made of PVC) are identical to ISO 11193-1:2008 + AMD 1:2012 (recently replaced by the 2020 edition) and ISO 11193-2:2006 (current), respectively. For details on the ISO standards, see 4.3.1.1.

Table 6.5 shows the requirements for medical examination gloves in the Brazilian market compared to those of the EU and US markets.

Table 6.5: Comparison between EU, US, and Brazilian standards for medical examination gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.1.3 of this guide.

Color code:

- Green: Products made to the Brazilian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Brazilian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Brazilian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	EU EN 455 series	Brazil Material specific NBR ISO 11193-1:2015 (rubber/ latex) NBR ISO 11193-2:2013 (PVC)	US ASTM— material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/testing method**	INMETRO PORTARIA N° 485 (2021) also applies; conformity assessment requirements are also specified in PORTARIA No. 672 of November 8, 2021
Freedom from holes	AQL =1.5 (EN 455-1:2020)	AQL =1.5	AQL =2.5 (ASTM D5151)	

(Market) standard	**EU EN 455 series**	**Brazil Material specific NBR ISO 11193-1:2015 (rubber/ latex) NBR ISO 11193-2:2013 (PVC)**	**US ASTM— material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/testing method**	INMETRO PORTARIA N° 485 (2021) also applies; conformity assessment requirements are also specified in PORTARIA No. 672 of November 8, 2021
Force at break (N) / Tensile strength (MPa), elongation at break (%) (Also, after ageing/challenge)	Non-thermoplastic materials ≥6.0N Thermoplastic materials (PVC, PE) ≥ 3.6N (EN 455-2 :2015, method A of ISO 23529:2010)	AQL = 4.0 (Before ageing) Rubber ≥ 7.0 N (Types 1 and 2)/elongation ≥ 650% (Type 1), 500% (Type 2) (After ageing) Rubber ≥ 6.0 N (Types 1 and 2)/elongation ≥ 500% Type 1), 400% (Type 2) PVC ≥ 7.0 N/elongation ≥ 350%	AQL = 4.0 Nitrile ≥ 14MPa/elongation ≥400% Latex (natural) ≥ 14MPa / Elongation ≥ 500% Polychloroprene ≥ 14MPa/elongation ≥ 400% PVC ≥ 11MPa/elongation ≥ 300% (ASTM D412, ASTM D573 (ageing))	In the EU, instead of AQL the median of 13 samples is used In general, the tensile properties and their limits specified in the Brazilian standards are an amalgam of the EU/ US ones Brazilian and EU standards specify minimum absolute force (N) for samples taken from the glove (varies with thickness); ASTM specifies in terms of tensile strength (MPa—force per unit area)
Biocompatibility	Pass (EN ISO 10993-5 and -10)	Pass; gloves should be previously evaluated as safe for use in contact with human skin	Pass (FDA regulations)	
Powder residue content	≤ 2.0mg/glove (EN 455-3, EN ISO 21171:2006)	n/a	≤ 2.0mg/glove (powder-free gloves) ≤ 10 mg/dm² (powdered gloves) (ASTM D6124)	
Aqueous soluble protein content	"Manufacturer shall monitor the content in natural rubber latex gloves and shall try to minimize it" (EN 455-3)	Gloves containing natural rubber latex must be subjected to operations and processing that ensure the reduction of protein content	≤ 200 µg/dm² Only for rubber gloves (ASTM D5712)	
Extractable antigenic protein content	Optional	n/a	≤ 10 µg/dm² Only for rubber gloves (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	Mandatory to indicate the type of sterilization on the packaging; gloves should be tested according to the methodology described in Annex C of Portaria N° 485 (2021)	Pass (US Pharmacopeia)	

6.3.2 Surgical gloves

Surgical gloves are regulated as medical devices in Brazil (see 3.4.1). The Brazilian standard ABNT NBR 10282:2014 is identical to ISO 10282:2014. For further details on ISO 10282 see 4.3.2.1.

Table 6.6 shows the requirements for surgical gloves in the Brazilian market compared to those of the EU and US markets.

Table 6.6: Comparison between EU, US, and Brazilian standards for surgical gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.2.3 of this guide.

Color code:

- Green: Products made to the Brazilian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Brazilian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Brazilian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU** **EN 455 series**	**Brazil** **ABNT NBR 10282:2015**	**US** **ASTM D3577-19** **Type 1: Natural rubber** **Type 2: Synthetic rubber**	**COMPARISON/COMMENTS** INMETRO PORTARIA N° 485 (2021) also applies
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Freedom from holes	AQL = 0.65 (EN 455-1:2020)	AQL = 0.65	AQL = 1.5 (ASTM D5151)	
Force at break (N) / Tensile strength (MPa), elongation (%) (Also, after ageing/ challenge)	All materials ≥ 9.0N (EN 455-2:2015, method A of ISO 23529:2010)	AQL = 4.0 (Before ageing) Type 1: Latex (natural) ≥12.5 N/elongation ≥700%/force at 300% ≤ 2N Type 2: Synthetic rubber ≥9.0N/ elongation ≥600%/ force at 300% ≤ 3N (After ageing) Type 1: Latex (natural) ≥9.5 N/elongation ≥550% Type: Synthetic rubber ≥9.0N/elongation ≥500%	AQL = 4.0 Type 1: Latex (natural) ≥18MPa/elongation ≥560% Type 2: Synthetic rubber ≥12Mpa/elongation ≥490% (ASTM D412, ASTM D573 [ageing])	In the EU, instead of AQL the median of 13 samples is used In general, the tensile properties and their limits specified in the Brazilian standards are an amalgam of the EU/US ones EU and Brazilian standards specify minimum absolute force (N) for samples taken from the glove (varies with thickness); ASTM standards specify in terms of tensile strength (MPa—force per unit area)
Biocompatibility	Pass (EN ISO 10993-5 and -10)	Pass; gloves should be previously evaluated as safe for use in contact with human skin	Pass (FDA regulations)	
Powder residue content	≤ 2.0 mg/glove (EN 455-3, EN ISO 21171:2006)	n/a	≤ 2.0mg/glove (ASTM D6124)	
Aqueous soluble protein content	"Manufacturer shall monitor the content in NRL gloves and shall try to minimize it" (EN 455-3, Annex A)	Gloves containing natural rubber latex must be subjected to operations and processing that ensure the reduction of protein content	≤ 200 µg/dm² (ASTM D5712)	

(Market) standard	**EU EN 455 series**	**Brazil ABNT NBR 10282:2015**	**US ASTM D3577-19 Type 1: Natural rubber Type 2: Synthetic rubber**	**COMPARISON/COMMENTS** INMETRO PORTARIA N° 485 (2021) also applies
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Extractable antigenic protein content	Optional (EN 455-3, Annex B)	n/a	≤ 10 µg/dm² (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	Mandatory to indicate the type of sterilization on the packaging; gloves should be tested according to the methodology described in Annex C of Portaria N° 485 (2021)	Pass (US Pharmacopeia)	

6.4 Clothing

6.4.1 Full-body and partial-body garments (other than surgical/isolation gowns)

The currently applicable standard is the nationally developed Brazilian standard ABNT NBR 16693:2018, "Textile products for health—non-surgical gowns and private clothing used for non-surgical procedure professionals and patients—requirements and test methods." This is currently undergoing revision and will be replaced by a new standard to be based on ANSI/AAMI PB70.

Table 6.7 shows the requirements for protective clothing in the Brazilian market compared to those of the EU and US markets. It should be noted that NBR 16693 makes a distinction between the requirements for garments to be used by health care professionals and those for patients in a non-surgical setting. The comparisons shown relate only to the requirements for health care professionals.

Table 6.7: Comparison between EU, US, and Brazilian standards for protective clothing

Notes:

For a more detailed comparison of EU and US standards (including test methods), see 4.4.1 of this guide.

For simplicity, only requirements for materials and whole suits are included (that is, requirements for seams, joins, assemblages, and integral components, such as visors, are *not* included)

For protection against infective agents only the following protection types, as defined in the standards, are considered here: Type 4 (spray-tight), Type PB [4] (partial-body protection—Type 4), Type 6 (limited protection against liquid chemicals) and Type PB [6] (partial-body protection—Type 6)

Color code:

- Green: Products made to the Brazilian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Brazilian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Brazilian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

Market	EU	Brazil	US	COMPARISON/ COMMENTS
Property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
I. General requirements	**EN ISO 13688:2013+A1:2021**	**ABNT NBR 16693:2018**	**NFPA 1999:2018**	ABNT NBR 16693 is currently under revision
Innocuousness	No harmful substances present No azo dyes present	n/a	no specific requirements	
Design and comfort	Acceptable (Annex C)	Not mentioned in NBR 16693, but required by ANVISA regulations	Acceptable (section 6.1) *Note*: Design requirements only ≥650 g/(m²24 h) *Note*: In the US for single-use garments/ ensembles "moisture vapor transmission rate" is specified (section 8.28 and ASTM E96) ≥450 W/m² *Note*: In the US for multiple-use garments/ensembles "total heat loss test" is specified (section 8.32 and ASTM F1868)	
II. Protection against infective agents	**EN 14126:2003 & EN 14605:2005+A1:2009 (for Types 4 and PB [4]) or EN 13034:2005+A1:2009 (for Types 6 and PB [6])**	**ABNT NBR 16693:2018**	**NFPA 1999:2018**	
1. Materials requirements				
a) Mechanical				

Market	EU	Brazil	US	COMPARISON/ COMMENTS
Property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Abrasion resistance	Class 1 to 6 (highest) (cl. 4.4 of EN 14325 and EN ISO 12947-2)	n/a	Abrasion resistance is considered as a precondition to barrier performance of materials (ASTM D4157)	
Flex cracking resistance	Class 1 to 6 (highest) (cl. 4.5, 4.6 EN 14325 and EN ISO 7854, method B)	n/a	Flex fatigue is considered as a precondition to barrier performance of materials (ASTM F392)	
Trapezoidal tear resistance	Class 1 to 6 (highest) (EN 14325 & EN ISO 9073-4:1997)	≥10 N (ABNT NBR 13351 for non-woven; ASTM D 1424 for woven)	Single-use: "Tear resistance-test two" ≥17 N (section 8.38 and ASTM D5733 for non-woven) Multiple-use: "Tear-resistance test one" ≥36 N (section 8.7 & ASTM D5587 for woven)	
Tensile strength	Class 1 to 6 (highest) (cl. 4.9 of EN 14325 and EN ISO 13934-1)	≥20 N (ABNT NBR 13041 for non-woven; ABNT NBR 14727 or ABNT NBR ISO 13934-1 for woven)	≥50 N (section 8.4 and ASTM D5034) Also bursting strength: ≥66N (single-use) ≥222.5N (multiple-use) (section 8.5 and ASTM D3787)	
Puncture resistance	Class 1 to 6 (highest) (cl. 4.10 of EN 14325 and EN 863)	n/a	≥12N (single-use) ≥25N (multiple-use) (section 8.6 and ASTM D2572)	
b) Chemical resistance				
Permeation by chemicals (applicable to Types 4 and PB [4])	Class 1 to 6 (highest) (EN ISO 6529, method A for liquids)	n/a	n/a	
Repellency to liquids (applicable to Types 6 and PB [6])	Class 1 to 3 (highest) (ISO 6530)	n/a	≤30% (section 8.31)	
Penetration by liquids (applicable to Types 6 and PB[6])	Class 1 to 3 (highest) (ISO 6530)	≥ 100 cm H_2O (EN 20811)	n/a	
c) Flammability				
Resistance to ignition or flame (more stringent)	Pass or min. Class 1 (cl. 4.14 EN 14325 and EN 13274-4, method 3)	n/a	Flame spread time≥3.5 s (section 8.39 and ASTM D1230)	
d) Penetration by infective agents				
Contaminated liquids under hydrostatic pressure	Class 1 to 6 (highest) (cl. 4.1.4.1 of EN 14126, ISO 16603 and ISO 16604)	BFE ≥ 99% (ABNT NBR 14873 for non-woven and ASTM F2101 for woven)	Pass *Note*: In the US the "bio-penetration test one" applies (section 8.3 and ASTM F1671)	

Market	EU	Brazil	US	COMPARISON/ COMMENTS
Property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Mechanical contact with contaminated liquids (wet bacterial penetration)	Class 1 to 6 (highest) (cl. 4.1.4.2 of EN 14126 and EN ISO 22610)	n/a	n/a	
(Biologically) contaminated liquid aerosols	Class 1 to 3 (highest) (cl. 4.1.4.3 of EN 14126)	n/a	n/a	
Contaminated solid particles (dry microbial penetration)	As above (cl. 4.1.4.4 of EN 14126 and ISO 22612)	n/a	n/a	
2. Whole-suit requirements				
Mist test (Type 6)	Pass (EN ISO 17491-4 (method A) as modified by cl. 5.2 of EN 13034)	n/a	Pass (Section 8.2) *Note*: In the US the "liquid tight integrity test one" applies	
Liquid spray test (Type 4)	Pass (cl. 4.3.4.2 etc. of EN 14605 and EN ISO 17491-4 [method B])	n/a	Pass (section 8.2)	
Practical performance	Pass (EN 14605/EN 13034—"seven movements" sequence while wearing the suit)	Not mentioned in NBR 16693, but required by ANVISA regulations	Demonstration of garment functionality is included as part of the liquid integrity testing applied to garments (ASTM F1154)	

6.4.2 Gowns

ABNT NBR 16064:2021, "Textiles for health—surgical drapes and gowns—requirements and test methods," is based on EN 13795-1:2019. It covers single-use and reusable gowns as well as drapes that are used as medical devices for patients, staff, and equipment, and also provides performance requirements and guidelines to users and buyers. The standard includes a recommendation for manufacturers to operate a quality management system meeting the requirements of ISO 13485.

Table 6.8 shows the requirements for gowns in the Brazilian market compared to those of the EU and US markets.

Table 6.8: Comparison between EU, US, and Brazilian standards for gowns

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.4.2.3 of this guide.

Color code:

- Green: Products made to the Brazilian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Brazilian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Brazilian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU** **EN 13795-1:2019** **Surgical gowns**	**Brazil** **ABNT NBR 16064:2021** **Surgical gowns**	**US** **ANSI/AAMI PB70:2012, ASTM F2407-20 (surgical gowns) and ASTM F3352-19 (isolation gowns)**	**COMPARISON/ COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Resistance to dry microbial penetration	≤ 300 CFU (less critical areas) (EN ISO 22612:2005)	≤ 300 CFU (less critical areas) (ISO 22612)	n/a	
Resistance to wet bacterial penetration	I_B ≥ 2.8 (critical areas, standard performance) I_B = 6.0 (critical areas, high performance) (EN ISO 22610:2006)	I_B ≥ 2.8 (critical areas, standard performance) I_B = 6.0 (critical areas, high performance) (ISO 22610)	n/a	
Viral/blood penetration	n/a	n/a	Pass (AQL 4%, RQL=20%) (AAMI Level 4) (ASTM F1671)	
Cleanliness microbial/bioburden	≤ 300 CFU/100 cm² (EN ISO 11737-1:2018)	≤ 300 CFU/100 cm² (ISO 11737-1)	n/a	
Particle release	Log_{10} (lint count) ≤ 4.0 (EN ISO 9073-10:2004)	Log_{10} (lint count) ≤ 4.0 (ISO 9073-10)	Optional	

(Market) standard	**EU** **EN 13795-1:2019** **Surgical gowns**	**Brazil** **ABNT NBR 16064:2021** **Surgical gowns**	**US** **ANSI/AAMI PB70:2012, ASTM F2407-20 (surgical gowns) and ASTM F3352-19 (isolation gowns)**	**COMPARISON/ COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Water resistance (hydrostatic pressure)	≥ 20 cm H_2O (critical areas, standard performance) ≥ 100 cm H_2O (critical areas, high performance) ≥ 10 cm H_2O (Less critical areas) (EN ISO 811:2018)	≥ 20 cm H_2O (critical areas, standard performance) ≥ 100 cm H_2O (critical areas, high performance) ≥ 10 cm H_2O (Less critical areas) (ISO 811)	≥ 20 cm H_2O (AAMI Level 2) ≥ 50 cm H_2O (AAMI Level 3) (AQL 4%, RQL=20%) (AATC 127)	
Water resistance (impact penetration)	n/a	n/a	≤ 4.5 g (AAMI Level 1) ≤ 1.0 g (AAMI Levels 2 and 3) (AQL 4%, RQL=20%) (AATC 42 or NWSP 80.3)	
Bursting strength (dry) (wet)	≥ 40 kPa ≥ 40 kPa (critical areas) (EN ISO 13938:1:1999)	≥ 40 kPa ≥ 40 kPa (critical areas) (ISO 13938:1)	n/a	
Tensile strength (dry) (wet)	≥ 20 N ≥ 20 N (critical areas) (EN 29073-3:1992)	≥ 20 N ≥ 20 N (critical areas) (EN 29073-3)	≥ 30 N (ASTM D 5034)	
Biocompatibility	Pass (EN ISO 10993-1:2009)	Pass and report results (ISO 10993-1)	Pass (ANSI/ AAMI BE78 or ISO 10993-10)	
Sterility	Packaging for terminally sterilized medical devices is recommended according to EN ISO 11607 series	Packaging for sterilized gowns required to meet ISO 11607 series	Assurance level of sterilization process: at least 10^{-6}	
Flammability	Manufacturer to provide fire risk information	Manufacturer to provide fire risk information	Class 1 (16 CFR 1610)	
Other criteria to consider	Comfort (depends on a variety of properties)	Comfort (depends on a variety of properties including thermophysical and ergonomic factors)	Optional: - Water vapor transmission Rate (ASTM D6701) - Evaporative resistance (ASTM F1868, Part B) - etc.	

PART 7
PRODUCT-SPECIFIC COMPARISONS (CANADA)

7.1 Masks

7.1.1 Respirators

No comparison is provided since Canada references the National Institute for Occupational Safety and Health (NIOSH) approval that is covered under 42 Code of Federal Regulations (CFR) Part 84 in the United States (see 4.1.1.2).

7.1.2 Medical face masks

No comparison is provided since Canada references ASTM F2100, as used in the United States (see 4.1.2.2).

If a visor is attached to the medical face mask, it must conform to the applicable criteria in the standard CSA Z94.3.1 (see 7.2).

7.1.3 Community face coverings

No Canadian standards for community face coverings have been identified. According to Health Canada,[63] "Health Canada has not set out or endorsed any standards for face coverings at this time. We are actively monitoring the development of standards for face coverings and may revise our position when new information becomes available." A number of reference documents outline the preferred material, design, and best practices for wearing face coverings. These include:

- AFNOR Spec: Barrier masks V1.0 by the French Standardization Association
- CWA 17553:2020: "Community face coverings—guide to minimum requirements, methods of testing, and use" by the European Committee for Standardization
- Québec Standards Bureau (BNQ) Attestation document 1922–900, an attestation program for face coverings established by the province of Québec and certified by "le Bureau de Normalisation du Québec."

Table 7.1 shows the requirements for community face coverings defined in the BNQ 1922-900 standard compared to those of the EU and US markets.

63 https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/personal-protective-equipment/medical-masks-respirators/face-covering-classifications-notice.html.

Table 7.1: Comparison between EU, US, and Canadian (Province of Québec) standards for community face coverings

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.3 of this guide.

Color code:

- Green: Products made to the BNQ 1922-900 standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the BNQ 1922-900 standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the BNQ 1922-900 standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU CWA 17553:2020**	**Canada Québec Province Spec 1922-900/2020 (including mod. 2, 2021-08-03)**	**US ASTM F3502-21**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	No National Canadian Standard
Breathing resistance	≤ 70 Pa/cm² EN 13274-3 (inhalation resistance of 2.4 mbar; exhalation resistance 3 mbar) EN 14683:2019, Annex C	≤ 6 mm H_2O/cm² (59 Pa/cm²) EN 14683:2019, Annex C	Subpart K of 42 CFR Part 84, modified by § 8.2 (Level 1 ≤ 15 mm H_2O Level 2 ≤ 5 mm H_2O)	In the EU, either breathing resistance or air permeability are measured
Air permeability	(≥ 96 l/s/m² @ 100 Pa) EN ISO 9237	n/a	n/a	
Particle filtration efficiency (PFE)	(Level 90% ≥ 90% Level 70% ≥ 70%) Particle size 3 (± 0.5) µm EN 13274-7 EN ISO 16890-2 or EN ISO 21083-1:2018 or BFE (see below)	≥ 80% filtration efficiency for particles of 20–800nm using NaCl Annex A (as modified)	Subpart K of 42 CFR Part 84, modified by § 8.1 (Level 1 ≥20%; Level 2 ≥ 50%)	Test for filtration of 3 µm particles is optional in Québec (≥ 95%), Annex A, as modified; limit is stricter than in EU
Bacterial filtration efficiency (BFE)	(Level 90% ≥ 90%; Level 70% ≥ 70%) EN 14683:2019	n/a	Manufacturer may choose to provide the BFE results (as per ASTM F 2101) along with PFE	In the EU, either PFE or BFE are measured

7.2 Eye and face protection

There are two relevant Canadian publications: a national standard, CSA Z94.3-20 (revised May 2021) "Eye and face protectors," and a guideline, CSA Z94.3.1-16, "Guideline for selection, use, and care of eye and face protectors." The standard CSA Z94.3-20 defines seven classes of protectors; the relevant ones for the purposes of this guide are: Class 1 (spectacles), 2 (goggles) and 6 (face shields). The standard contains general requirements (applicable to all classes) and class-specific requirements, while testing methods are included in Chapter 12 of the standard. The additional guideline mentioned complements the standard, providing advice for the proper selection of eye and face protection in relation to the specific hazardous activity involved.

Table 7.2 shows the requirements for eye and face protection in the Canadian market compared to those of the EU and US markets.

Table 7.2: Comparison between EU, US, and Canadian standards for eye and face protection

Notes:

- In general, requirements for lenses (only) have not been included.
- For a more detailed comparison of EU and US standards (including test methods), see 4.2.1 of this guide.

Color code:

- Green: Products made to the Canadian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Canadian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Canadian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 166:2001**	**Canada CSA Z94.3-20, revised May 2021**	**US ANSI/ISEA Z87.1:2020**	**COMPARISON/ COMMENTS**
Characteristic/property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Construction and materials	Pass	n/a	Pass (ANSI Z80.1)	No specific testing done in the CSA; covered by other characteristics
Headband	Pass	n/a	n/a	
Basic (EU)/fundamental (US) requirements		**Called "general requirements" in the CSA**		
Field of vision	Pass (EN 168)	(Class 1, 2) ≥40° horizontally & ≥80° vertically	n/a	Called "field of view" in CSA Different limits/method than in EU
Min. coverage area	Not a requirement, except for special uses	Min. dimensions are provided in cl. 6.8 (Classes 1, 2) and cl. 10.2.1 (Class 5)	Ellipse with axes ≥40 mm and ≥ 33mm	Called "size" in CSA. Generally same as in US
Transmittance of oculars without filtering action	> 74.4% (EN 167)	(Classes 1,2 and 6) ≥85% ≥78% (for double glazed) Clause 12.8.5	≥ 85% (or ≥ 78% if relaxed optics)	Limits/method similar as in US
Haze	n/a	≤2% (Classes 1, 2) ≤3% (Class 6) ASTM D1003	≤3% (ASTM D1003-13)	Same or stricter requirements as in US

(Market) standard	EU EN 166:2001	Canada CSA Z94.3-20, revised May 2021	US ANSI/ISEA Z87.1:2020	COMPARISON/ COMMENTS
Characteristic/property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Increased robustness	Pass (EN 168)	Pass Clauses 6.1, 12.2	Pass	Called "impact resistance" in CSA; using different steel ball diameter/speed than in EU
Thermal stability	Pass (EN 168)	n/a	n/a	Not a requirement unless for use at extreme temperatures
Resistance to corrosion	Pass (EN 168)	n/a	Pass	
Resistance to ignition	Pass (EN 168)	Pass Clause 12.3	Pass	Very similar method to EU/ US
Particular requirements (EU)				
Droplets and splashes of liquid	No color present for goggles Face shields pass the area coverage test (EN 168)	n/a	No color present for goggles Face shields pass the area coverage test	No specific testing done in the CSA; covered by construction characteristics
Lateral protection (optional)	Pass (EN 168)	(Classes 1, 2) Pass Clause 6.9	Pass	Called "side protection" in CSA; similar limits/different method than EU
Optional requirements (EU)				
Resistance to fogging (only for oculars, not complete eye protectors)	Time without fogging ≥ 8 s (EN 168)	n/a	Time without fogging ≥ 8 s	

Eye/face protection equipment used in health care settings are regulated as Class I medical devices in Canada, see 3.5.1.

7.3 Gloves

7.3.1 Medical examination gloves

No comparison is made since Canada references ISO 11193-1 (the 2008 edition, even though recently a 2020 edition was issued), as well as ASTM D3578 used in the United States for rubber examination gloves. It also references ISO 11193-2:2006 for PVC gloves as well as ASTM standards for gloves made of other materials (for details of the ISO standards, see 4.3.1.1).

In Canada, all medical gloves are Class II medical devices.

7.3.2 Surgical gloves

No comparison is made since Canada references ISO 10282 (the 2002 edition, even though a 2014 edition exists), as well as ASTM D3577-19 (for details of the ISO standard, see 4.3.2.1).

In Canada, all medical gloves are Class II medical devices.

7.4 Clothing

7.4.1 Full-body and partial-body garments (other than surgical/isolation gowns)

No comparison is made since Canada references EN 14126 (see 4.4.1.1 on EU market requirements).

7.4.2 Gowns

In Canada the relevant standard is CSA Z314-2018, "Canadian medical device reprocessing" which, among others, replaced two standards on gowns: Z314.10.1, "Selection and use of gowns and drapes intended for use in health care facilities', and Z314.10.2, "Laundering, maintenance, and preparation of reusable gowns, drapes, and wrappers for health care settings and laundries." This standard is intended to address the safe, effective, and reliable reprocessing of *reusable* medical devices at each phase of the reprocessing workflow, including, among others:

- Selection and use of gowns and drapes (in Chapter 19)
- Laundering, maintenance, and preparation of reusable gowns, drapes, and wrappers (in Chapter 20).

The standard contains requirements from the applicable standard in the United States (ANSI/AAMI PB 72) regarding barrier properties and also explicit requirements for flammability and biocompatibility. Regarding other material properties, there are general requirements such as having sufficient strength to maintain integrity and sterility during normal handling and distribution, and resistance to tears and punctures during use but without reference to specific limits or testing methods. In this aspect it is noted that Health Canada accepts conformance to ASTM F2407-20 and recognizes EN 13795-1. Both standards cover single-use and reusable gowns; for details on their requirements see 4.4.2. Finally, while CSA Z314 addresses both surgical and isolation gowns, it does *not* address single-use or disposable gowns.

Table 7.3 shows the requirements for medical gowns in the Canadian market compared to those of the EU and US markets.

Table 7.3: Comparison between EU, US, and Canadian standards for gowns

Note:

For a more detailed comparison of EU and US standards (including test methods), see 4.4.2.3 of this guide.

Color code:

- Green: Products made to the Canadian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Canadian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Canadian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 13795-1:2019 Surgical gowns**	**Canada CSA Z314-2018 (only reusable surgical/isolation gowns)**	**US ANSI/AAMI PB70:2012 (all gowns) ASTM F2407-20 (surgical gowns) and ASTM F3352-19 (isolation gowns)**	**COMPARISON/ COMMENTS**
Characteristic/property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Resistance to dry microbial penetration	≤ 300 CFU (less critical areas) *Note*: For critical product areas, wet bacterial penetration limits apply instead EN ISO 22612:2005	n/a	n/a	AAMI PB 70 standard specifically excludes dry microbial penetration from its scope
Resistance to wet bacterial penetration	I_B ≥ 2.8 (critical areas, standard performance) I_B = 6.0 (critical areas, high performance) EN ISO 22610:2006	n/a	n/a	US requires (only for Level 4) a stricter characteristic (viral penetration; see next row in table)
Viral penetration	n/a	Pass (AQL 4%, RQL=20%) (AAMI Level 4) ASTM F1671	Pass (AQL 4%, RQL=20%) (AAMI Level 4) ASTM F1671	
Cleanliness microbial/ bioburden	≤ 300 CFU/100 cm² EN ISO 11737-1:2018	n/a	n/a	
Particle release	Log_{10} (lint count) ≤ 4.0 EN ISO 9073-10:2004	Requirement included but no limits or testing methods are specified	Optional in the US	Health Canada accepts by reference the limits/ methods in the EN and ASTM standards
Water resistance (hydrostatic pressure)	≥ 20 cm H_2O (critical areas, std. performance) ≥ 100 cm H_2O (critical areas, high performance) ≥ 10 cm H_2O (less critical areas) EN ISO 811:2018	≥ 20 cm H_2O (AAMI Level 2) ≥ 50 cm H_2O (AAMI Level 3) (AQL 4%, RQL=20%) AATC 127	≥ 20 cm H_2O (AAMI Level 2) ≥ 50 cm H_2O (AAMI Level 3) (AQL 4%, RQL=20%) AATC 127	For critical areas/zones, US limits are the same as EU ones (for standard performance) or lower (for high performance) Limits in the US apply only to critical zone components (akin to critical areas in the EU); EU and US methods are similar

(Market) standard	**EU EN 13795-1:2019 Surgical gowns**	**Canada CSA Z314-2018 (only reusable surgical/isolation gowns)**	**US ANSI/AAMI PB70:2012 (all gowns) ASTM F2407-20 (surgical gowns) and ASTM F3352-19 (isolation gowns)**	**COMPARISON/ COMMENTS**
Characteristic/property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Water resistance (impact penetration)	n/a	≤ 4.5 g (AAMI Level 1) ≤ 1.0 g (AAMI Level 2 and 3) (AQL 4%, RQL=20%) AATC 42 or NWSP 80.3	≤ 4.5 g (AAMI Level 1) ≤ 1.0 g (AAMI Level 2 and 3) (AQL 4%, RQL=20%) AATC 42 or NWSP 80.3	Limits in the US apply only to critical zone components (akin to critical areas in the EU)
Bursting strength (dry) (wet)	≥ 40 kPa ≥ 40 kPa (critical areas) EN ISO 13938:1:1999	n/a	n/a	
Tensile strength (dry) (wet)	≥ 20 N ≥ 20 N (critical areas) EN 29073-3:1992	Requirement included but no limits/testing methods specified	≥ 30 N ASTM D5034	Health Canada accepts by reference the limits/ methods in the EN and ASTM standards. In the US, additionally, limits are set for tear strength (≥ 10 N per ASTM D5587 or D5733) and seam strength (≥ 30 N per ASTM D1683/D1683M); physical property limits are same for all barrier levels per AAMI
Biocompatibility	Pass EN ISO 10993-1:2009	Pass ISO 10993-1:2009	Pass ANSI/AAMI BE78 or ISO 10993-10	
Sterility	Packaging for terminally sterilized medical devices is recommended According to EN ISO 11607 series	Typically, reusable gowns will be sterilized after purchase/use	Assurance level of sterilization process: at least 10^{-6}	
Flammability	Manufacturer to provide fire risk information	Class 1 16 CFR 1610	Class 1 16 CFR 1610	
Other criteria to consider	Comfort (depends on a variety of properties)	Optional	Optional: - Water vapor transmission rate (ASTM D6701) - Evaporative resistance (ASTM F1868, Part B) - etc.	Canadian standard states: "Gowns should, to the greatest extent possible, be comfortable" *Note*: The comfort and usability of gowns can be influenced by a number of factors, including design, fit, breathability, weight, "hand" (that is, the overall feel of the material), electrostatic properties, light reflectance (glare), and odor"

Surgical/isolation gowns are regulated as Class I medical devices in Canada; see 3.5.1.

PART 8
PRODUCT-SPECIFIC COMPARISONS (COLOMBIA)

8.1 Masks

8.1.1 Respirators

The relevant Colombian standards for respiratory protection devices (RPD) are:

- NTC 3852:2020, "Respiratory protection devices—filtering half-masks protection against particles—requirements, tests, marking," which is identical to EN 149:2001+A1:2009 (current)
- NTC 6486:2020: "Respiratory protective devices," a comprehensive native standard which covers devices for protection against harmful atmospheres or escape from them, powered or not. Among others, this standard adopts the requirements in US 42 Code of Federal Regulations (CFR) Part 84 for N series respirator masks
- Lastly, NTC 6435:2020, "Standard practice for respiratory protection" is an adoption of ASTM F3387-19, which is not a product standard but provides guidance on the selection, proper use, and maintenance of RPD.

Table 8.1 shows the requirements for respirators in the Colombian market compared to those of the EU and US markets.

Table 8.1: Comparison between EU, US, and Colombian standards for respirators

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.1 of this guide.

Color code:

- Green: Products made to the Colombian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Colombian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Colombian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 149:2001 +A1:2009, Classes FFP2 and FFP3**	**Colombia NTC 3852:2020, Classes FFP2 and FFP3**	**Colombia NTC 6486:2020, Series/Levels N95 and N99**	**US 42 CFR Part 84, Series/Levels N95 and N99**	**COMPARISON/ COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	The two Colombian standards are identical adoptions of EN 149 and US Federal regulations, respectively
Practical performance	Pass	Pass	Pass	Pass	N95 and N99 respirators according to NTC 6486 cannot be magenta in color (reserved for P100 ones)
Total inward leakage	**FFP2** ≤ 11% (individual) ≤ 8% (mean)	**FFP2** ≤ 11% (individual) ≤ 8% (mean)	n/a	n/a	
	FFP3 ≤ 5% (individual) ≤ 2 % (mean)	**FFP3** ≤ 5% (individual) ≤ 2 % (mean)	n/a	n/a	
Filtering efficiency	**FFP2** ≥ 94% @ 95 L/min (NaCl and paraffin oil— EN 13274-7)	**FFP2** ≥ 94% @ 95 L/min (NaCl and paraffin oil—EN 13274-7)	**N95** ≥ 95% @ 85 L/min (NaCl only)	**N95** ≥ 95% @ 85 L/min (NaCl only)	
	FFP3 ≥ 99% @ 95 L/min (NaCl and paraffin oil— EN 13274-7)	**FFP3** ≥ 99% @ 95 L/min (NaCl and paraffin oil—EN 13274-7)	**N99** ≥ 99%@ 85 L/min (NaCl only)	**N99** ≥ 99%@ 85 L/min (NaCl only)	
Compatibility with skin	Pass	Pass	n/a	n/a	
Flammability	Pass	Pass	n/a	n/a	
Carbon dioxide content	Average ≤ 1% by volume in "dead space"	Average ≤ 1% by volume in "dead space"	n/a	n/a	
Field of vision	Pass	Pass	Pass	Pass	
Breathing resistance (inhalation)	**FFP2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min	**FFP2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min	**N95** ≤ 343 Pa @ 85 L/min	**N95** ≤ 343 Pa @ 85 L/ min	In NTC 6486 limit is specified as 35 mm H_2O
	FFP3 ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min	**FFP3** ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min	**N99** ≤ 343 Pa @ 85 L/min	**N99** ≤ 343 Pa @ 85 L/ min	As above
Breathing resistance (exhalation)	**FFP2 and FFP3** ≤ 300 Pa @160 L/ min	**FFP2 and FFP3** ≤ 300 Pa @160 L/ min	**N95 and N99** ≤ 245 Pa @ 85 L/min	**N95 and N99** ≤ 245 Pa @ 85 L/min	In NTC 6486 limit is specified as 25 mm H_2O

8.1.2 Medical face masks

In Colombia there are national adoptions of both the EN and ASTM standards, namely NTC 1733:2020, "Surgical masks—requirements and test methods," identical to EN 14683:2019, and NTC 6436:2020, "Standard specification for the performance of the materials used in medical masks," identical to ASTM F2100-19 (since revised as ASTM F2100-21).

Table 8.2 shows the requirements for medical face masks in the Colombian market compared to those of the EU and US markets.

Table 8.2: Comparison between EU, US, and Colombian standards for medical face masks

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.2 of this guide.

Color code:

- Green: Products made to the Colombian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Colombian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Colombian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 14683:2019 Types I, II and IIR**	**Colombia NTC 1733:2020 Types I, II and IIR**	**Colombia NTC 6436:2020 Levels 1, 2 and 3**	**US ASTM F2100–21 Levels 1, 2 and 3**	**COMPARISON/ COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	National adoptions of both EN 14683 and ASTM F2100 exist
Bacterial filtration efficiency (BFE)	≥ 95% (Type I) ≥ 98% (Types II, IIR)	≥ 95% (Type I) ≥ 98% (Types II, IIR)	≥ 95% (Level 1) ≥ 98% (Levels 2,3) Using ASTM F2101	≥ 95% (Level 1) ≥ 98% (Levels 2,3) Using ASTM F2101	
Differential pressure	< 40 Pa/cm² (Type I, II) < 60 Pa/cm² (Type IIR) (Tested at 8L/ min flowrate)	< 40 Pa/cm² (Type I, II) < 60 Pa/cm² (Type IIR) (Tested at 8L/min flowrate)	<49 Pa/cm² (Level 1) <58.8 Pa/cm² (Levels 2 and 3) Using EN 14683	<49 Pa/cm² (Level 1) <58.8 Pa/cm² (Levels 2 and 3) Using EN 14683	
Sub-micron particulate filtration efficiency	n/a	n/a	≥ 95 (Level 1) ≥ 98 (Levels 2,3) Both at 0.1 micron, using ASTM F2299	≥ 95 (Level 1) ≥ 98 (Levels 2,3) Both at 0.1 micron, using ASTM F2299	
Splash-resistance pressure	Not required (Types I, II) ≥ 16.0 kPa (Type IIR) Using ISO 22609:2004	Not required (Types I, II) ≥ 16.0 kPa (Type IIR) Using ISO 22609:2004	≥ 10.7 kPa (Level 1) ≥16 kPa (Level 2) ≥21.4 kPa (Level 3) Using ASTM F1862	≥ 10.7 kPa (Level 1) ≥16 kPa (Level 2) ≥21.4 kPa (Level 3) Using ASTM F1862	
Microbial cleanliness	≤ 30 CFU/g Using EN ISO 11737-1:2018	≤ 30 CFU/g Using EN ISO 11737-1:2018	n/a	n/a	
Biocompatibility	Pass Using ISO EN 10993-1:2009	Pass Using EN ISO 10993-1:2009	Pass Using FDA regulations	Pass Using ISO 10993-1	
Flame spread	n/a	n/a	Class 1 Using 16 CFR Part 1610	Class 1 Using 16 CFR Part 1610	

8.1.3 Community face coverings

The Colombian standard is NTC 6449:2020, "Masks (face masks) for use in environments other than the health sector." The standard specifies the basic characteristics of bacterial filtration efficiency (BFE), breathing resistance (differential pressure), splash resistance and dimensions, and makes reference to EN as well as ASTM/AATC standards. Table 8.3 shows the requirements for community face coverings in the Colombian market compared to those of the EU and US markets.

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.3 of this guide.

Table 8.3: Comparison between EU, US, and Colombian standards for community face coverings

Color code:

- Green: Products made to the Colombian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Colombian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Colombian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	EU CWA 17553:2020	Colombia NTC 6449:2020	US ASTM F3502-21	COMPARISON/ COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/testing Method**	**Requirement/testing method**	
Breathing resistance	EN 14683:2019, Annex C (≤ 70 Pa/cm²) EN 13274-3 (Inhalation resistance of 2.4 mbar; exhalation resistance 3 mbar)	Differential pressure ≤60 Pa/cm²; (NTC 1733 or EN 14683:2019)	Subpart K of 42 CFR Part 84, modified by §8.2 (Level 1 ≤ 15 mm H_2O Level 2 ≤ 5 mm H_2O)	For the EU, either breathing resistance or air permeability is measured; NTC 1733 is identical to EN 14683
Air permeability	EN ISO 9237 (≥ 96 l/s/m² @ 100 Pa)	n/a	n/a	
Particle filtration efficiency (PFE)	EN 13274-7:2019 OR EN ISO 16890-2 OR EN ISO 21083-1:2018, or measure BFE (see below) (Level 90% ≥ 90% Level 70% ≥ 70%) Particle size 3 (± 0.5) µm	n/a	Subpart K of 42 CFR Part 84, modified by §8.1 (Level 1 ≥ 20%; Level 2 ≥ 50%)	For the EU, either PFE or BFE is measured while for Colombia only BFE; for PFE, the CEN Workshop Agreement (CWA) provides for alternative methods
Bacterial filtration efficiency (BFE)	EN 14683:2019 (Level 90% ≥ 90% Level 70% ≥ 70%)	≥ 90% (NTC 1733 or EN 14683 or ASTM F2101)	Manufacturer may choose to provide the BFE results (as per ASTM F 2101) along with PFE	NTC equals or exceeds the requirements in the EU
Splash resistance	n/a	Passes (AATC 42/ISO 18695 or AATC 22/ISO 4920 or ASTM F1862)	n/a	Only required in Colombia

8.2 Eye and face protection

In Colombia there are national adoptions of both the EN and US standards, namely NTC 6493:2020, "Individual eye protection—specifications," identical to EN 166:2001 and NTC 3610:2020, "Eye and face personal protection devices at work and education," identical to ANSI/ISEA Z87.1:2015 (there is now a 2020 edition).

Table 8.4 shows the requirements for eye and face protection in the Colombian market compared to those of the EU and US markets.

Table 8.4: Comparison between EU, US, and Colombian standards for eye and face protection

Notes:

- In general, requirements for lenses (only) have not been included.
- For a more detailed comparison of EU and US standards (including test methods), see 4.2.1 of this guide.

Color code:

- Green: Products made to the Colombian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Colombian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Colombian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 166:2001**	**Colombia NTC 6493:2020**	**Colombia NTC 3610:2020**	**US ANSI/ISEA Z87.1:2020**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	National adoptions of both EN 166 and ANSI/ISEA Z87.1 (2015 edition) exist
Construction and materials	Pass	Pass	Pass (ANSI Z80.1)	Pass (ANSI Z80.1)	
Headband	Pass	Pass	n/a	n/a	
Basic (EU)/ fundamental (US) requirements					
Field of vision	Pass (EN 168)	Pass (EN 168)			
Min. coverage area	Not a requirement, except for special uses	Not a requirement, except for special uses	Ellipse with axes ≥40 mm and ≥ 33 mm	Ellipse with axes ≥40 mm and ≥ 33 mm	
Transmittance of oculars without filtering action	> 74.4% (EN 167)	> 74.4% (EN 167)	≥ 85%	≥ 85% (or ≥ 78% if relaxed optics)	
Haze	n/a	n/a	≤3% (ASTM D1003-13)	≤3% (ASTM D1003-13)	
Increased robustness	Pass (EN 168)	Pass (EN 168)	Pass	Pass	
Thermal stability	Pass (EN 168)	Pass (EN 168)	n/a	n/a	
Resistance to corrosion	Pass (EN 168)	Pass (EN 168)	Pass	Pass	
Resistance to ignition	Pass (EN 168)	Pass (EN 168)	Pass	Pass	

(Market) standard	EU EN 166:2001	Colombia NTC 6493:2020	Colombia NTC 3610:2020	US ANSI/ISEA Z87.1:2020	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	National adoptions of both EN 166 and ANSI/ISEA Z87.1 (2015 edition) exist
Particular requirements (EU)					
Droplets and splashes of liquid	No color present for goggles Face shields pass the area coverage test (EN 168)	No color present for goggles Face shields pass the area coverage test (EN 168)	No color present for goggles Face shields pass the area coverage test	No color present for goggles Face shields pass the area coverage test	
Lateral protection (optional)	Pass (EN 168)	Pass (EN 168)	Pass	Pass	
Optional requirements (EU)					
Resistance to fogging (only for oculars, not complete eye protectors)	Time without fogging ≥ 8 s (EN 168)	Time without fogging ≥ 8 s (EN 168)	n/a	n/a	US requirement (same as in EU) was added in the 2020 edition

8.3 Gloves

8.3.1 Medical examination gloves

The relevant standards are NTC-ISO 11193-1:2020 (for gloves made of rubber/latex), identical to ISO 11193-1:2008 (last revised in 2020) and NTC-ISO 11193-2:2020 (made of PVC), identical to ISO 11193-2:2006 (current). For details on the ISO standards, see 4.3.1.1.

For completeness, the standards NTC 6492:2020, "Protection gloves—general requirements and test methods," identical to EN 420:2004+A1:2010 (since replaced by EN ISO 21420), and NTC ISO 374-5:2020, "Protective gloves against dangerous chemicals and micro-organisms—Part 5: Terminology and performance requirements for micro-organisms risks," identical to ISO 374-5:2016 (current), are also mentioned. As it has been analyzed in section 4.3.1.1 on EU requirements for examination gloves, standards on "protective gloves" (as opposed to "medical gloves") will not be further detailed.

Table 8.5 shows the requirements for medical examination gloves in the Colombian market compared to those of the EU and US markets.

Table 8.5: Comparison between EU, US, and Colombian standards for medical examination gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.1.3 of this guide.

Color code:

- Green: Products made to the Colombian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Colombian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Colombian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 455 series**	**Colombia Material-specific NTC-ISO 11193-1:2020 (rubber) NTC-ISO 11193-2:2020 (PVC)**	**US ASTM material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)**	**COMPARISON/ COMMENTS**
Characteristic/property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Freedom from holes	AQL =1.5 (EN 455-1:2020)	AQL =2.5	AQL =2.5 (ASTM D5151)	
Force at break (N) / Tensile strength (MPa), elongation at break (%) (Also, after ageing/ challenge)	Non-thermoplastic materials ≥6.0N Thermoplastic materials (PVC, PE) ≥ 3.6N (EN 455-2 :2015, method A of ISO 23529:2010)	AQL = 4.0 For rubber ≥ 6.0 N Elongation ≥ 500% (Type 1) and ≥ 400% (Type 2) For PVC ≥ 7.0 N Elongation ≥ 350%	AQL = 4.0 Nitrile ≥ 14MPa/elongation ≥400% Latex (natural) ≥ 14MPa / elongation ≥ 500% Polychloroprene ≥ 14MPa/elongation ≥ 400% PVC ≥ 11MPa/elongation ≥ 300% (ASTM D412, ASTM D573 [ageing])	In the EU, instead of AQL, the median of 13 samples is used In general, the tensile properties and their limits specified in the Colombian standards are an amalgam of the EU/US ones Colombian and EU standards specify minimum absolute force (N) for samples taken from the glove (varies with thickness); ASTM specifies in terms of tensile strength
Biocompatibility	Pass (EN ISO 10993-5 and -10)	No explicit requirements	Pass (FDA regulations)	
Powder-residue content	≤ 2.0 mg/glove (EN 455-3, EN ISO 21171:2006)	n/a	≤ 2.0mg/glove (powder-free gloves) ≤ 10 mg/dm² (powdered gloves) (ASTM D6124)	The requirement was first introduced in the 2020 edition of ISO 11193-1, while NTC-ISO 11193-1 is based on the 2008 edition
Aqueous soluble protein content	"Manufacturer shall monitor the content in natural rubber latex gloves and shall try to minimize it" (EN 455-3)	n/a	≤ 200 µg/dm² (only for rubber gloves) (ASTM D5712)	

(Market) standard	EU EN 455 series	Colombia Material-specific NTC-ISO 11193-1:2020 (rubber) NTC-ISO 11193-2:2020 (PVC)	US ASTM material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)	COMPARISON/ COMMENTS
Characteristic/property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Extractable antigenic protein content	Optional	n/a	≤ 10 µg/dm² (only for rubber gloves) (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	If gloves are sterilized, the nature of the sterilization process shall be disclosed on request	Pass (US Pharmacopeia)	

8.3.2 Surgical gloves

There appears to be no relevant NTC standard for surgical gloves, such as an adoption of ISO 10282. Therefore, no comparison to EU/US standards can be provided.

8.4 Clothing

8.4.1 Full-body and partial-body garments (other than surgical/isolation gowns)

It is noted that, unlike in most countries/regions covered in this guide, in Colombia there are also native-specific standards for disposable hats/caps and disposable foot covers. These two product types will be dealt with in a separate subsection.

8.4.1.1 Suits, coveralls, and aprons

The relevant Colombian standards include the direct use or adoption of the majority of the corresponding ISO and EN ones:

- ISO 13688 on general requirements of protective clothing has not been adopted. Instead, in Colombia, reference to the previous version of it, EN 340, is made
- NTC 6434:2020, "Protective clothing—requirements and test methods for clothing protection against biological agents," is identical to EN 14126:2003 (current)
- EN 14325 has not been adopted, but the latest edition of it is referenced by NTC 6434 (see above)
- NTC-EN 14605:2020, "Protective clothing against liquid chemicals—requirements performance for clothing with liquid-tight seams (Type 3) or with spray-tight joints (Type 4), including garments that offer protection only to certain parts of the body (Types PB [3] and PB [4])," is identical to EN 14605:2005+A1:2009 (current)
- NTC-EN 13034:2020, "Protective clothing against liquid chemicals—requirements performance for chemical protective clothing that offers protection limited against liquid chemicals (Types 6 and PB [6] equipment)," is identical to EN 13034:2005+A1:2009 (current)
- The testing standards ISO 16603 (synthetic blood penetration) and ISO 16604 (bacteriophage method) are referenced directly, while the current editions of ISO 22610 (wet bacterial penetration) and ISO 22612 (dry microbial penetration) have been adopted as NTC-ISO ones.

Table 8.6 shows the requirements for protective clothing in the Colombian market compared to those of the EU and US markets.

Table 8.6: Comparison between EU, US, and Colombian standards for suits, coveralls, and aprons

Notes:

For a more detailed comparison of EU and US standards (including test methods), see 4.4.1 of this guide.

For simplicity, only requirements for materials and whole suits are included (that is, requirements for seams, joins, assemblages, and integral components, such as visors, are *not* included).

For protection against infective agents only the following protection types, as defined in the standards, are considered here: Type 4 (spray-tight), Type PB [4] (partial-body protection—Type 4), Type 6 (limited protection against liquid chemicals) and Type PB [6] (partial-body protection—Type 6).

Color code:

- Green: Products made to the Colombian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Colombian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Colombian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

Market	EU	Colombia	US	COMPARISON/ COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	
I. General requirements	**EN ISO 13688:2013+A1:2021**	**EN 340:2003**	**NFPA 1999:2018**	
Innocuousness	No harmful substances present No azo dyes present	No harmful substances present No azo dyes present	No specific requirements	
Design and comfort	Acceptable (Annex C)	Acceptable	Acceptable (section 6.1) *Note*: Design requirements only ≥650 g/(m²24 h) *Note*: In the US for single-use garments/ensembles "moisture vapor transmission rate" is specified (section 8.28 and ASTM E96) ≥450 W/m² *Note*: In the US for multiple-use garments/ensembles "total heat loss test" is specified (section 8.32 and ASTM F1868)	
II. Protection against infective agents	**EN 14126:2003 and EN 14605:2005+A1:2009 (for Types 4 and PB [4]) or EN 13034:2005+A1:2009 (for Types 6 and PB [6])**	**NTC 6434:2020 and NTC-EN 14605:2020 (for Types 4 and PB[4]) or NTC-EN 13034:2020 (for Types 6 and PB[6])**	**NFPA 1999:2018**	
1. Materials requirements				
a) Mechanical				

Market	EU	Colombia	US	COMPARISON/ COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	
Abrasion resistance	Class 1 to 6 (highest) (cl. 4.4 of EN 14325 and EN ISO 12947-2)	Class 1 to 6 (highest) (cl. 4.4 of EN 14325 and EN ISO 12947-2)	Abrasion resistance is considered as a precondition to barrier performance of materials (ASTM D4157)	
Flex cracking resistance	Class 1 to 6 (highest) (cl. 4.5, 4.6 EN 14325 and EN ISO 7854, method B)	Class 1 to 6 (highest) (cl. 4.5, 4.6 EN 14325 and EN ISO 7854, method B)	Flex fatigue is considered as a precondition to barrier performance of materials (ASTM F392)	
Trapezoidal tear resistance	Class 1 to 6 (highest) (EN 14325 and EN ISO 9073-4:1997)	Class 1 to 6 (highest) (EN 14325 and EN ISO 9073-4:1997)	Single-use: "Tear-resistance test two" ≥17 N (section 8.38 and ASTM D5733 for non-woven) Multiple-use: "Tear-resistance test one" ≥36 N (section 8.7 and ASTM D5587 for woven)	
Tensile strength	Class 1 to 6 (highest) (cl. 4.9 of EN 14325 and EN ISO 13934-1)	Class 1 to 6 (highest) (cl. 4.9 of EN 14325 and EN ISO 13934-1)	≥50 N (section 8.4 and ASTM D5034) Also bursting strength: ≥66N (single-use) ≥222.5N (multiple-use) (section 8.5 and ASTM D3787)	Bursting strength was eliminated in EU and also not present in NTC
Puncture resistance	Class 1 to 6 (highest) (cl. 4.10 of EN 14325 and EN 863)	Class 1 to 6 (highest) (cl. 4.10 of EN 14325 and EN 863)	≥12N (single-use) ≥25N (multiple-use) (section 8.6 and ASTM D2572)	
b) Chemical resistance				
Permeation by chemicals (applicable to Types 4 and PB [4])	Class 1 to 6 (highest) (EN ISO 6529, method A for liquids)	Class 1 to 6 (highest) (EN ISO 6529, method A for liquids)		
Repellency to liquids (applicable to Types 6 and PB [6])	Class 1 to 3 (highest) (ISO 6530)	Class 1 to 3 (highest) (ISO 6530)	≤30% (section 8.31)	In the US, it is called "water-absorption resistance test"; it applies only to multiple-use garments/ensembles
Penetration by liquids (applicable to Types 6 and PB [6])	Class 1 to 3 (highest) (ISO 6530)	Class 1 to 3 (highest) (ISO 6530)		
c) Flammability				
Resistance to ignition or flame (more stringent)	Pass or min. class 1 (cl. 4.14 EN 14325 & EN 13274-4, method 3)	Pass or min. class 1 (cl. 4.14 EN 14325 & EN 13274-4, method 3)	Flame spread time≥3.5 s (section 8.39 and ASTM D1230)	
d) Penetration by infective agents				
Contaminated liquids under hydrostatic pressure	Class 1 to 6 (highest) (cl. 4.1.4.1 of EN 14126, ISO 16603 and ISO 16604)	Class 1 to 6 (highest) (cl. 4.1.4.1 of EN 14126, ISO 16603 and ISO 16604)	Pass *Note*: In the US the "bio-penetration test one" applies (section 8.3 and ASTM F1671)	

Market	EU	Colombia	US	COMPARISON/ COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	
Mechanical contact with contaminated liquids (wet bacterial penetration)	Class 1 to 6 (highest) (cl. 4.1.4.2 of EN 14126 and EN ISO 22610)	Class 1 to 6 (highest) (cl. 4.1.4.2 of EN 14126 and NTC- ISO 22610)	n/a	ISO 22610:2018 has been adopted as NTC-ISO
(Biologically) contaminated liquid aerosols	Class 1 to 3 (highest) (cl. 4.1.4.3 of EN 14126)	Class 1 to 3 (highest) (cl. 4.1.4.3 of EN 14126)	n/a	
Contaminated solid particles (dry microbial penetration)	As above (cl. 4.1.4.4 of EN 14126 and ISO 22612)	As above (cl. 4.1.4.4 of EN 14126 and NTC-ISO 22612)	n/a	ISO 22612:2006 has been adopted as NTC-ISO
2. Whole-suit requirements				
Mist test (Type 6)	Pass (EN ISO 17491-4 (method A) as modified by cl. 5.2 of EN 13034)	Pass (EN ISO 17491-4 (method A) as modified by cl. 5.2 of EN 13034)	Pass (section 8.2) *Note*: In the US the "liquid tight integrity test one" applies	
Liquid spray test (Type 4)	Pass (cl. 4.3.4.2 etc. of EN 14605 and EN ISO 17491-4 [method B])	Pass (cl. 4.3.4.2 etc. of EN 14605 and EN ISO 17491-4 [method B])	Pass (section 8.2)	
Practical performance	Pass (EN 14605/EN 13034—"seven movements" sequence while wearing the suit)	Pass (EN 14605/EN 13034—"seven movements" sequence while wearing the suit)	Demonstration of garment functionality is included as part of the liquid integrity testing applied to garments (ASTM F1154)	

8.4.1.2 Head and shoe covers

In Colombia there are national standards specific for disposable head and shoe covers (typically used in health care settings). These are:

- NTC 6457:2020, "Disposable hats/caps," which includes requirements present in EN 14683 (medical face masks) such as splash-resistance and bacterial filtration efficiency, as well as requirements in EN 13795-1 (for surgical gowns), such as particle release and tensile strength
- NTC 6451:2020, "Disposable foot covers," which includes requirements present in EN 14683 (medical face masks) such as splash resistance, as well as requirements in EN 13795-1 (for surgical gowns), such as tensile strength.

Because of the above characteristics, comparison of requirements is not made against EU/US standards for protective clothing but against those for gowns (see also 8.4.2). As would be expected, only a few of the requirements for gowns apply to head and shoe covers because of their limited body coverage and less critical areas. It is also emphasized that surgical caps and shoe covers are excluded from the scope of the ANSI/AAMI PB70:2012 and ASTM F2407-20 standards valid in the United States. Therefore, the US column has limited use and is only retained for consistency of format.

Table 8.7 shows the requirements for head and shoe covers in the Colombian market compared to those of the EU and US markets.

Table 8.7: Comparison between EU, US, and Colombian standards for head and shoe covers

Notes:

For a more detailed comparison of EU and US standards (including test methods), see 4.4.2.3 of this guide.

For simplicity, only requirements related to barrier performance of gown materials and seams are specified.

Color code:

- Green: Products made to the Colombian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Colombian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Colombian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU** **EN 13795-1:2019** **Surgical gowns**	**Colombia** **NTC 6457:2020** **Head covers** **NTC 6451:2020** **Shoe covers**	**US** **ANSI/AAMI PB70:2012 (all gowns)** **ASTM F2407-20 (surgical gowns) and ASTM F3352-19 (isolation gowns)**	**COMPARISON/ COMMENTS**
Characteristic/property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Density of material	n/a	For head covers: ≥12 g/m² For shoe covers: ≥30 g/m²	n/a	1. Only a requirement in Colombia 2. The Colombian standards specify that non-woven fabrics must be used
Resistance to dry microbial penetration	≤ 300 CFU (less critical areas) *Note*: For critical product areas, wet bacterial penetration limits apply instead EN ISO 22612:2005	n/a	n/a	AAMI PB 70 standard specifically excludes dry microbial penetration from its scope
Resistance to wet bacterial penetration	I_B ≥ 2.8 (critical areas, standard performance) I_B = 6.0 (critical areas, high performance) EN ISO 22610:2006	n/a	n/a	US requires (only for Level 4) a stricter characteristic (viral penetration; see next row in table)
Viral penetration	n/a	n/a	Pass (AQL 4%, RQL=20%) (AAMI Level 4) ASTM F1671	
Cleanliness microbial/ bioburden	≤ 300 CFU/100 cm² EN ISO 11737-1:2018	n/a	n/a	
Particle release	Log_{10} (lint count) ≤ 4.0 EN ISO 9073-10:2004	For head covers: Log_{10} (lint count) ≤ 4.0 ISO 9073-10		Optional in the US **Note*: It is assumed that the requirement is also not applicable for shoe covers in the EU
	n/a *Note**	For shoe covers: n/a		

(Market) standard	**EU** **EN 13795-1:2019** **Surgical gowns**	**Colombia** **NTC 6457:2020** **Head covers** **NTC 6451:2020** **Shoe covers**	**US** **ANSI/AAMI PB70:2012 (all gowns)** **ASTM F2407-20 (surgical gowns) and ASTM F3352-19 (isolation gowns)**	**COMPARISON/ COMMENTS**
Characteristic/property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Water resistance (hydrostatic pressure)	≥ 20 cm H_2O (critical areas, std. performance) ≥ 100 cm H_2O (critical areas, high performance) ≥ 10 cm H_2O (less critical areas) EN ISO 811:2018	n/a	≥ 20 cm H_2O (AAMI Level 2) ≥ 50 cm H_2O (AAMI Level 3) (AQL 4%, RQL=20%) AATC 127	
Water resistance (impact penetration)	n/a	≥ 16kPa ISO 22609	≤ 4.5 g (AAMI Level 1) ≤ 1.0 g (AAMI Levels 2, 3) (AQL 4%, RQL=20%) AATC 42 or NWSP 80.3	Test in Colombian standard used as an alternate to splash resistance (see row below)
Splash resistance	n/a	≥ 16kPa ISO 18695	n/a	Alternatively, use the water impact penetration test above
Bacterial filtration efficiency (BFE)	n/a	For head covers: ≥ 90% NTC 1733 or EN 14683 For shoe covers: n/a	n/a	NTC is identical to EN; in the EU/US this requirement applies only to medical face masks
Tensile strength (dry) (wet)	≥ 20 N ≥ 20 N (critical areas) EN 29073-3:1992	≥ 20 N NTC 2600 or ISO 9073-3	≥ 30 N ASTM D5034	In the Colombian standards, testing only in dry state is performed; NTC 2600 is identical to ISO 9073-2
Biocompatibility	Pass EN ISO 10993-1:2009	For head covers: use materials compatible with skin For shoe covers: n/a	Pass ANSI/AAMI BE78 or ISO 10993-10	
Flammability	Manufacturer to provide fire risk information	n/a	Class 1 16 CFR 1610	

8.4.2 Gowns

The relevant Colombian Standard, NTC 5623:2020, "Surgical drapes and sheets—requirements and test methods. Part 1: Surgical drapes and gowns," is identical to EN 13795-1:2019 (current—for details on the EN, see 4.4.2.1). Table 8.8 shows the requirements for gowns in the Colombian market compared to those of the EU and US markets.

Table 8.8: Comparison between EU, US, and Colombian standards for gowns

Notes:

For a more detailed comparison of EU and US standards (including test methods), see 4.4.2.3 of this guide.

For simplicity, only requirements related to barrier performance of gown materials and seams are specified.

Color code:

- Green: Products made to the Colombian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Colombian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Colombian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU** **EN 13795-1:2019** **Surgical gowns**	**Colombia** **NTC 5623:2020** **Surgical gowns**	**US** **ANSI/AAMI PB70:2012 (all gowns)** **ASTM F2407-20 (surgical gowns) and ASTM F3352-19 (isolation gowns)**	**COMPARISON/ COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	NTC 5623 is an identical adoption of EN 13795-1
Resistance to dry microbial penetration	≤ 300 CFU (less critical areas) *Note*: For critical product areas, wet bacterial penetration limits apply instead EN ISO 22612:2005	≤ 300 CFU (less critical areas) *Note*: For critical product areas, wet bacterial penetration limits apply instead BS EN ISO 22612:2005	n/a	AAMI PB 70 standard specifically excludes dry microbial penetration from its scope
Resistance to wet bacterial penetration	I_B ≥ 2.8 (critical areas, standard performance) I_B = 6.0 (critical areas, high performance) EN ISO 22610:2006	I_B ≥ 2.8 (critical areas, standard performance) I_B = 6.0 (critical areas, high performance) EN ISO 22610:2006	n/a	US requires (only for Level 4) a stricter characteristic (viral penetration; see next row in table)
Viral penetration	n/a	n/a	Pass (AQL 4%, RQL=20%) (AAMI Level 4) ASTM F1671	
Cleanliness microbial/ bioburden	≤ 300 CFU/100 cm² EN ISO 11737-1:2018	≤ 300 CFU/100 cm² EN ISO 11737-1:2018	n/a	
Particle release	Log_{10} (lint count) ≤ 4.0 EN ISO 9073-10:2004	Log_{10} (lint count) ≤ 4.0 EN ISO 9073-10:2004		Optional in the US

(Market) standard	**EU** **EN 13795-1:2019** **Surgical gowns**	**Colombia** **NTC 5623:2020** **Surgical gowns**	**US** **ANSI/AAMI PB70:2012 (all gowns)** **ASTM F2407-20 (surgical gowns) and ASTM F3352-19 (isolation gowns)**	**COMPARISON/ COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	NTC 5623 is an identical adoption of EN 13795-1
Water resistance (hydrostatic pressure)	≥ 20 cm H_2O (critical areas, std. performance) ≥ 100 cm H_2O (critical areas, high performance) ≥ 10 cm H_2O (less critical areas) EN ISO 811:2018	≥ 20 cm H_2O (critical areas, std. performance) ≥ 100 cm H_2O (critical areas, high performance) ≥ 10 cm H_2O (less critical areas) EN ISO 811:2018	≥ 20 cm H_2O (AAMI Level 2) ≥ 50 cm H_2O (AAMI Level 3) (AQL 4%, RQL=20%) AATC 127	For critical areas/zones, US limits are the same as EU/Colombian ones (for standard performance) or lower (for high performance). Limits in the US apply only to critical zone components (akin to critical areas in EU/ Colombia). EU/Colombia and US methods are similar
Water resistance (impact penetration)	n/a	n/a	≤ 4.5 g (AAMI Level 1) ≤ 1.0 g (AAMI Levels 2, 3) (AQL 4%, RQL=20%) AATC 42 or NWSP 80.3	Limits in the US apply only to critical zone components (akin to critical areas in the EU/UK)
Bursting strength (dry) (wet)	≥ 40 kPa ≥ 40 kPa (critical areas) EN ISO 13938:1:1999	≥ 40 kPa ≥ 40 kPa (critical areas) EN ISO 13938:1:1999		
Tensile strength (dry) (wet)	≥ 20 N ≥ 20 N (critical areas) EN 29073-3:1992	≥ 20 N ≥ 20 N (critical areas) EN 29073-3:1992	≥ 30 N ASTM D5034	Higher limit in the US compared to the EU/UK. Additionally, limits are set for tear strength (≥ 10 N per ASTM D5587 or D5733) and seam strength (≥ 30 N per ASTM D1683/D1683M). Physical property limits are same for all barrier levels per AAMI
Biocompatibility	Pass EN ISO 10993-1:2009	Pass EN ISO 10993-1:2009	Pass ANSI/AAMI BE78 or ISO 10993-10	
Sterility	Packaging for terminally sterilized medical devices is recommended according to EN ISO 11607 series	Packaging for terminally sterilized medical devices is recommended according to EN ISO 11607 series	Assurance level of sterilization process: at least 10^{-6}	
Flammability	Manufacturer to provide fire risk information	Manufacturer to provide fire risk information	Class 1 16 CFR 1610	
Other criteria to consider	Comfort (depends on a variety of properties)	Comfort (depends on a variety of properties)	Optional: - Water vapor transmission rate (ASTM D6701) - Evaporative resistance (ASTM F1868, Part B) - etc.	

PART 9
PRODUCT-SPECIFIC COMPARISONS (INDIA)

9.1 Masks

9.1.1 Respirators

The applicable standard, IS 9473:2002 (reaffirmed 2019), "Respiratory protective devices—filtering half-masks to protect against particles—specification," is based on a previous edition (1991) of EN 149. EN 149 has since been revised in a 2001 edition and an amendment was issued in 2009. Table 9.1 shows the main product requirements for respirators in the Indian market compared to those of the EU and US markets.

Table 9.1: Comparison between EU, US, and Indian standards for respirators

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.1 of this guide.

Color code:

Green: Products made to the Indian standard are likely to meet or exceed the EU or US standard
Yellow: Products made to the Indian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
Red: Significantly different criteria—products made to the Indian standard are not likely to meet the EU or US standard and/or additional testing will be required
Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU** **EN 149:2001 +A1:2009, Classes FFP 2 and FFP 3**	**India** **IS 9473:2002, Classes FFP2 and FFP 3**	**US** **42 CFR Part 84, Series/ Levels N95 and N99**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	*Note*: Other classes of respirators are not included—not suitable for COVID-19 context
Practical performance	Pass	Pass	Pass	In the US, fit testing before use (required by OSHA, not NIOSH)
Total inward leakage	**FFP2** ≤ 11% (individual) ≤ 8% (mean)	**FFP2** ≤ 11% (individual) ≤ 8% (mean)	n/a	In the US, not specified in 42 CFR Part 84
	FFP3 ≤ 5% (individual) ≤ 2 % (mean)	**FFP3** ≤ 5% (individual) ≤ 2 % (mean)	n/a	In the US, not specified in 42 CFR Part 84

(Market) standard	**EU** **EN 149:2001 +A1:2009,** **Classes FFP 2 and FFP 3**	**India** **IS 9473:2002,** **Classes FFP2 and FFP 3**	**US** **42 CFR Part 84, Series/** **Levels N95 and N99**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	*Note*: Other classes of respirators are not included—not suitable for COVID-19 context
Filtering efficiency	**FFP2** ≥ 94% @ 95 L/min (NaCl and paraffin oil, EN 13274-7)	**FFP2** ≥ 94% @ 95 L/min (NaCl)—*Note* 1 ≥ 98% @ 95 L/min (paraffin oil)—*Note* 2	**N95** ≥ 95%@ 85 L/min (NaCl only)	*Note* 1: Specified as max penetration of 6% *Note* 2: Specified as max penetration of 2 % Different limits apply in India for NaCl and paraffin oil (stricter) aerosols Limits are close but not identical between India and the EU Unlike in the EN, method is directly contained in the Indian standard
	FFP3 ≥ 99% @ 95 L/min (NaCl and paraffin oil, EN 13274-7)	**FFP 3** ≥ 97% @ 95 L/min (NaCl)—Note 3 ≥ 99% @ 95 L/min (paraffin oil)—*Note* 4	**N99** ≥ 99% @ 85 L/min NaCl only)	*Note* 3: Specified as max penetration of 3% *Note* 4: Specified as max penetration 1% Different limits apply in India for NaCl and paraffin oil (stricter) aerosols Limits are close but not identical between India and the EU Unlike in the EN, method is directly contained in the Indian standard
Compatibility with skin	Pass	Pass	n/a	
Flammability	Pass	Pass	n/a	
Carbon dioxide content	Average ≤ 1% by volume in "dead space"	Average ≤ 1% by volume in "dead space"	n/a	
Field of vision	Pass	Pass	Pass	
Breathing resistance (inhalation)	**FFP2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min	**FFP2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min	**N95** ≤ 343 Pa @ 85 L/min	Performance criteria same and test methods similar between EU and India
	FFP 3 ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min	**FFP 3** ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min	**N99** ≤ 343 Pa @ 85 L/min)	Performance criteria same and test methods similar between EU and India
Breathing resistance (exhalation)	FFP2 and FFP3 ≤ 300 Pa @160 L/min	≤ 300 Pa @160 L/min	**N95 and N99** ≤ 245 Pa @ 85 L/min	Performance criteria same and test methods similar between EU and India

Respirators meant to be used in health care settings are regulated as medical devices (Class B) in India; see 3.7.1.

9.1.2 Medical face masks

The relevant standard is IS 16289:2014 (reaffirmed 2019), "Medical textiles—surgical face masks—specification." The scope of the standard covers not only masks used during surgical procedures, but also encompasses other health services. The standard defines three Classes (1, 2, and 3) of masks. Class 1 has min. 95 percent bacterial filtration efficiency (BFE), while Classes 2 and 3 have min. 98 percent BFE. Unlike in the United States, only the highest class (3) has splash-resistance properties, and it is also the only class where requirements for sub-micron particulate filtration efficiency are defined. The testing methods are defined in the standard itself with the exception of BFE testing, which is done according to IS 16288:2014 (reaffirmed 2019), similar to corresponding US/ISO methods.

Table 9.2 shows the requirements for medical face masks in the Indian market compared to those of the EU and US markets.

Table 9.2: Comparison between EU, US, and Indian standards for medical face masks

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.2 of this guide

Color code:

- Green: Products made to the Indian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Indian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Indian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 14683:2019 Types I, II and IIR**	**India IS 16289:2014 Classes 1, 2 and 3**	**US ASTM F2100–21 Levels 1, 2 and 3**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Bacterial filtration efficiency (BFE)	≥ 95% (Type I) ≥ 98% (Types II, IIR)	≥ 95% (Class 1) ≥ 98% (Classes 2, 3) Using IS 16288:2014	≥ 95% (Level 1) ≥ 98% (Levels 2,3) Using ASTM F2101	Essentially the same to both EU/US (for corresponding types)
Differential pressure	< 40 Pa/cm² (Type I, II) < 60 Pa/cm² (Types IIR) (Tested at 8L/min flowrate)	< 29.4 Pa/cm² (Classes 1, 2) < 49 Pa/cm² (Class 3) (Tested at 8L/min flowrate)	<49 Pa/cm² (Level 1) <58.8 Pa/cm² (Levels 2, 3) Using EN 14683	Indian standards are same or stricter than EU/US equivalents for different categories (that is, same or better breathability)
Sub-micron particulate filtration efficiency	n/a	Not required (Classes 1, 2) ≥ 98% (Class 3) Using latex spheres	≥ 95 (Level 1) ≥ 98 (Levels 2,3) Both at 0.1 micron, using ASTM F2299	Classes 1 and 2 of Indian standard not required to be tested; Class 3 has same requirements as US Level 3
Splash-resistance pressure	Not required (Types I, II) ≥ 16.0 kPa (Type IIR) Using ISO 22609:2004	Not required (Classes 1, 2) ≥16 kPa (Class 3) *Note* 1 Using ISO 22609:2004	≥ 10.7 kPa (Level 1) ≥16 kPa (Level 2) ≥21.4 kPa (Level 3) Using ASTM F1862	Note 1 - specified as ≥120 mm Hg
Microbial cleanliness	≤ 30 CFU/g Using EN ISO 11737-1:2018	n/a	n/a	

(Market) standard	EU EN 14683:2019 Types I, II and IIR	India IS 16289:2014 Classes 1, 2 and 3	US ASTM F2100–21 Levels 1, 2 and 3	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Biocompatibility	Pass Using ISO EN 10993-1:2009	n/a	Pass Using ISO 10993-1	
Flame spread	n/a	n/a	Class 1 Using 16 CFR Part 1610	

Medical face masks are regulated as medical devices (Class B) in India; see 3.7.1.

9.1.3 Community face coverings

There is not yet a relevant standard or specification in India (under development). Therefore, no comparison to EU or US requirements can be made.

9.2 Eye and face protection

IS 5983:1980 (reaffirmed in 2018), "Specification for eye protectors," is based on (but is not identical to) ISO 4849 "Personal eye protectors—specifications," ISO 4850 (welding applications), and ISO 4851 (protection against UV radiation). These three ISO standards were replaced in 2021 by the ISO 16321 series of standards (three parts). IS 5983 references two testing standards: IS 7524-1:1980 (reaffirmed 2018) for non-optical methods and IS 7524-2:1979 (reaffirmed 2018) for optical methods, based on ISO 4855 and ISO 4854, respectively. These ISO standards were replaced in 2020 by the ISO 18526 series of standards (four parts) and, following that, the IS 7524 series of standards (Parts 1 to 4) were issued/revised, being identical to the corresponding parts of ISO 18526. Nevertheless, in the table below, the previous editions of IS 7524-1 and IS 7524-2 are used, as they are dated references in IS 5983.

Additionally, there is another relevant product standard, IS 8521-1:1977 (reaffirmed 2018), "Specification for industrial face shields—Part I: With plastic visor." This standard, among others, contains requirements for impact and penetration resistance, flammability, and disinfection.

Table 9.3 shows the requirements for eye and face protection in the Indian market (using only IS 5983) compared to those of the EU and US markets.

Table 9.3: Comparison between EU, US, and Indian standards for eye and face protection

Notes:

- In general, requirements for lenses (only) have not been included.
- Requirements only for the following uses of eye protectors in the Indian standard are included: "general purpose" and "splashes."

For a more detailed comparison of EU and US standards (including test methods), see 4.2.1 of this guide.

Color code:

- Green: Products made to the Indian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Indian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Indian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 166:2001**	**India IS 5983:1980 (reaffirmed 2018)**	**US ANSI/ISEA Z87.1-2020**	**COMPARISON/COMMENTS**
Characteristic/property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Construction and materials	Pass		Pass (ANSI Z80.1)	
Headband	Pass	Width ≥ 10mm	n/a	
Basic (EU)/fundamental (US) requirements				Called "general requirements" in India
Field of vision	Pass (EN 168)	Temporal (downward) field of vision ≥50° (≥60°), respectively	Ellipse with axes ≥40 mm and ≥ 33mm	
Transmittance of oculars without filtering action	> 74.4% (EN 167)	Within limits for shade number 1.2	≥ 85% or ≥ 78% (if relaxed optics)	Limits/method not directly comparable with EU/US
Haze	n/a		≤3% (ASTM D1003-13)	
Increased robustness	Pass (EN 168)		Pass	
Thermal stability	Pass (EN 168)	Pass (Clause 3 of IS 7524-1)	n/a	Similar limits/method as in EU
Resistance to corrosion	Pass (EN 168)	Pass (Clause 6 of IS 7524-1)	Pass	As above
Resistance to ignition	Pass (EN 168)	Pass (Clause 8.1 of IS 7524-1)	Pass	Similar limits/method as in EU Requirement belongs to the specific requirements category below but is listed here for ease of comparison
Suitability for disinfection	n/a	Pass (Clause 7 of IS 7524-1)	n/a	An Indian requirement only
Particular requirements (per EU)				Called "specific requirements" in India
Droplets and splashes of liquid	No color present for goggles Face shields pass the area coverage (EN 168)	No color present for eye protectors (Clause 12 of IS 7524-1)	No color present for goggles Face shields pass the area coverage	Testing in IS also covers fine droplets
Lateral protection (optional)	Pass (EN 168)	Not an explicit requirement for the uses included	Pass	

Eye and face protection equipment meant to be used in health care settings are regulated as medical devices (Class A) in India; see 3.7.1.

9.3 Gloves

9.3.1 Medical examination gloves

There are two Indian standards for medical examination gloves: IS 15354-1:2018 (for gloves made of rubber/latex), identical to ISO 11193-1:2008 (now superseded by the 2020 edition) and IS 15354-2:2018 (for gloves made of PVC) which is identical to ISO 11193-2:2006. For details of the ISO standards, see 4.3.1.1.

For completeness, it is mentioned that in 2021 ISO standards on protective gloves were adopted in India as the IS 6994 series. In particular, IS 6994-5:2021 "Protective gloves against dangerous chemicals and micro-organisms—Part 5: Terminology and performance requirements for micro-organisms risks," is identical to ISO 374-5:2016 and IS 6994-7:2021, "Protective gloves—general requirements and test methods," is identical to ISO 21420:2020. As mentioned in section 4.3.1.1 on EU and ISO requirements for medical examination gloves, standards on "protective gloves" (as opposed to "medical gloves") will not be further detailed.

Table 9.4 shows the requirements for medical examination gloves in the Indian market compared to those of the EU and US markets.

Table 9.4: Comparison between EU, US, and Indian standards for medical examination gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.1 of this guide

Color code:

- Green: Products made to the Indian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Indian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Indian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 455 series**	**India Material specific IS 15354-1:2018 (rubber) IS 15354-2:2018 (PVC)**	**US ASTM—material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Freedom from holes	AQL =1.5 (EN 455-1:2020)	AQL =2.5	AQL =2.5 (ASTM D5151)	
Force at break (N) / Tensile strength (MPa), elongation at break (%) (Also, after ageing/ challenge)	Non-thermoplastic materials ≥6.0N Thermoplastic materials (PVC, PE) ≥ 3.6N (EN 455-2 :2015, method A of ISO 23529:2010)	AQL = 4.0 For rubber ≥ 6.0 N Elongation ≥ 500% (Type 1) and ≥ 400% (Type 2) For PVC ≥ 7.0 N Elongation ≥ 350%	AQL = 4.0 Nitrile ≥ 14MPa/elongation ≥400% Latex (natural) ≥ 14MPa / Elongation ≥ 500% Polychloroprene ≥ 14MPa/elongation ≥ 400% PVC ≥ 11MPa/elongation ≥ 300% (ASTM D412, ASTM D573 (ageing))	In the EU, instead of AQL, the median of 13 samples is used In general, the tensile properties and their limits specified in the Indian standards are an amalgam of the EU/US ones Indian and EU standards specify minimum absolute force (N) for Samples taken from the glove (varies with thickness); ASTM specifies in terms of tensile strength

(Market) standard	EU EN 455 series	India Material specific IS 15354-1:2018 (rubber) IS 15354-2:2018 (PVC)	US ASTM—material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Biocompatibility	Pass (EN ISO 10993-5 and -10)	No explicit requirements	Pass (FDA regulations)	
Powder residue content	≤ 2.0mg/glove (EN 455-3, EN ISO 21171:2006)	n/a	≤ 2.0mg/glove (powder-free gloves) ≤ 10 mg/dm² (powdered gloves) (ASTM D6124)	The requirement was first introduced in the 2020 edition of ISO 11193-1 while IS 15354-1 is based on the 2008 edition
Aqueous soluble protein content	"Manufacturer shall monitor the content in natural rubber latex gloves and shall try to minimize it" (EN 455-3)	n/a	≤ 200 µg/dm² Only for rubber gloves (ASTM D5712)	
Extractable antigenic protein content	Optional	n/a	≤ 10 µg/dm² Only for rubber gloves (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	If gloves are sterilized, the nature of the sterilization process shall be disclosed on request	Pass (US Pharmacopeia)	

Medical examination gloves are regulated as medical devices (Class A) in India: see 3.7.1.

9.3.2 Surgical gloves

IS 13422:1992 (reaffirmed 2018) is based on ASTM D3577-88 (the current edition is 2019). For details on the ASTM standard see 4.3.2.2. There is also IS 4148:1989 (reaffirmed 2017) on *reusable* surgical gloves. The main difference in the last standard is the testing of properties after autoclaving (for repeated sterilizations). Table 9.5 shows the requirements for surgical gloves in the Indian market (single-use only) compared to those of the EU and US markets.

Table 9.5: Comparison between EU, US, and Indian standards for surgical gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.2.3 of this guide

Color code:

- Green: Products made to the Indian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Indian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Indian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 455 series**	**India IS 13422:1992 (reaffirmed 2018)**	**US ASTM D3577-19 Type 1: Natural rubber Type 2: Synthetic rubber**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Freedom from holes	AQL = 0.65 (EN 455-1:2020)	*Note**	AQL = 1.5 (ASTM D5151)	**Note*: Instead of AQL, IS 13422 specifies sample sizes and acceptance numbers for various lots Instead of watertightness (most commonly used today) IS 13422 specifies air tightness
Force at break (N) Tensile strength (MPa), elongation (%) (Also, after ageing/challenge)	All materials ≥ 9.0N (EN 455-2 :2015, method A of ISO 23529:2010)	Type 1: Latex (natural) ≥18MPa/elongation ≥560% Type 2: Synthetic rubber ≥12Mpa/elongation ≥490%	AQL = 4.0 Type 1: Latex (natural) ≥18MPa/elongation ≥560% Type 2: Synthetic rubber ≥12Mpa/elongation ≥490% (ASTM D412, ASTM D573 (ageing))	In the EU, instead of AQL, the median of 13 samples is used In general, the tensile properties and their limits specified in the Indian standards are an amalgam of the EU/US ones EU standards specify minimum absolute force (N) for samples taken from the glove (varies with thickness); ASTM and IS standards specify in terms of tensile strength (MPa—force per unit area)
Biocompatibility	Pass (EN ISO 10993-5 and -10)	No explicit requirements	Pass (FDA regulations)	
Powder residue content	≤ 2.0 mg/glove (EN 455-3, EN ISO 21171:2006)	No explicit requirements	≤ 2.0mg/glove (ASTM D6124)	
Aqueous soluble protein content	"Manufacturer shall monitor the content in NRL gloves and shall try to minimize it" (EN 455-3, Annex A)	No explicit requirements	≤ 200 µg/dm² (ASTM D5712)	
Extractable antigenic protein content	Optional (EN 455-3, Annex B)	No explicit requirements	≤ 10 µg/dm² (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	According to Indian Pharmacopeia	Pass (US Pharmacopeia)	

Surgical gloves are regulated as medical devices (Class B) in India; see 3.7.1.

9.4 Clothing

9.4.1 Full-body and partial-body garments (other than surgical/isolation gowns)

IS 17423:2020, "Medical textiles—coveralls for COVID-19—specification," was developed rapidly to meet the urgent needs of the COVID-19 pandemic and had performance requirements only for blood resistance. It was revised in October 2021 and renamed "Medical textiles—bio-protective coveralls—specification," while the 2020 edition may continue to be used for some time. The revised standard incorporates some characteristics of the standard for surgical gowns, IS 17334:2019, discussed in section 9.4.2. The scope of IS 17423 has been modified to include multiple use/reusable bio-protective coveralls. As for surgical gowns, four levels of performance are defined for bio-protective coveralls. Coveralls may or may not be supplied in a sterile package.

In addition to IS 17423, there is also the standard IS 15071:2002 (reaffirmed 2014) on chemical protective clothing which is a largely design-oriented standard including protection Type 4 but not directly relatable to EN/ISO standards. This standard is not included in the comparison as it does not address protection against infective agents. Table 9.6 shows the requirements for protective clothing in the Indian market compared to those of the EU and US markets.

Table 9.6: Comparison between EU, US, and Indian standards for protective clothing

(bio-protective coveralls)

Notes:

- For a more detailed comparison of EU and US standards (including test methods), see 4.4.1 of this guide.
- For simplicity, only requirements for materials and whole suits are included (that is, requirements for seams, joins, assemblages, and integral components, such as visors, are not included).
- For protection against infective agents only the following protection types, as defined in the standards, are considered here: Type 4 (spray-tight), Type PB [4] (partial-body protection— Type 4), Type 6 (limited protection against liquid chemicals) and Type PB [6] (partial-body protection—Type 6)

Color code:

- Green: Products made to the Indian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Indian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Indian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

Market	**EU**	**India**	**US**	**COMPARISON/ COMMENTS**
Property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
I. General requirements	**EN ISO 13688:2013+A1:2021**	**IS 17423:2021 Levels 1 to 4**	**NFPA 1999:2018**	
Innocuousness	No harmful substances present No azo dyes present	Made from non-irritant material	No specific requirements	

Market	EU	India	US	COMPARISON/ COMMENTS
Property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Design and comfort	Acceptable (Annex C)	Meets manufacture requirements of Clause 4 (coverall with integrated hood, shoe covers, and so on) Water vapor transmission rate ≥1200 g/(m²24 h) for Levels 1 and 2 ≥ 800 g/(m²24 h) for Levels 3 and 4 (Annex F, IS 16390)	Acceptable (section 6.1) *Note*: Design requirements only ≥650 g/(m²24 h) *Note*: In the US for single-use garments/ ensembles "moisture vapor transmission rate" is specified (section 8.28 and ASTM E96) ≥450 W/m² *Note*: In the US, for multiple-use garments/ensembles "total heat loss test" is specified (section 8.32 and ASTM F1868)	
II. Protection against infective agents	**EN 14126:2003 & EN 14605:2005+A1:2009 (for Types 4 and PB [4]) or EN 13034:2005+A1:2009 (for Types 6 and PB [6])**	**No requirements in IS**	**NFPA 1999:2018**	
1. Materials requirements				
a) Mechanical		**No requirements for mechanical properties**		
Abrasion resistance	Class 1 to 6 (highest) (cl. 4.4 of EN 14325 & EN ISO 12947-2)	n/a	Abrasion resistance is considered as a precondition to barrier performance of materials (ASTM D4157)	
Flex cracking resistance	Class 1 to 6 (highest) (cl. 4.5, 4.6 EN 14325 & EN ISO 7854, method B)	n/a	Flex fatigue is considered as a precondition to barrier performance of materials (ASTM F392)	
Trapezoidal tear resistance	Class 1 to 6 (highest) (EN 14325 & EN ISO 9073-4:1997)	n/a	Single-use: "Tear-resistance test two" ≥17 N (section 8.38 and ASTM D5733 for non-woven) Multiple-use: "Tear-resistance test one" ≥36 N (section 8.7 and ASTM D5587 for woven)	
Tensile strength	Class 1 to 6 (highest) (cl. 4.9 of EN 14325 & EN ISO 13934-1)	≥ 20 N for Levels 1 and 2 ≥ 40 N for Levels 3 and 4 (both dry and wet) (IS 15891 Part 3 for non-woven, IS 1969 Part 1 for woven)	≥50 N (section 8.4 and ASTM D5034) Also bursting strength: ≥66N (single-use) ≥222.5N (multiple-use) (section 8.5 and ASTM D3787)	
Bursting strength	n/a	≥ 40 kPa for Level 1 to 4 (both dry and wet) (IS 1966 [Part 1])	≥66N (single-use) ≥222.5N (multiple-use) (section 8.5 and ASTM D3787)	Bursting strength was eliminated in EU
Puncture resistance	Class 1 to 6 (highest) (cl. 4.10 of EN 14325 and EN 863)	n/a	≥12N (single-use) ≥25N (multiple-use) (section 8.6 and ASTM D2572)	
b) Chemical resistance		**No requirements for chemical resistance properties**		

Market	EU	India	US	COMPARISON/ COMMENTS
Property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Permeation by chemicals (applicable to Types 4 and PB [4])	Class 1 to 6 (highest) (EN ISO 6529, method A for liquids)	n/a		
Repellency to liquids (applicable to Types 6 and PB[6])	Class 1 to 3 (highest) (ISO 6530)	n/a	≤30% (section 8.31)	In the US it is called "water-absorption resistance test"; it applies only to multiple-use garments/ensembles
Penetration by liquids (applicable to Types 6 and PB [6])	Class 1 to 3 (highest) (ISO 6530)	n/a		
c) Flammability		No requirements for flammability		
Resistance to ignition or flame (more stringent)	Pass or min. class 1 (cl. 4.14 EN 14325 & EN 13274-4, method 3)	n/a	Flame spread time ≥3.5 s (section 8.39 and ASTM D1230)	
d) Penetration by infective agents				
Contaminated liquids under hydrostatic pressure	Class 1 to 6 (highest) (cl. 4.1.4.1 of EN 14126, ISO 16603, and ISO 16604)	Synthetic blood penetration resistance: Pass. Use procedure D of IS 16546 (for pressure cycle up to 1.75 kPa for Level 1, 3.5kPa for Level 2, 7 kPa for Level 3) Viral penetration resistance: n/a for Levels 1 and 2, pass (for pressure cycle up to 3.5 kPa for level 3, 7 kPa for Level 4). Use procedure D of IS 16545	Pass *Note*: In the US the "bio-penetration test one" applies (section 8.3 and ASTM F1671)	IS 16546 is identical to ISO 16603 *Note*: Compared to the 2020 edition of IS 17423, testing per IS 16545 (identical to ISO 16604-bloodborne pathogens) is specified for Levels 3 and 4
Mechanical contact with contaminated liquids (wet bacterial penetration)	Class 1 to 6 (highest) (cl. 4.1.4.2 of EN 14126 and EN ISO 22610)	n/a	n/a	
(Biologically) contaminated liquid aerosols	Class 1 to 3 (highest) (cl. 4.1.4.3 of EN 14126)	n/a	n/a	
Contaminated solid particles (dry microbial penetration)	As above (cl. 4.1.4.4 of EN 14126 and ISO 22612)	n/a for Levels 1 and 2 log (CFU) < 1 for Levels 3 and 4 (IS 16548)	n/a	
e) Other properties				

Market	**EU**	**India**	**US**	**COMPARISON/ COMMENTS**
Property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Cleanliness-microbial	n/a	≤ 300 CFU/100 cm^2 (ISO 11737-1)	n/a	Same limits/method as for surgical gowns Can be also supplied in sterile packaging (in which case, the listed IS/ISO standards and Medical Device Rule, 2017 have to be followed)
Biocompatibility	n/a	No cytotoxicity (IS/ISO 10993-5) Non-irritant and non-sensitizer (IS/ISO 10993-10)	n/a	Same limits/method as for surgical gowns
2. Whole-suit requirements		No requirements for whole suits		
Mist test (Type 6)	Pass (EN ISO 17491-4 (method A) as modified by cl. 5.2 of EN 13034)	n/a	Pass (section 8.2) *Note*: In the US the "liquid tight integrity test one" applies	
Liquid spray test (Type 4)	Pass (cl. 4.3.4.2 etc. of EN 14605 and EN ISO 17491-4 [method B])	n/a	Pass (section 8.2)	
Practical performance	Pass (EN 14605/EN 13034—"seven movements" sequence while wearing the suit)	n/a	Demonstrate garment functionality is included as part of the liquid integrity testing applied to garments (ASTM F1154)	

9.4.2 Gowns

The relevant standard in India is IS 17334:2019, "Medical textiles—surgical gowns and surgical drapes—specification." IS 17334 specifies characteristics from both the EN and US standards. In it, gowns of Level 0 to 3 are defined, roughly corresponding to Level 1 to 4 in the United States.

Table 9.7 shows the requirements for gowns in the Indian market compared to those of the EU and US markets.

Table 9.7: Comparison between EU, US, and Indian standards for gowns

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.4.2.3 of this guide.

Color code:

- Green: Products made to the Indian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Indian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Indian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing methods are only mentioned separately when they are not defined in the product standard.

(Market) standard	**EU EN 13795-1:2019 Surgical gowns**	**India IS 17334:2019 Surgical gowns**	**US ANSI/AAMI PB70:2012, ASTM F2407-20 (surgical gowns) and ASTM F3352-19 (isolation gowns)**	**COMPARISON/ COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Resistance to dry microbial penetration	≤ 300 CFU (less critical areas) (EN ISO 22612:2005)	≤ 300 CFU (Level 1) ≤ 300 CFU (Level 2, for less critical zones) (IS 16548)	n/a	Similar limits/method as in EU
Resistance to wet bacterial penetration	I_B ≥ 2.8 (critical areas, standard performance) I_B = 6.0 (critical areas, high performance) (EN ISO 22610:2006)	I_B = 6.0 (for critical zones), Level 2 (IS 16549)	n/a	
Viral/blood penetration	n/a	Pass (Level 3) IS 16546 (blood) Pass (Level 3) IS 16545 (viral)	Pass (AQL 4%, RQL=20%) (AAMI Level 4) (ASTM F1671)	Additional "blood-resistance" test compared to US where only "viral resistance" is needed
Cleanliness microbial/ bioburden	≤ 300 CFU/100 cm² (EN ISO 11737-1:2018)	≤ 300 CFU/100 cm² (ISO 11737-1)	n/a	Same limits/method as in EU
Particle release	Log_{10} (lint count) ≤ 4.0 (EN ISO 9073-10:2004)	Log_{10} (lint count) ≤ 4.0 (IS 15891-10)	Optional	Limits same as in EU (method similar to EN ISO)
Water resistance (hydrostatic pressure)	≥ 20 cm H_2O (critical areas, standard performance) ≥ 100 cm H_2O (critical areas, high performance) ≥ 10 cm H_2O (less critical areas) (EN ISO 811:2018)	≥ 20 cm H_2O (Level 1) ≥ 50 cm H_2O (Level 2) (ISO 811)	≥ 20 cm H_2O (AAMI Level 2) ≥ 50 cm H_2O (AAMI Level 3) (AQL 4%, RQL=20%) (AATC 127)	Limits same as for the US (same method as in EU)

(Market) standard	**EU** **EN 13795-1:2019** **Surgical gowns**	**India** **IS 17334:2019** **Surgical gowns**	**US** **ANSI/AAMI PB70:2012, ASTM F2407-20 (surgical gowns) and ASTM F3352-19 (isolation gowns)**	**COMPARISON/ COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Water resistance (impact penetration)	n/a	≤ 4.5 g (Level 0) (ISO 16895)	≤ 4.5 g (AAMI Level 1) ≤ 1.0 g (AAMI Levels 2 and 3) (AQL 4%, RQL=20%) (AATC 42 or NWSP 80.3)	
Bursting strength (dry) (wet)	≥ 40 kPa ≥ 40 kPa (critical areas) (EN ISO 13938:1:1999)	≥ 40 kPa (both dry and wet) (IS 1966 Part 1)	n/a	Same limits as in the EU
Tensile strength (dry) (wet)	≥ 20 N ≥ 20 N (critical areas) (EN 29073-3:1992)	≥ 20 N (both dry and wet) (IS 15891 Part 3 for non-woven; IS 1969 Part 1 for woven)	≥ 30 N (ASTM D 5034)	
Biocompatibility	Pass (EN ISO 10993-1:2009)	Pass (IS/ISO 10993-5 IS/ISO 10993-10)	Pass (ANSI/ AAMI BE78 or ISO 10993-10)	Similar methodology as in EU/US
Sterility	Packaging for terminally sterilized medical devices is recommended according to EN ISO 11607 series	For packaging and sterilization, the Medical Device Rule, 2017 shall be followed	Assurance level of sterilization process: at least 10^{-6}	
Flammability	Manufacturer to provide fire risk information		Class 1 (16 CFR 1610)	
Other criteria to consider	Comfort (depends on a variety of properties)		Optional: - Water vapor transmission Rate (ASTM D6701) - Evaporative resistance (ASTM F1868, Part B)	

PART 10 PRODUCT-SPECIFIC COMPARISONS (JORDAN)

As indicated in section 3.8, some Jordanian standards are denominated as "technical standards" making their application mandatory (equivalent to "technical regulations").

10.1 Masks

10.1.1 Respirators

There is a Jordanian "technical (mandatory) standard," JS 1937:2011, **"**Respiratory protective devices—valved filtering half-masks to protect against gases or gases and particles—requirement, testing, marking," identical to EN 405:2001+A1:2009. However, this standard covers respirators other than the FFP class, which is typically used in situations where user protection in health care settings is desired.

The applicable Jordanian standard, JS 1943:2011, "Respiratory protective devices-filtering half masks to protect against particles—requirements, testing and marking" is identical to EN 149:2001 (without the amendment A1 that was issued in the EU in 2009). Table 10.1 shows the requirements for respirators in the Jordanian market compared to those of the EU and US markets.

Table 10.1: Comparison between EU, US, and Jordanian standards for respirators

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.1 of this guide

Color code:

- Green: Products made to the Jordanian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Jordanian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Jordanian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	EU EN 149:2001 +A1:2009, Classes FFP2 and FFP3	Jordan JS 1943:2011, Classes FFP2 and FFP3	US 42 CFR Part 84, Series/Levels N95 and N99	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Practical performance	Pass (based on two subjects performing various tasks)	Pass (based two subjects performing various tasks)	Fit testing before use (required by OSHA, not NIOSH)	

(Market) standard	EU EN 149:2001 +A1:2009, Classes FFP2 and FFP3	Jordan JS 1943:2011, Classes FFP2 and FFP3	US 42 CFR Part 84, Series/Levels N95 and N99	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Total inward leakage	**FFP2** ≤ 11% (individual) ≤ 8% (mean)	**FFP2** ≤ 11% (individual) ≤ 8% (mean)	Not specified	
	FFP3 ≤ 5% (individual) ≤ 2 % (mean)	**FFP3** ≤ 5% (individual) ≤ 2 % (mean)	Not specified	
Filtering efficiency	**FFP2** ≥ 94% @ 95 L/min (NaCl and paraffin oil—EN 13274-7)	**FFP2** ≥ 94% @ 95 L/min (NaCl and paraffin oil)	**N95** ≥ 95% @ 85 L/min (NaCl only)	In Jordan, as in the EU, penetration of filtering material, is specified (100%-filtering efficiency) There are some variations between the JS 1943 and EN test method requirements; the JS requires testing according to EN 143, while testing specified by EN 149 (as amended in 2009) is according to EN 13274-7
	FFP3 ≥ 99% @ 95 L/min (NaCl and paraffin oil—EN 13274-7)	**FFP3** ≥ 99% @ 95 L/min (NaCl and paraffin oil)	**N99** ≥ 99% @ 85 L/min (NaCl only)	
Compatibility with skin	Pass	Pass	n/a	
Flammability	Pass	Pass	n/a	
Carbon dioxide content	Average ≤ 1% by volume in "dead space"	Average ≤ 1% by volume in "dead space"	n/a	
Field of vision	Pass (in the practical performance test)	Pass (in the practical performance test)	Pass	
Breathing resistance (inhalation)	**FFP2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min	**FFP2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min	**N95** ≤ 343 Pa @ 85 L/min	
	FFP 3 ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min	**FFP 3** ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min	**N99** ≤ 343 Pa @ 85 L/min	
Breathing resistance (exhalation)	**FFP2 and FFP3** ≤ 300 Pa @160 L/min	**FFP2 and FFP3** ≤ 300 Pa @160 L/min	**N95 and N99** ≤ 245 Pa @ 85 L/min	

10.1.2 Medical face masks

The Jordanian technical standard for medical face masks is JS 1745:2007, "Disposable surgical masks-requirement and test methods." The standard is based on EN 14683:2005 (since revised). There is also a draft technical standard, WD 115:2022, which will be aligned to the current EN 14683:2019.

Additionally, two Jordanian standards that adopt ASTM testing methods for face masks exist:

- JS 1753:2022 equivalent to ASTM F1862:2017 (splash resistance)
- JS 1754:2022 equivalent to ASTM F2101:2019 (BFE testing method)

Table 10.2 shows the requirements for medical face masks in the Jordanian market compared to those of the EU and US markets.

Table 10.2: Comparison between EU, US and Jordanian standards for medical face masks

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.2 of this guide.

Color code:

- Green: Products made to the Jordanian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Jordanian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Jordanian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 14683:2019 Types I, II and IIR**	**Jordan JS 1745:2007 Types I, II and IIR**	**US ASTM F2100–21 Levels 1, 2 and 3**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Tensile strength of strap	n/a	≥20 N	n/a	Only a requirement in Jordan (dimensional limits also apply)
Dimensions	n/a	For adults: Width: 170 – 195 mm Depth: 90 – 100 mm	n/a	Other limits apply for young children and children; additional design requirements apply
Bacterial filtration efficiency (BFE)	≥ 95% (Types I) ≥ 98% (Types II, IIR)	≥ 95% (Type I) ≥ 98% (Types II, IIR)	≥ 95% (Level 1) ≥ 98% (Levels 2,3) Using ASTM F2101	
Differential pressure	< 40 Pa/cm² (Types I, II) < 60 Pa/cm² (Type IIR) (Tested at 8L/min flowrate)	< 40 Pa/cm² (Types I, II) < 60 Pa/cm² (Type IIR) (Tested at 8L/min flowrate)	<49 Pa/cm² (Level 1) <58.8 Pa/cm² (Levels 2, 3) Using EN 14683	
Sub-micron particulate filtration efficiency	n/a	n/a	≥ 95 (Level 1) ≥ 98 (Levels 2,3) Both at 0.1 micron, using ASTM F2299	

(Market) standard	EU EN 14683:2019 Types I, II and IIR	Jordan JS 1745:2007 Types I, II and IIR	US ASTM F2100–21 Levels 1, 2 and 3	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Splash-resistance pressure	Not required (Types I, II) ≥ 16. 0 kPa (Type IIR) Using ISO 22609:2004	Not required (Types I, II) ≥ 16 kPa (Type IIR) Using ISO 22609	≥ 14.7 kPa (Level 1) ≥16 kPa (Level 2) ≥21.4 kPa (Level 3) Using ASTM F1862	
Microbial cleanliness	≤ 30 CFU/g Using EN ISO 11737-1:2018	≤ 30 CFU/g Using ISO 11737-1	n/a	
Biocompatibility	Pass Using ISO EN 10993-1:2009	Pass Using ISO 10993-1	Pass Using ISO 10993-1	
Flame spread	n/a	n/a	Class 1 Using 16 CFR Part 1610	

10.1.3 Community face coverings

In Jordan, there is currently a normative document under development,[64] FDJS 2339:2022, based on ASTM F3502-21 (for details on the ASTM standard, see 4.1.3.2). As a result, no comparison to EU or ASTM standards can be made at this time.

64 February 2022. Communication with JSMO.

10.2 Eye and face protection

The relevant technical standard, JS 268:2008, "Personal eye protection—specifications," is an identical adoption of EN 166 (for details, see 4.2.1). Table 10.3 shows the requirements for eye and face protection in the Jordanian market compared to those of the EU and US markets.

Table 10.3: Comparison between EU, US, and Jordanian standards for eye and face protection

Notes:

- In general, requirements for lenses (only) have not been included.
- For a more detailed comparison of EU and US standards (including test methods), see 4.2.1 of this guide.

Color code:

- Green: Products made to the Jordanian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Jordanian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Jordanian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 166:2001**	**Jordan JS 268:2002**	**US ANSI/ISEA Z87.1:2020**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/testing method**	JS is an identical adoption of EN 166
Construction and materials	Pass	Pass	Pass (ANSI Z80.1)	
Headband	Pass	Pass	n/a	
Basic (EU)/ fundamental (US) requirements				
Field of vision	Pass (EN 168)	Pass (EN 168)		
Min. coverage area	Not a requirement, except for special uses	Not a requirement, except for special uses	Ellipse with axes ≥40 mm and ≥ 33 mm	
Transmittance of oculars without filtering action	> 74.4% (EN 167)	> 74.4% (EN 167)	≥ 85% (or ≥ 78% if relaxed optics)	
Haze	n/a	n/a	≤3% (ASTM D1003-13)	
Increased robustness	Pass (EN 168)	Pass (EN 168)	Pass	
Thermal stability	Pass (EN 168)	Pass (EN 168)	n/a	
Resistance to corrosion	Pass (EN 168)	Pass (EN 168)	Pass	
Resistance to ignition	Pass (EN 168)	Pass (EN 168)	Pass	
Particular requirements (EU)				

(Market) standard	**EU EN 166:2001**	**Jordan JS 268:2002**	**US ANSI/ISEA Z87.1:2020**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/testing method**	JS is an identical adoption of EN 166
Droplets and splashes of liquid	No color present for goggles Face shields pass the area coverage test (EN 168)	No color present for goggles Face shields pass the area coverage test (EN 168)	No color present for goggles Face shields pass the area coverage test	
Lateral protection (optional)	Pass (EN 168)	Pass (EN 168)	Pass	
Optional requirements (EU)				
Resistance to fogging (only for oculars, not complete eye protectors)	Time without fogging ≥ 8 s (EN 168)	Time without fogging ≥ 8 s (EN 168)	Time without fogging ≥ 8 s	US requirement added in the 2020 edition

10.3 Gloves

10.3.1 Medical examination gloves

The relevant technical standards are the JS 809 series adopting the EN 455 series:

- JS 809-1:2005 adopting EN 455-1:2000. "Medical gloves for single use—Part 1: requirements and testing for freedom from holes" (not the latest version)
- JS 809-2:2014 adopting EN 455-2:2009, "Medical gloves for single use—Part 2: requirements and testing for physical properties" (not the latest version)
- JS 809-3:2014 adopting EN 455-3:2006, "Medical gloves for single use—Part 3: requirements and testing for biological evaluation" (not the latest version)
- JS 809-4:2014 adopting EN 455-4:2009, "Medical gloves for single use—Part 4: requirements and testing for shelf-life determination" (current)

The Jordanian standards apply to surgical gloves and to medical examination gloves. This situation is true in the EU/UK as well, and it differs from the approach taken in ISO or ASTM standards where distinct standards apply for the two uses and different standards cover various materials of construction.

Table 10.4 shows the requirements for medical examination gloves in the Jordanian market compared to those of the EU and US markets.

Table 10.4: Comparison between EU, US, and Jordanian standards for medical examination gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.1 of this guide

Color code:

- Green: Products made to the Jordanian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Jordanian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Jordanian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 455 series**	**Jordan JS 809 series**	**US ASTM—material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Freedom from holes	AQL =1.5 (EN 455-1:2020)	AQL =1.5	AQL =2.5 (ASTM D5151)	
Force at break (N) / Tensile strength (MPa), elongation at break (%) (Also, after ageing/ challenge)	Non-thermoplastic materials ≥6.0N Thermoplastic materials (PVC, PE) ≥ 3.6N (EN 455-2 :2015, method A of ISO 23529:2010)	Non-thermoplastic materials ≥6.0N Thermoplastic materials (PVC, PE) ≥ 3.6N (JS 809-2:2014, method A of ISO 23529:2010)	AQL = 4.0 Nitrile ≥ 14MPa/elongation ≥400% Latex (natural) ≥ 14MPa / Elongation ≥ 500% Polychloroprene ≥ 14MPa/elongation ≥ 400% PVC ≥ 11MPa/elongation ≥ 300% (ASTM D412, ASTM D573 (ageing))	
Biocompatibility	Pass (EN ISO 10993-5 and -10)	Pass (ISO 10993-5 and -10)	Pass (FDA regulations)	
Powder residue content	≤ 2.0mg/glove (EN 455-3, EN ISO 21171:2006)	≤ 2.0 mg/glove	≤ 2.0mg/glove (powder-free gloves) ≤ 10 mg/dm² (powdered gloves) (ASTM D6124)	
Aqueous soluble protein content	"Manufacturer shall monitor the content in natural rubber latex gloves and shall try to minimize it" (EN 455-3)	"ALARP" (as low as reasonably possible)	≤ 200 µg/dm² Only for rubber gloves. (ASTM D5712)	JS 809-3 is in line with the 2006 edition of EN 455-3 (was more stringent than current version)
Extractable antigenic protein content	Optional (EN 455-3, Annex B)	Optional (JS 809-3, Annex B)	≤ 10 µg/dm² (ASTM D6499)	

(Market) standard	EU EN 455 series	Jordan JS 809 series	US ASTM—material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	JS 809-4 refers to ISO 11607 (sterile barrier integrity during shelf-life)	Pass (US Pharmacopeia)	

10.3.2 Surgical gloves

As mentioned in section 10.3.1, surgical gloves in Jordan comply with the JS 809 series of technical standards, which also covers medical examination gloves.

Table 10.5 shows the requirements for surgical gloves in the Jordanian market compared to those of the EU and US markets.

Table 10.5: Comparison between EU, US, and Jordanian standards for surgical gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.2 of this guide.

Color code:

- Green: Products made to the Jordanian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Jordanian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Jordanian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	EU EN 455 series	Jordan JS 809 series	US ASTM D3577-19 Type 1: Natural rubber Type 2: Synthetic Rubber	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Freedom from holes	AQL = 0.65 (EN 455-1:2020)	AQL = 1.5	AQL = 1.5 (ASTM D5151)	The 2020 edition of EN 455-1 has stricter AQL than JS 809-1
Force at break (N) / Tensile strength (MPa), elongation (%) (Also, after ageing/ challenge)	All materials ≥ 9.0N (EN 455-2:2015, method A of ISO 23529:2010)	All materials ≥ 9.0N (JS 809-2, method A of ISO 23529:2010)	AQL = 4.0 Type 1: Latex (natural) ≥18MPa/elongation ≥560% Type 2: Synthetic rubber ≥12Mpa/elongation ≥490% (ASTM D412, ASTM D573 (ageing))	
Biocompatibility	Pass (EN ISO 10993-5 and -10)	Pass (ISO 10993-5 and -10)	Pass (FDA regulations)	
Powder residue content	≤ 2.0 mg/glove (EN 455-3, EN ISO 21171:2006)	≤ 2.0 mg/glove (JS 809-3)	≤ 2.0mg/glove (ASTM D6124)	

(Market) standard	EU EN 455 series	Jordan JS 809 series	US ASTM D3577-19 Type 1: Natural rubber Type 2: Synthetic Rubber	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Aqueous soluble protein content	"Manufacturer shall monitor the content in NRL gloves and shall try to minimize it" (EN 455-3, Annex A)	"ALARP" (as low as reasonably possible)	≤ 200 µg/dm² (ASTM D5712)	JS 809-3 is in line with the 2006 edition of EN 455-3 (was more stringent than current version)
Extractable antigenic protein content	Optional (EN 455-3, Annex B)	Optional (JS 809-3, Annex B)	≤ 10 µg/dm² (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	JS 809-4 refers to ISO 11607 (sterile barrier integrity during shelf-life)	Pass (US Pharmacopeia)	

10.4 Clothing

10.4.1 Full-body and partial-body garments (other than surgical/isolation gowns)

The Jordanian technical standard that could be identified is JS 1899:2009, "Protective clothing for protection against chemicals—classification, labeling and performance requirements," identical to ISO 16602:2007, since amended in 2012. No adoptions of ISO 13688, "Protective clothing—general requirements," or the EN series on chemical/infective agent protection (EN 14126, EN 14325, EN 13034, and EN 14605) were found. Similarly, the test method standards ISO 16603 (synthetic blood penetration) and ISO 16604 (bacteriophage method) have not been adopted.

Table 10.6 shows the requirements for protective clothing in the Jordanian market compared to those of the EU and US markets.

Table 10.6: Comparison between EU, US, and Jordanian standards for protective clothing

Notes:

For a more detailed comparison of EU and US standards (including test methods), see 4.4.1 of this guide.

For simplicity, only requirements for materials and whole suits are included (that is, requirements for seams, joins, assemblages, and integral components, such as visors, are *not* included).

For protection against infective agents only the following protection types, as defined in the standards, are considered here: Type 4 (spray-tight), Type PB [4] (partial-body protection— Type 4), Type 6 (limited protection against liquid chemicals) and Type PB [6] (partial-body protection— Type 6).

Color code:

- Green: Products made to the Jordanian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Jordanian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Jordanian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

Market	**EU**	**Jordan**	**US**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	
I. General requirements	**EN ISO 13688:2013+A1:2021**	**No requirements**	**NFPA 1999:2018**	No Jordanian standard could be identified that is similar to ISO 13688 (general requirements)
Innocuousness	No harmful substances present No azo dyes present	n/a	No specific requirements	
Design & comfort	Acceptable (Annex C)	n/a	Acceptable (section 6.1) *Note*: Design requirements only ≥650 g/(m²24 h) *Note*: In the US, for single-use garments/ensembles "moisture vapor transmission rate" is specified (section 8.28 and ASTM E96) ≥450 W/m² *Note*: In the US for multiple-use garments/ensembles "total heat loss test" is specified (section 8.32 and ASTM F1868)	
II. Protection against infective agents	**EN 14126:2003 & EN 14605:2005+A1:2009 (for Type 4 and PB [4]) or EN 13034:2005+A1:2009 (for Types 6 and PB [6])**	**JS 1899:2009**	**NFPA 1999:2018**	JS 1899 (ISO 16602) is really about protective clothing against chemicals—not against infective agents Requirements on mechanical properties and chemical resistance of materials are included, as well as whole-suit requirements No Jordanian standard could be identified similar to EN 14126 (protection against infective agents)
1. Materials requirements				

Market	EU	Jordan	US	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	
a) Mechanical				
Abrasion resistance	Class 1 to 6 (highest) (cl. 4.4 of EN 14325 & EN ISO 12947-2)	Class 1 to 6 (highest) (ISO 12947-2)	Abrasion resistance is considered as a precondition to barrier performance of materials (ASTM D4157)	EU/JS: Same limits/essentially same method
Flex cracking resistance	Class 1 to 6 (highest) (cl. 4.5, 4.6 EN 14325 and EN ISO 7854, method B)	Class 1 to 6 (highest) (ISO 7854, method B)	Flex fatigue is considered as a precondition to barrier performance of materials (ASTM F392)	As above
Trapezoidal tear resistance	Class 1 to 6 (highest) (EN 14325 & EN ISO 9073-4:1997)	Class 1 to 6 (highest) (ISO 9073-4)	Single-use: "Tear-resistance test two" ≥17 N (section 8.38 and ASTM D5733 for non-woven) Multiple-use: "Tear-resistance test one" ≥36 N (Section 8.7 and ASTM D5587 for woven)	As above
Tensile strength	Class 1 to 6 (highest) (cl. 4.9 of EN 14325 & EN ISO 13934-1)	Class 1 to 6 (highest) (ISO 13934-1) Bursting strength: Class 1 to 6 (highest) (ISO 13938-1)	≥50 N (section 8.4 and ASTM D5034) Also bursting strength: ≥66N (single-use) ≥222.5N (multiple-use) (section 8.5 and ASTM D3787)	In the JS/US there is also bursting strength which was eliminated in the EU
Puncture resistance	Class 1 to 6 (highest) (cl. 4.10 of EN 14325 & EN 863)	Class 1 to 6 (highest) ISO 13996	≥12N (single-use) ≥25N (multiple-use) (section 8.6 and ASTM D2572)	
b) Chemical resistance				
Permeation by chemicals (applicable to Types 4 and PB [4])	Class 1 to 6 (highest) (EN ISO 6529, method A for liquids)	Class 1 to 6 (highest) (ISO 6529, method A for liquids)		
Repellency to liquids (applicable to Type 6 and PB [6])	Class 1 to 3 (highest) (ISO 6530)	Class 1 to 3 (highest) (JS 607)	≤30% (section 8.31)	JS 607 is identical to ISO 6530. In the US it is called "water-absorption resistance test"; it applies only to multiple-use garments/ensembles
Penetration by liquids (applicable to Types 6 and PB [6])	Class 1 to 3 (highest) (ISO 6530)	Class 1 to 3 (highest) (ISO 6530)		
c) Flammability				
Resistance to ignition or flame (more stringent)	Pass or min. class 1 (cl. 4.14 EN 14325 and EN 13274-4, method 3)	Pass or Min. class 1 (EN 13274-4, method 3)	Flame spread time ≥3.5 s (section 8.39 and ASTM D1230)	Requirement has been eliminated in ISO 16602 AMD1:2012 (not yet adopted in JS)
d) Penetration by infective agents				

Market	EU	Jordan	US	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	
Contaminated liquids under hydrostatic pressure	Class 1 to 6 (highest) (cl. 4.1.4.1 of EN 14126, ISO 16603 and ISO 16604)	n/a	Pass *Note*: In the US the "bio-penetration test one" applies (section 8.3 and ASTM F1671)	Requirement does not apply in JS 1899
Mechanical contact with contaminated liquids (wet bacterial penetration)	Class 1 to 6 (highest) (cl. 4.1.4.2 of EN 14126 and EN ISO 22610)	n/a	n/a	
(Biologically) contaminated liquid aerosols	Class 1 to 3 (highest) (cl. 4.1.4.3 of EN 14126)	n/a	n/a	
Contaminated solid particles (dry microbial penetration)	As above (cl. 4.1.4.4 of EN 14126 and ISO 22612)	n/a	n/a	
2. Whole-suit requirements				
Mist test (Type 6)	Pass (EN ISO 17491-4 (method A) as modified by cl. 5.2 of EN 13034)	Pass ISO 17491-4 (method A)	Pass (section 8.2) *Note*: In the US the "liquid tight integrity test one" applies	EU/JS: same limits/essentially same method
Liquid spray test (Type 4)	Pass (cl. 4.3.4.2 etc. of EN 14605 and EN ISO 17491-4 (method B))	Pass ISO 17491-4 (method B)	Pass (section 8.2)	As above
Practical performance	Pass (EN 14605/EN 13034—"seven movements" sequence while wearing the suit)	Pass JS 1899, Annex A	Demonstration of garment functionality is included as part of the liquid integrity testing applied to garments (ASTM F1154)	As above

10.4.2 Gowns

The relevant Jordanian technical standards for gowns are:

- JS 983-1:2007, "Surgical drapes, gowns, and clean air suits, used as medical devices, for patients, clinical staff and equipment—Part 1: General requirements for manufacturers, processors, and products," equivalent to EN 13795-1:2002 (since revised)
- JS 983-2:2007, "Surgical drapes, gowns, and clean air suits, used as medical devices, for patients, clinical staff, and equipment—Part 2: Test methods," equivalent to EN 13795-2:2002 (since revised and changed scope)
- JS 983-3:2008, "Surgical drapes, gowns, and clean air suits, used as medical devices, for patients, clinical staff, and equipment—Part 3: Performance requirements and performance levels, equivalent to EN 13795-3:2006 (since withdrawn).

It is noted that the EN 13795 series of standards (originally consisting of three parts) was consolidated in a single standard, EN 13795, which was later separated again into two standards, EN 13795-1:2019 and EN 13795-2:2019. The latest edition of EN 13795-1 contains both requirements and test methods for surgical drapes and gowns, while the latest EN 13795-2 deals only with clean air suits (which are outside the scope of this guide). For details on EN 13795-1:2019, the standard that is relevant to the scope of this guide, see 4.4.2.1. It is noted

that the alignment of JS 983 series to the current EN 13795 series is in progress.[65]

Table 10.7 shows the requirements for gowns in the Jordanian market compared to those of the EU and US markets.

Table 10.7: Comparison between EU, US, and Jordanian standards for gowns

Notes:

For a more detailed comparison of EU and US standards (including test methods), see 4.4.2.3 of this guide.

For simplicity, only requirements related to barrier performance of gown materials and seams are specified.

Color code:

- Green: Products made to the Jordanian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Jordanian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Jordanian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 13795-1:2019 Surgical gowns**	**Jordan JS 983-1:2007 JS 983-3:2008 Surgical gowns**	**US ANSI/AAMI PB70:2012 (all gowns) ASTM F2407-20 (surgical gowns) and ASTM F3352-19 (isolation gowns)**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	JS 983-1 and -3 are adoptions of previous versions of EN 13795-1 and -3, containing only general and performance requirements, respectively
Resistance to dry microbial penetration	≤ 300 CFU (less critical areas) *Note*: For critical product areas, wet bacterial penetration limits apply instead EN ISO 22612:2005	≤ 300 CFU (less critical areas) EN ISO 22612	n/a	JS 983-2 is an adoption of a previous version of EN 13795-2 containing only testing methods Limit in JS expressed as $\log_{10}$(CFU) ≤ 2 which is considered equivalent to ≤ 300 CFU AAMI PB 70 standard specifically excludes dry microbial penetration from its scope
Resistance to wet bacterial penetration	I_B ≥ 2.8 (critical areas, standard performance) I_B = 6.0 (critical areas, high performance) EN ISO 22610:2006	I_B ≥ 2.8 (critical areas, standard performance) I_B = 6.0 (critical areas, high performance) EN ISO 22610	n/a	US requires (only for Level 4) a stricter characteristic (viral penetration; see next row in table)
Viral penetration	n/a	n/a	Pass (AQL 4%, RQL=20%) (AAMI Level 4) ASTM F1671	
Cleanliness microbial/ bioburden	≤ 300 CFU/100 cm² EN ISO 11737-1:2018	≤ 300 CFU/100 cm² EN 1174 series	n/a	

65 February 2022. Communication with JSMO.

(Market) standard	**EU EN 13795-1:2019 Surgical gowns**	**Jordan JS 983-1:2007 JS 983-3:2008 Surgical gowns**	**US ANSI/AAMI PB70:2012 (all gowns) ASTM F2407-20 (surgical gowns) and ASTM F3352-19 (isolation gowns)**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	JS 983-1 and -3 are adoptions of previous versions of EN 13795-1 and -3, containing only general and performance requirements, respectively
Particle release	Log_{10} (lint count) ≤ 4.0 EN ISO 9073-10:2004	Log_{10} (lint count) ≤ 4.0 IPM ≤3.5 ISO 9073-10		Optional in the US In EN 13795-1, the Index for Particulate Matter (IPM) and the lint count have been combined
Water resistance (hydrostatic pressure)	≥ 20 cm H_2O (critical areas, std. performance) ≥ 100 cm H_2O (critical areas, high performance) ≥ 10 cm H_2O (less critical areas) EN ISO 811:2018	≥ 20 cm H_2O (critical areas, std. performance) ≥ 100 cm H_2O (critical areas, high performance) ≥ 10 cm H_2O (less critical areas) EN 20811	≥ 20 cm H_2O (AAMI Level 2) ≥ 50 cm H_2O (AAMI Level 3) (AQL 4%, RQL=20%) AATC 127	For critical areas/zones, US limits are the same as EU/Jordanian ones (for standard performance) or lower (for high performance) Limits in the US apply only to critical zone components (akin to critical areas in the EU/Jordan) EU/Jordanian and US methods are similar
Water resistance (impact penetration)	n/a	n/a	≤ 4.5 g (AAMI Level 1) ≤ 1.0 g (AAMI Levels 2 and 3) (AQL 4%, RQL=20%) AATC 42 or NWSP 80.3	Limits in the US apply only to critical zone components (akin to critical areas in the EU/Jordan)
Bursting strength (dry) (wet)	≥ 40 kPa ≥ 40 kPa (critical areas) EN ISO 13938-1:1999	≥ 40 kPa ≥ 40 kPa (critical areas) EN ISO 13938-1		
Tensile strength (dry) (wet)	≥ 20 N ≥ 20 N (critical areas) EN 29073-3:1992	≥ 20 N ≥ 20 N (critical areas) EN 29073-3	≥ 30 N ASTM D5034	Higher limit in the US compared to the EU/Jordan Additionally, limits are set for tear strength (≥ 10 N per ASTM D5587 or D5733) and seam strength ((≥ 30 N per ASTM D1683/D1683M) Physical property limits are same for all barrier levels per AAMI
Biocompatibility	Pass EN ISO 10993-1:2009	n/a	Pass ANSI/AAMI BE78 or ISO 10993-10	
Sterility	Packaging for terminally sterilized medical devices is recommended according to EN ISO 11607 series	Validated manufacturing and processing procedures shall be used	Assurance level of sterilization process: at least 10^{-6}	
Flammability	Manufacturer to provide fire risk information	No explicit requirements	Class 1 16 CFR 1610	
Other criteria to consider	Comfort (depends on a variety of properties)	Comfort (depends on a variety of properties)	Optional: - Water vapor transmission Rate (ASTM D6701) - Evaporative resistance (ASTM F1868, Part B) - etc.	

PART 11
PRODUCT-SPECIFIC COMPARISONS (KENYA)

11.1 Masks

11.1.1 Respirators

The relevant Kenyan standard, KS 2409-6:2018, "Health care wastes management commodities—specification—Part 6: Filtering face masks to protect against particles," is based on EN 149:2001 (an amendment of which was issued in 2009). Table 11.1 shows the requirements for respirators in the Kenyan market compared to those of the EU and US markets.

Table 11.1: Comparison between EU, US, and Kenyan standards for respirators

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.1 of this guide.

Color code:

- Green: Products made to the Kenyan standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Kenyan standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Kenyan standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 149:2001 +A1:2009 Classes FFP2 and FFP3**	**Kenya KS 2409-6:2018 Classes FFP2 and FFP3**	**US 42 CFR Part 84, Series/Levels N95 and N99**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Practical performance	Pass (based on two subjects performing various tasks)	Part of the leakage testing	Fit testing before use (required by OSHA, not NIOSH)	
Total inward leakage	**FFP2** ≤ 11% (individual) ≤ 8% (mean)	**FFP2** ≤ 11% (individual) (Annex C)	Not specified	Limit in KS is less strict than EN
	FFP3 ≤ 5% (individual); ≤ 2 % (mean)	**FFP3** ≤ 2% (individual) (Annex C)	Not specified	Limit in KS is stricter than EN

(Market) standard	**EU** **EN 149:2001** **+A1:2009** **Classes FFP2 and FFP3**	**Kenya** **KS 2409-6:2018** **Classes FFP2 and FFP3**	**US** **42 CFR Part 84, Series/Levels N95 and N99**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Filtering efficiency	**FFP2** ≥ 94% @ 95 L/min (NaCl and paraffin oil—EN 13274-7)	**FFP2** ≥ 94% @ 95 L/min (NaCl and paraffin oil) (Annex D)	**N95** ≥ 95% @ 85 L/min (NaCl only)	In Kenya, as in the EU, penetration of filtering material is specified (100%-filtering efficiency) Some variations exist between KS 2409-6 and EN test method requirements; KS 2409-6 requires testing according to Annex D, while testing specified by EN 149 (2009) is according to EN 13274-7
	FFP3 ≥ 99% @ 95 L/min (NaCl and paraffin oil—EN 13274-7)	**FFP3** ≥ 99% @ 95 L/min (NaCl and paraffin oil) (Annex D)	**N99** ≥ 99% @ 85 L/min (NaCl only)	
Compatibility with skin	Pass	n/a	n/a	
Flammability	Pass	Pass (Annex E)	n/a	Similar methodology, same requirement as in EU
Carbon dioxide content	Average ≤ 1% by volume in "dead space"	n/a	n/a	
Field of vision	Pass (in the practical performance test)	Pass	Pass	
Breathing resistance (inhalation)	**FFP2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min	**FFP2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min *Note* 1 (Annex F)	**N95** ≤ 343 Pa @ 85 L/min	*Note* 1: Limits in KS specified in mbar (1 mbar = 100 Pa)
	FFP 3 ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min	**FFP 3** ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min *Note* 1 (Annex F)	**N99** ≤ 343 Pa @ 85 L/min	
Breathing resistance (exhalation)	**FFP2 and FFP3** ≤ 300 Pa @160 L/min	**FFP2 and FFP3** ≤ 300 Pa @160 L/min *Note* 1 (Annex F)	**N95 and N99** ≤ 245 Pa @ 85 L/min	

11.1.2 Medical face masks

The Kenyan standard for medical face masks, KS 2636:2021, "Medical face masks-specification," is similar to EN 14683 (for details, see 4.1.2.1), but it also contains some additional dimensional/design requirements. Table 11.2 shows the requirements for medical face masks in the Kenyan market compared to those of the EU and US markets.

Table 11.2: Comparison between EU, US, and Kenyan standards for medical face masks

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.2 of this guide.

Color code:

- Green: Products made to the Kenyan standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Kenyan standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Kenyan standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 14683:2019 Types I, II and IIR**	**Kenya KS 2636:2021 Types I, II and IIR**	**US ASTM F2100–21 Levels 1, 2 and 3**	**COMPARISON/ COMMENTS**
Characteristic/ property	**Requirement/ Testing method**	**Requirement/ Testing Method**	**Requirement/ Testing method**	
Tensile strength of strap	n/a	≥20 N	n/a	Only a requirement in Kenya (dimensional limits also apply)
Dimensions	n/a	For adults: Width: 170–195 mm Depth: 90–100 mm	n/a	Other limits apply for young children and children; additional design requirements apply
Bacterial filtration efficiency (BFE)	≥ 95% (Type I) ≥ 98% (Types II, IIR)	≥ 95% (Type I) ≥ 98% (Types II, IIR)	≥ 95% (Level 1) ≥ 98% (Levels 2,3) Using ASTM F2101	
Differential pressure	< 40 Pa/cm² (Types I, II) < 60 Pa/cm² (Type IIR) (Tested at 8L/min flowrate)	< 40 Pa/cm² (Types I, II) < 60 Pa/cm² (Type IIR) (Tested at 8L/min flowrate)	<49 Pa/cm² (Level 1) <58.8 Pa/cm² (Levels 2, 3) Using EN 14683	
Sub-micron particulate filtration efficiency	n/a	n/a	≥ 95 (Level 1) ≥ 98 (Level 2,3) Both at 0.1 micron, using ASTM F2299	
Splash-resistance pressure	Not required (Types I, II) ≥ 16.0 kPa (Type IIR) Using ISO 22609:2004	Not required (Types I, II) ≥ 16 kPa (Type IIR) Using KS ISO 22609	≥ 15.7 kPa (Level 1) ≥16 kPa (Level 2) ≥21.4 kPa (Level 3) Using ASTM F1862	
Microbial cleanliness	≤ 30 CFU/g Using EN ISO 11737-1:2018	≤ 30 CFU/g Using KS ISO 11737-1	n/a	
Biocompatibility	Pass Using ISO EN 10993-1:2009	Pass Using KS ISO 10993-1	Pass Using ISO 10993-1	
Flame spread	n/a	n/a	Class 1 Using 16 CFR Part 1610	

11.1.3 Community face coverings

In Kenya, the standard KS 2924:2020, "Personal protective equipment—face masks—masks for public use—specification," was developed. The standard makes reference to standards for medical face masks from Kenya, the EU, and the United States. Table 11.3 shows the requirements for community face coverings in the Kenyan market compared to those of the EU and US markets.

Table 11.3: Comparison between EU, US, and Kenyan standards for community face coverings

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.3.3 of this guide.

Color code:

- Green: Products made to the Kenyan standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Kenyan standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Kenyan standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU CWA 17553:2020**	**Kenya KS 2924:2020**	**US ASTM F3502-21**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/ testing method**	**Requirement/testing method**	
Breaking strength of mask band at the joint	n/a	≥20 N	n/a	Only a requirement in Kenya (it appears as a max. limit in the standard; apparently an error. Also, no details of the method are provided)
Breathing resistance	EN 14683:2019, Annex C (≤ 70 Pa/cm²) or EN 13274-3 (inhalation resistance of 2.4 mbar; exhalation resistance 3 mbar)	Differential pressure ≤29.4 Pa/ cm²	Subpart K of 42 CFR Part 84, modified by §8.2 (Level 1 ≤ 15 mm H_2O Level 2 ≤ 5 mm H_2O)	For EU, either breathing resistance or air permeability is measured; stricter limits for breathing resistance in Kenya compared to the EU
Air permeability	EN ISO 9237 (≥ 96 l/s/m² @ 100 Pa)	n/a	n/a	
Particle filtration efficiency (PFE)	EN 13274-7:2019 or EN ISO 16890-2 OR EN ISO 21083-1:2018, or measure BFE (see below) (Level 90% ≥ 90% Level 70% ≥ 70%) Particle size 3 (± 0.5) µm	≥ 90% (salt medium) ≥ 80% (oil medium)	Subpart K of 42 CFR Part 84, modified by §8.1 (Level 1 ≥20% Level 2 ≥ 50%)	For EU, either PFE or BFE is measured; for PFE, the CEN Workshop Agreement (CWA) provides for alternative methods
Bacterial filtration efficiency (BFE)	EN 14683:2019 (Level 90% ≥ 90% Level 70% ≥ 70%)	n/a	Manufacturer may choose to provide the BFE results (as per ASTM F 2101) along with PFE	In Annex C of the KS, the apparatus of measuring BFE is used to measure differential pressure
Microbial cleanliness	n/a	≤ 200 CFU/g Using KS ISO 11737-1	n/a	Limits for specific bacteria/fungi also apply

11.2 Eye and face protection

There are two relevant normative documents in Kenya: KS 2409-8:2018, "Health care wastes management commodities—specification—Part 8: Safety goggles," and KPAS 2919:2020, "Personal protective equipment—face shield—specification."

The former standard makes reference to the relevant "particular requirements" of Clause 7.2 of KS ISO 4849, such as protection against chemical droplets. The corresponding ISO 4849 has been replaced by ISO 16321-1:2021 (see 4.2.1. for details). The latter document, KPAS 2919:2020, "Personal protective equipment—face shield—specification," was developed in response to the COVID-19 pandemic. This document provides the key requirements of a face shield but not a comprehensive list of requirements.

Table 11.4 shows the requirements for eye and face protection in the Kenyan market, as incorporated in KPAS 2919, compared to those of the EU and US markets.

Table 11.4: Comparison between EU, US, and Kenyan standards for eye and face protection

Notes:

- In general, requirements for lenses (only) have not been included.
- For a more detailed comparison of EU and US standards (including test methods), see 4.2.1 of this guide.

Color code:

- Green: Products made to the Kenyan standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Kenyan standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Kenyan standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 166:2001**	**Kenya KPAS 2919:2020**	**US ANSI/ISEA Z87.1:2020**	**COMPARISON/ COMMENTS**
Characteristic/ property	**Requirement/ Testing method**	**Requirement/ Testing Method**	**Requirement/testing method**	This specification only addresses face shields and only key requirements. Safety goggles are addressed in KS 2409-08, based on a since replaced ISO standard
Construction and materials	Pass	Pass	Pass (ANSI Z80.1)	
Headband	Pass	Pass	n/a	
Basic (EU)/ fundamental (US) requirements				
Field of vision	Pass (EN 168)	n/a	n/a	
Min. coverage area	Not a requirement, except for special uses	Ellipse with axes ≥40 mm and ≥ 33 mm	Ellipse with axes ≥40 mm and ≥ 33 mm	
Transmittance of oculars without filtering action	> 74.4% (EN 167)	n/a	≥ 85% (or ≥ 78% if relaxed optics)	
Haze	n/a	≤3% (ASTM D1003-13)	≤3% (ASTM D1003-13)	

(Market) standard	EU EN 166:2001	Kenya KPAS 2919:2020	US ANSI/ISEA Z87.1:2020	COMPARISON/ COMMENTS
Characteristic/ property	**Requirement/ Testing method**	**Requirement/ Testing Method**	**Requirement/testing method**	This specification only addresses face shields and only key requirements. Safety goggles are addressed in KS 2409-08, based on a since replaced ISO standard
Creased robustness	Pass (EN 168)	n/a	Pass	
Thermal stability	Pass (EN 168)	n/a	n/a	
Resistance to corrosion	Pass (EN 168)	n/a	Pass	
Resistance to ignition	Pass (EN 168)	n/a	Pass	
Particular requirements (EU)				
Droplets and splashes of liquid	No color present for goggles Face shields pass the area coverage test (EN 168)	No color present	No color present for goggles Face shields pass the area coverage test	
Lateral protection (optional)	Pass (EN 168)	n/a	Pass	
Optional requirements (EU)				
Resistance to fogging (only for oculars, not complete eye protectors)	Time without fogging ≥ 8 s (Acc to EN 168)	n/a	Time without fogging ≥ 8 s	US requirement added in the 2020 edition In the Kenyan specification, test methods are provided in Annex B (informative) but there is no requirement

11.3 Gloves

11.3.1 Medical examination gloves

The relevant standards are KS ISO 11193-1:2020 (for gloves made of rubber/latex), identical to ISO 11193-1:2008 + AMD1:2012 (revised in 2020) and KS ISO 11193-2:2020 (made of PVC), identical to ISO 11193-2:2006 (current). For details on the ISO standards, see 4.3.1.1.

For completeness, the normative document KNWA 2409-10:2012, "Health care wastes management commodities—Part 10: Gloves for health care waste handling—specifications," is also mentioned. This document is related to the EN 374 series (since replaced by the EN ISO 374 series) for protective gloves. As it has been analyzed in part 4.3.1.1 on EU requirements for examination gloves, standards on "protective gloves" as opposed to "medical gloves" will not be further detailed.

Table 11.5 shows the requirements for medical examination gloves in the Kenyan market compared to those of the EU and US markets.

Table 11.5: Comparison between EU, US, and Kenyan standards for medical examination gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.1 of this guide.

Color code:

- Green: Products made to the Kenyan standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Kenyan standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Kenyan standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 455 series**	**Kenya Material specific KS ISO 11193-1:2020 (rubber) KS ISO 11193-2:2006 (PVC)**	**US ASTM—material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)**	**COMPARISON/COMMENTS**
Characteristic/property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/testing method**	
Freedom from holes	AQL =1.5 (EN 455-1:2020)	AQL =2.5	AQL =2.5 (ASTM D5151)	
Force at break (N) / Tensile strength (MPa), elongation at break (%) (Also, after ageing/challenge)	Non-thermoplastic materials ≥6.0N Thermoplastic materials (PVC, PE) ≥ 3.6N (EN 455-2 :2015, method A of ISO 23529:2010)	AQL = 4.0 For rubber ≥ 6.0 N Elongation ≥ 500% (Type 1) and ≥ 400% (Type 2) For PVC ≥ 7.0 N Elongation ≥ 350%	AQL = 4.0 Nitrile ≥ 14MPa/ elongation ≥400% Latex (natural) ≥ 14MPa / Elongation ≥ 500% Polychloroprene ≥ 14MPa/elongation ≥ 400% PVC ≥ 11MPa/ elongation ≥ 300% (ASTM D412, ASTM D573 [ageing])	In the EU, instead of AQL, the median of 13 samples is used In general, the tensile properties and their limits specified in the Kenyan standards are an amalgam of the EU/US ones Kenyan and EU standards specify minimum absolute force (N) for samples taken from the glove (varies with thickness); ASTM specifies in terms of tensile strength
Biocompatibility	Pass (EN ISO 10993-5 and -10)	No explicit requirements	Pass (FDA regulations)	
Powder residue content	≤ 2.0 mg/glove (EN 455-3, EN ISO 21171:2006)	n/a	≤ 2.0mg/glove (powder-free gloves) ≤ 10 mg/dm² (powdered gloves) (ASTM D6124)	The requirement was first introduced in the 2020 edition of ISO 11193-1 while KS ISO 11193-1 is based on the previous edition
Aqueous soluble protein content	"Manufacturer shall monitor the content in natural rubber latex gloves and shall try to minimize it" (EN 455-3)	n/a	≤ 200 µg/dm² Only for rubber gloves (ASTM D5712)	

(Market) standard	EU EN 455 series	Kenya Material specific KS ISO 11193-1:2020 (rubber) KS ISO 11193-2:2006 (PVC)	US ASTM—material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)	COMPARISON/COMMENTS
Characteristic/property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/testing method**	
Extractable antigenic protein content	Optional	n/a	≤ 10 µg/dm² Only for rubber gloves (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	If gloves are sterilized, the nature of the sterilization process shall be disclosed on request	Pass (US Pharmacopeia)	

11.3.2 Surgical gloves

The relevant standard, KS ISO 10282:2014 is equivalent to ISO 10282:2014 (current; for details on the ISO standard, see 4.3.2.1). Table 11.6 shows the requirements for surgical gloves in the Kenyan market compared to those of the EU and US markets.

Table 11.6: Comparison between EU, US, and Kenyan standards for surgical gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.2 of this guide.

Color code:

- Green: Products made to the Kenyan standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Kenyan standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Kenyan standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	EU EN 455 series	Kenya KS ISO 10282:2014 Type 1: Natural rubber Type 2: Synthetic rubber	US ASTM D3577-19 Type 1: Natural rubber Type 2: Synthetic rubber	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Freedom from holes	AQL = 0.65 (EN 455-1:2020)	AQL = 1.5	AQL = 1.5 (ASTM D5151)	
Force at break (N) Tensile strength (MPa), elongation (%) (Also, after ageing/challenge)	All materials ≥ 9.0N (EN 455-2 :2015, method A of ISO 23529:2010)	AQL = 4.0 Type 1: Latex (natural) ≥18MPa/elongation ≥560% Type 2: Synthetic rubber ≥12Mpa/elongation ≥490%	AQL = 4.0 Type 1: Latex (natural) ≥18MPa/elongation ≥560% Type 2: Synthetic rubber ≥12Mpa/elongation ≥490% (ASTM D412, ASTM D573 [ageing])	EU standard does not specify AQL EU standards specify minimum absolute force (N) for samples taken from the glove (varies with thickness); ASTM and Kenyan standards specify in terms of tensile strength (MPa—force per unit area)

(Market) standard	EU EN 455 series	Kenya KS ISO 10282:2014 Type 1: Natural rubber Type 2: Synthetic rubber	US ASTM D3577-19 Type 1: Natural rubber Type 2: Synthetic rubber	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Biocompatibility	Pass (EN ISO 10993-5 and -10)	Pass	Pass (FDA regulations)	KS specifies generally similar testing methodology with EU/US
Powder residue content	≤ 2.0 mg/glove (EN 455-3, EN ISO 21171:2006)	n/a	≤ 2.0mg/glove (ASTM D6124)	
Aqueous soluble protein content	"Manufacturer shall monitor the content in NRL gloves and shall try to minimize it" (EN 455-3, Annex A)	n/a	≤ 200 µg/dm² (ASTM D5712)	
Extractable antigenic protein content	Optional (EN 455-3, Annex B)	n/a	≤ 10 µg/dm² (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	Gloves shall be sterilized; the nature of the sterilization process shall be disclosed on request	Pass (US Pharmacopeia)	

11.4 Clothing

11.4.1 Full-body and partial-body garments (other than surgical/isolation gowns)

11.4.1.1 Suits and coveralls

The standards that could be identified are:

- KS ISO 13688:2013, "Protective clothing—general requirements," identical to ISO 13688:2013 (an amendment to the ISO standard was issued in 2021). KS ISO 13688:2013 only specifies general requirements about (any type of) protective clothing and it supplements standards with requirements for specific protection
- KS 2409-07:2018, "Health care wastes management commodities—Part 7: Overall clothing — specification," is also somewhat relevant, providing design and sizing requirements. It also specifies min. density of 250 g/m² and seam strength requirements of 185 N for load bearing seams and 135 N for other seams, measured per KS ISO 3935-1.

No Kenyan standard could be identified similar to EN 14126 (protection against infective agents). Table 11.7 shows the requirements for protective clothing in the Kenyan market (as expressed in KS ISO 13688:2013) compared to those of the EU and US markets.

Table 11.7: Comparison between EU, US, and Kenyan standards for suits and coveralls

Notes:

- For a more detailed comparison of EU and US standards (including test methods), see 4.4.1 of this guide.
- For simplicity, only requirements for materials and whole suits are included (that is, requirements for seams, joins, assemblages, and integral components, such as visors, are *not* included).
- For protection against infective agents, only the following protection types, as defined in the standards, are considered here: Type 4 (spray-tight), Type PB [4] (partial-body protection— Type 4), Type 6 (limited protection against liquid chemicals) and Type PB [6] (partial-body protection— Type 6)

Color code:

- Green: Products made to the Kenyan standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Kenyan standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Kenyan standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

Market	**EU**	**Kenya**	**US**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	
I. General requirements	**EN ISO 13688:2013+A1:2021**	**KS ISO 13688:2013**	**NFPA 1999:2018**	No Kenyan standard could be identified similar to EN 14126 (protection against infective agents)
Innocuousness	No harmful substances present No azo dyes present	No harmful substances present No azo dyes present	No specific requirements	KS is identical to ISO 13688:2013 (without the amendment 1 issued in 2021)
Design and comfort	Acceptable (Annex C)	Acceptable Assessment in Annex C	Acceptable (section 6.1) *Note*: Design requirements only ≥650 g/(m²24 h) *Note*: In the US for single-use garments/ ensembles "moisture vapor transmission rate" is specified (section 8.28 and ASTM E96) ≥450 W/m² *Note*: In the US for multiple-use garments/ ensembles "total heat loss test" is specified (section 8.32 and ASTM F1868)	
II. Protection against infective agents	**EN 14126:2003 & EN 14605:2005+A1:2009 (for Types 4 and PB [4]) or EN 13034:2005+A1:2009 (for Types 6 and PB [6])**	**No requirements**	**NFPA 1999:2018**	
1. Materials requirements				
a) Mechanical		**No requirements for mechanical properties**		

Market	**EU**	**Kenya**	**US**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	
Abrasion resistance	Class 1 to 6 (highest) (cl. 4.4 of EN 14325 & EN ISO 12947-2)	n/a	Abrasion resistance is considered as a precondition to barrier performance of materials (ASTM D4157)	
Flex cracking resistance	Class 1 to 6 (highest) (cl. 4.5, 4.6 EN 14325 & EN ISO 7854, method B)	n/a	Flex fatigue is considered as a precondition to barrier performance of materials (ASTM F392)	
Trapezoidal tear resistance	Class 1 to 6 (highest) (EN 14325 and EN ISO 9073-4:1997)	n/a	Single-use: "Tear-resistance test two" ≥17 N (section 8.38 and ASTM D5733 for non-woven) Multiple-use: "Tear-resistance test one" ≥36 N (Section 8.7 and ASTM D5587 for woven)	
Tensile strength	Class 1 to 6 (highest) (cl. 4.9 of EN 14325 and EN ISO 13934-1)	n/a	≥50 N (section 8.4 and ASTM D5034) Also bursting strength: ≥66N (single-use) ≥222.5N (multiple-use) (section 8.5 and ASTM D3787)	Bursting strength was eliminated in EU
Puncture resistance	Class 1 to 6 (highest) (cl. 4.10 of EN 14325 and EN 863)	n/a	≥12N (single-use) ≥25N (multiple-use) (section 8.6 and ASTM D2572)	
b) Chemical resistance		**No requirements for chemical resistance properties**		
Permeation by chemicals (applicable to Types 4 and PB [4])	Class 1 to 6 (highest) (EN ISO 6529, method A for liquids)	n/a		
Repellency to liquids (applicable to Types 6 and PB [6])	Class 1 to 3 (highest) (ISO 6530)	n/a	≤30% (section 8.31)	In the US it is called "water-absorption resistance test"; it applies only to multiple-use garments/ensembles
Penetration by liquids (applicable to Types 6 and PB [6])	Class 1 to 3 (highest) (ISO 6530)	n/a		
c) Flammability		**No requirements for flammability**		
Resistance to ignition or flame (more stringent)	Pass or min. class 1 (cl. 4.14 EN 14325 and EN 13274-4, method 3)	n/a	Flame spread time ≥3.5 s (section 8.39 and ASTM D1230)	
d) Penetration by infective agents		**Requirement/testing method**		

Market	EU	Kenya	US	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	
Contaminated liquids under hydrostatic pressure	Class 1 to 6 (highest) (cl. 4.1.4.1 of EN 14126, ISO 16603 and ISO 16604)	n/a	Pass *Note*: In the US the "bio-penetration test one" applies (section 8.3 and ASTM F1671)	
Mechanical contact with contaminated liquids (wet bacterial penetration)	Class 1 to 6 (highest) (cl. 4.1.4.2 of EN 14126 and EN ISO 22610)	n/a	n/a	
(Biologically) contaminated liquid aerosols	Class 1 to 3 (highest) (cl. 4.1.4.3 of EN 14126)	n/a	n/a	
Contaminated solid particles (dry microbial penetration)	As above (cl. 4.1.4.4 of EN 14126 and ISO 22612)	n/a	n/a	
2. Whole-suit requirements		**No requirements for whole suits**		
Mist test (Type 6)	Pass (EN ISO 17491-4 (method A) as modified by cl. 5.2 of EN 13034)	n/a	Pass (section 8.2) *Note*: In the US the "liquid tight integrity test one" applies	
Liquid spray test (Type 4)	Pass (cl. 4.3.4.2 etc. of EN 14605 and EN ISO 17491-4 (method B))	n/a	Pass (section 8.2)	
Practical performance	Pass (EN 14605/EN 13034—"seven movements" sequence while wearing the suit)	n/a	Demonstration of garment functionality is included as part of the liquid integrity testing applied to garments (ASTM F1154)	

11.4.1.2 Partial-body garments

A Kenyan standard for aprons was identified, KS 2409-3:2018, "Health care wastes management commodities—specification—Part 3: Plastic apron." This standard sets requirements for PVC-coated aprons, among others, for density of materials, dimensions of the apron, and its straps and the strength of its straps.

Table 11.8 shows the requirements for aprons in the Kenyan market compared to those of the EU and US markets.

Table 11.8: Comparison between EU, US, and Kenyan standards for aprons

Notes:

- For a more detailed comparison of EU and US standards (including test methods), see 4.4.1 of this guide.
- For simplicity, only requirements for materials and whole suits are included (that is, requirements for seams, joins, assemblages, and integral components, such as visors, are *not* included).
- For protection against infective agents, only the following protection types, as defined in the standards, are considered here: Type 4 (spray-tight), Type PB [4] (partial-body protection—Type 4), Type 6 (limited protection against liquid chemicals) and Type PB [6] (partial-body protection—Type 6).

Color code:

- Green: Products made to the Kenyan standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Kenyan standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Kenyan standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

Market	**EU**	**Kenya**	**US**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	
I. General requirements	**EN ISO 13688:2013+A1:2021**	**KS ISO 13688:2013**	**NFPA 1999:2018**	No Kenyan standard could be identified similar to EN 14126 (protection against infective agents)
Innocuousness	No harmful substances present No azo dyes present	No harmful substances present No azo dyes present	No specific requirements	KS is identical to ISO 13688:2013 (without the amendment 1 issued in 2021)
Design and comfort	Acceptable (Annex C)	Acceptable Assessment in Annex C	Acceptable (section 6.1) *Note*: Design requirements only ≥650 g/(m²24 h) *Note*: In the US for single-use garments/ensembles "moisture vapor transmission rate" is specified (section 8.28 and ASTM E96) ≥450 W/m² *Note*: In the US for multiple-use garments/ensembles, "total heat loss test" is specified (section 8.32 and ASTM F1868)	
II. Protection against infective agents	**EN 14126:2003 & EN 14605:2005+A1:2009 (for Types 4 and PB [4]) or EN 13034:2005+A1:2009 (for Types 6 and PB [6])**	**KS 2409-03:2018 (plastic aprons only)**	**NFPA 1999:2018**	
1. Materials requirements				
a) Mechanical				

Market	**EU**	**Kenya**	**US**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	
Abrasion resistance	Class 1 to 6 (highest) (cl. 4.4 of EN 14325 & EN ISO 12947-2)	n/a	Abrasion resistance is considered as a precondition to barrier performance of materials (ASTM D4157)	
Flex cracking resistance	Class 1 to 6 (highest) (cl. 4.5, 4.6 EN 14325 and EN ISO 7854, method B)	n/a	Flex fatigue is considered as a precondition to barrier performance of materials (ASTM F392)	
Trapezoidal tear resistance	Class 1 to 6 (highest) (EN 14325 & EN ISO 9073-4:1997)	Meets tear requirements of KS 1148-2 *Note* 1	Single-use: "Tear-resistance test two" ≥17 N (section 8.38 and ASTM D5733 for non-woven) Multiple-use: "Tear-resistance test one" ≥36 N (section 8.7 and ASTM D5587 for woven)	*Note* 1: KS 1148-2:1995 "Specification for fabrics for water-resistant clothing—Part 2: PVC-coated fabrics"
Tensile strength	Class 1 to 6 (highest) (cl. 4.9 of EN 14325 & EN ISO 13934-1)	n/a	≥50 N (section 8.4 and ASTM D5034) Also bursting strength: ≥66N (single-use) ≥222.5N (multiple-use) (section 8.5 and ASTM D3787)	Bursting strength was eliminated in EU
Density	n/a	≥ 140 g/m²	n/a	Only a Kenyan requirement
Dimensions	n/a	Length: ≥ 900 mm Width: ≥750 mm	n/a	Only a Kenyan requirement; there are also limits for length of waist, shoulder or neck-loop straps
Strap strength	n/a	≥ 500 N (Annex A and ISO 13934-1)	n/a	Only a Kenyan requirement
Puncture resistance	Class 1 to 6 (highest) (cl. 4.10 of EN 14325 & EN 863)	n/a	≥12N (single-use) ≥25N (multiple-use) (section 8.6 and ASTM D2572)	
b) Chemical resistance		**No requirements for chemical resistance properties**		
Permeation by chemicals (applicable to Types 4 and PB [4])	Class 1 to 6 (highest) (EN ISO 6529, method A for liquids)	n/a		
Repellency to liquids (applicable to Types 6 and PB [6])	Class 1 to 3 (highest) (ISO 6530)	n/a	≤30% (section 8.31)	In the US it is called "water-absorption resistance test"; it applies only to multiple-use garments/ensembles
Penetration by liquids (applicable to Types 6 and PB [6])	Class 1 to 3 (highest) (ISO 6530)	Meets resistance to corrosive elements requirements of KS 1148-2 *Note* 1		
c) Flammability		**No requirements for flammability**		

Market	**EU**	**Kenya**	**US**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	
Resistance to ignition or flame (more stringent)	Pass or min. class 1 (cl. 4.14 EN 14325 & EN 13274-4, method 3)	n/a	Flame spread time ≥ 3.5 s (section 8.39 and ASTM D1230)	
d) Penetration by infective agents		**Requirement/ testing method**		
Contaminated liquids under hydrostatic pressure	Class 1 to 6 (highest) (cl. 4.1.4.1 of EN 14126, ISO 16603 and ISO 16604)	n/a	Pass *Note*: In the US the "bio-penetration test one" applies (section 8.3 and ASTM F1671)	
Mechanical contact with contaminated liquids (wet bacterial penetration)	Class 1 to 6 (highest) (cl. 4.1.4.2 of EN 14126 and EN ISO 22610)	n/a	n/a	
(Biologically) contaminated liquid aerosols	Class 1 to 3 (highest) (cl. 4.1.4.3 of EN 14126)	n/a	n/a	
Contaminated solid particles (dry microbial penetration)	As above (cl. 4.1.4.4 of EN 14126 and ISO 22612)	n/a	n/a	
2. Whole-suit requirements		**No requirements for whole suits**		
Mist test (Type 6)	Pass (EN ISO 17491-4 (method A) as modified by cl. 5.2 of EN 13034)	n/a	Pass (section 8.2) *Note*: In the US the "liquid tight integrity test one" applies	
Liquid spray test (Type 4)	Pass (cl. 4.3.4.2 etc. of EN 14605 and EN ISO 17491-4 (method B))	n/a	Pass (section 8.2)	
Practical performance	Pass (EN 14605/EN 13034—"seven movements" sequence while wearing the suit)	n/a	Demonstration of garment functionality is included as part of the liquid integrity testing applied to garments (ASTM F1154)	

11.4.2 Gowns

No Kenyan standard for either surgical or isolation gowns could be identified, therefore no comparison table to EU/US standards can be provided.

PART 12
PRODUCT-SPECIFIC COMPARISONS (MALAYSIA)

12.1 Masks

12.1.1 Respirators

The applicable Malaysian standard, MS 2323:2010, "Respiratory protective devices—filtering half-masks to protect against particles—specification," is identical to EN 149:2001 (without the amendment A1 that was issued in 2009). Table 12.1 shows the requirements for respirators in the Malaysian market compared to those of the EU and US markets.

Table 12.1: Comparison between EU, US, and Malaysian standards for respirators

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.1 of this guide.

Color code:

- Green: Products made to the Malaysian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Malaysian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Malaysian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU** **EN 149:2001 +A1:2009, Classes FFP2 and FFP3**	**Malaysia** **MS 2323:2010, Classes FFP2 and FFP3**	**US** **42 CFR Part 84, Series/Levels N95 and N99**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Practical performance	Pass (based on two subjects performing various tasks)	Pass (based on two subjects performing various tasks)	Fit testing before use (required by OSHA, not NIOSH)	
Total inward leakage	**FFP2** ≤ 11% (individual) ≤ 8% (mean)	**FFP2** ≤ 11% (individual) ≤ 8% (mean)	Not specified	
	FFP3 ≤ 5% (individual) ≤ 2 % (mean)	**FFP3** ≤ 5% (individual) ≤ 2 % (mean)	Not specified	

(Market) standard	**EU EN 149:2001 +A1:2009, Classes FFP2 and FFP3**	**Malaysia MS 2323:2010, Classes FFP2 and FFP3**	**US 42 CFR Part 84, Series/Levels N95 and N99**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Filtering efficiency	**FFP2** ≥ 94% @ 95 L/min (NaCl and paraffin oil—EN 13274-7)	**FFP2** ≥ 94% @ 95 L/min (NaCl and paraffin oil)	**N95** ≥ 95% @ 85 L/min (NaCl only)	In Malaysia, as in the EU, penetration of filtering material is specified (100%-filtering efficiency). Some variations exist between the MS 2323 and EN test method requirements: MS 2323 requires testing according to EN 143, while testing specified by EN 149 (2009) is according to EN 13274-7
	FFP3 ≥ 99% @ 95 L/min (NaCl and paraffin oil—EN 13274-7)	**FFP3** ≥ 99% @ 95 L/min (NaCl and paraffin oil)	**N99** ≥ 99% @ 85 L/min (NaCl only)	
Compatibility with skin	Pass	Pass	n/a	
Flammability	Pass	Pass	n/a	
Carbon dioxide content	Average ≤ 1% by volume in "dead space"	Average ≤ 1% by volume in "dead space"	n/a	
Field of vision	Pass (in the practical performance test)	Pass (in the practical performance test)	Pass	
Breathing resistance (inhalation)	**FFP2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min	**FFP2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min	**N95** ≤ 343 Pa @ 85 L/min	
	FFP 3 ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min	**FFP 3** ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min	**N99** ≤ 343 Pa @ 85 L/min	
Breathing resistance (exhalation)	**FFP2 and FFP3** ≤ 300 Pa @160 L/min	**FFP2 and FFP3** ≤ 300 Pa @160 L/min	**N95 and N99** ≤ 245 Pa @ 85 L/min	

Respirators meant for health care settings are regulated as Class A medical devices in Malaysia; see section 3.10.3.

12.1.2 Medical face masks

The current version of EN 14683:2019 is adopted in Malaysia as MS EN 14683:2021. For details on EN 14683, see 4.1.2.1. Table 12.2 shows the requirements for medical face masks in the Malaysian market compared to those of the EU and US markets.

Table 12.2: Comparison between EU, US, and Malaysian standards for medical face masks

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.2 of this guide.

Color code:

- Green: Products made to the Malaysian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Malaysian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Malaysian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 14683:2019 Types I, II and IIR**	**Malaysia MS EN 14683:2021 Types I, II and IIR**	**US ASTM F2100 – 21 Levels 1, 2 and 3**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/ testing method**	Malaysian standard identical to current EN standard
Bacterial filtration efficiency (BFE)	≥ 95% (Type I) ≥ 98% (Types II, IIR)	≥ 95% (Type I) ≥ 98% (Types II, IIR)	≥ 95% (Level 1) ≥ 98% (Levels 2,3) Using ASTM F2101	
Differential pressure	< 40 Pa/cm² (Types I, II) < 60 Pa/cm² (Types IIR) (Tested at 8L/min flowrate)	< 40 Pa/cm² (Types I, II) < 60 Pa/cm² (Type IIR) (Tested at 8L/min flowrate)	<49 Pa/cm² (Level 1) <58.8 Pa/cm² (Levels 2,3) Using EN 14683	
Sub-micron particulate filtration efficiency	n/a	n/a	≥ 95 (Level 1) ≥ 98 (Levels 2,3) Both at 0.1 micron, using ASTM F2299	
Splash-resistance pressure	Not required (Types I, II) ≥ 16.0 kPa (Type IIR) Using ISO 22609:2004	Not required (Types I, II) ≥ 16.0 kPa (Type IIR) Using ISO 22609:2004	≥ 10.7 kPa (Level 1) ≥16 kPa (Level 2) ≥21.4 kPa (Level 3) Using ASTM F1862	
Microbial cleanliness	≤ 30 CFU/g Using EN ISO 11737-1:2018	≤ 30 CFU/g Using EN ISO 11737-1:2018	n/a	
Biocompatibility	Pass Using ISO EN 10993-1:2009	Pass Using ISO EN 10993-1:2009	Pass Using ISO 10993-1	
Flame spread	n/a	n/a	Class 1 Using 16 CFR Part 1610	

Medical face masks are regulated as Class A medical devices in Malaysia; see 3.10.3.

12.1.3 Community face coverings

No standards for community face coverings have been identified in Malaysia, therefore no comparison table can be provided. The closest is a guidance document, "Effectiveness of fabric mask in the community," published by the Malaysian Health Technology Assessment Section (MaHTAS) of the Ministry of Health in

June 2020, which specifies the following only:

"Non-medical masks should consist of at least three layers of different material as follows:

- An innermost layer of a hydrophilic material (for example, cotton or cotton blends)
- An outermost layer made of hydrophobic material (for example, polypropylene, polyester, or their blends) which may limit external contamination from penetration through to the wearer's nose and mouth
- A middle hydrophobic layer of synthetic non-woven material such as polypropylene or a cotton layer which may enhance filtration or retain droplets."

A regulation is under development by the Ministry of Domestic Trade and Consumer Affairs, to be based on MS EN 14683.[66]

12.2 Eye and face protection

No standards for eye and face protection in Malaysia have been identified. Therefore, no comparison table can be provided.

12.3 Gloves

In Malaysia, as in the EU (and unlike the US or ISO), there are only standards for medical gloves for single-use and no separate standards for medical examination gloves and surgical gloves. Also, there are no separate standards depending on the material of manufacture.

The following Malaysian standards are adoptions of EN standards:

- MS 2299-1:2010, "Medical gloves for single-use—Part 1: Requirements and testing for freedom from holes" (EN 455-1:2000, revised in 2020)
- MS 2299-3:2010, "Medical gloves for single-use—Part 3: Requirements and testing for biological evaluation" (EN 455-3:2006, revised in 2015).

There are no Malaysian equivalents to the other two standards in the EN 455 series, that is, EN 455-2 (for physical properties) and EN 455-4 (for shelf-life).

12.3.1 Medical examination gloves

Table 12.3 compares the (single) set of requirements for "medical gloves" in Malaysia with the EU and US requirements for medical examination gloves.

66 November 2021. Communication with Standards Malaysia.

Table 12.3: Comparison between EU, US, and Malaysian standards for medical examination gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.1 of this guide.

Color code:

- Green: Products made to the Malaysian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Malaysian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Malaysian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 455 series**	**Malaysia MS 2299 (2010) series**	**US ASTM—material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)**	**COMPARISON/COMMENTS**
Characteristic/ Property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Freedom from holes	AQL =1.5 (EN 455-1:2020)	AQL =1.5	AQL =2.5 (ASTM D5151)	
Force at break (N) / Tensile strength (MPa), elongation at break (%) (Also, after ageing/challenge)	Non-thermoplastic materials ≥6.0N Thermoplastic materials (PVC, PE) ≥ 3.6N (EN 455-2 :2015, method A of ISO 23529:2010)	n/a	AQL = 4.0 Nitrile ≥ 14MPa/elongation ≥400% Latex (natural) ≥ 14MPa / Elongation ≥ 500% Polychloroprene ≥ 14MPa/elongation ≥ 400% PVC ≥ 11MPa/elongation ≥ 300% (ASTM D412, ASTM D573 [ageing])	Not clear if Malaysia references EN 455-2 (or an ISO standard) regarding tensile properties
Biocompatibility	Pass (EN ISO 10993-5 and -10)	Pass (EN ISO 10993-5 and -10)	Pass (FDA regulations)	
Powder residue content	≤ 2.0mg/glove (EN 455-3, EN ISO 21171:2006)	≤ 2.0 mg/glove	≤ 2.0mg/glove (powder-free gloves) ≤ 10 mg/dm² (powdered gloves) (ASTM D6124)	Test methods MS 1459 and MS 1450 for powder-free and powdered gloves, respectively are based on a superseded version of ASTM D6124
Aqueous soluble protein content	"Manufacturer shall monitor the content in natural rubber latex gloves and shall try to minimize it" (EN 455-3)	"ALARP" (as low as reasonably possible)	≤ 200 µg/dm² Only for rubber gloves (ASTM D5712)	This is in line with the 2006 edition of EN 455-3 (was more stringent than current version)
Extractable antigenic protein content	Optional (EN 455-3, Annex B)	Optional (EN 455-3, Annex B)	≤ 10 µg/dm2 (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)		Pass (US Pharmacopeia)	It appears that EN 455-4 has not been adopted in Malaysia

Medical examination gloves are regulated as Class A medical devices in Malaysia (see 3.10.1).

12.3.2 Surgical gloves

Table 12.4 compares the (single) set of requirements for "medical gloves" in Malaysia, with the EU and US requirements for surgical gloves.

Table 12.4: Comparison between EU, US, and Malaysian standards for surgical gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.2 of this guide.

Color code:

- Green: Products made to the Malaysian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Malaysian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Malaysian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 455 series**	**Malaysia MS 2299 (2010) series**	**US ASTM D3577-19 Type 1: Natural rubber Type 2: Synthetic rubber**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/ testing method**	**Requirement/testing method**	
Freedom from holes	AQL = 0.65 (EN 455-1:2020)	AQL = 1.5	AQL = 1.5 (ASTM D5151)	The 2020 edition of EN 455-1 has stricter AQL
Force at break (N) / Tensile strength (MPa), elongation (%) (Also, after ageing/ challenge)	All materials ≥ 9.0N (EN 455-2 :2015, method A of ISO 23529:2010)	n/a	AQL = 4.0 Type 1: Latex (natural) ≥18MPa/elongation ≥560% Type 2: Synthetic rubber ≥12Mpa/elongation ≥490% (ASTM D412, ASTM D573 (ageing))	Not clear if Malaysia has adopted EN 455-2 (or an ISO standard) regarding tensile properties
Biocompatibility	Pass (EN ISO 10993-5 and -10)	Pass (EN ISO 10993-5 and -10)	Pass (FDA regulations)	
Powder residue content	≤ 2.0 mg/glove (EN 455-3, EN ISO 21171:2006)	≤ 2.0 mg/glove	≤ 2.0mg/glove (ASTM D6124)	Test methods MS 1459 and MS 1450 for powder-free/powdered gloves, respectively are based on a superseded version of ASTM D6124
Aqueous soluble protein content	"Manufacturer shall monitor the content in NRL gloves and shall try to minimize it" (EN 455-3, Annex A)	"ALARP" (as low as reasonably possible)	≤ 200 µg/dm² (ASTM D5712)	This is in line with the 2006 edition of EN 455-3 (was more stringent than current version)
Extractable antigenic protein content	Optional (EN 455-3, Annex B)	Optional (EN 455-3, Annex B)	≤ 10 µg/dm² (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)		Pass (US Pharmacopeia)	It appears that EN 455-4 has not been adopted in Malaysia

Surgical gloves are regulated as Class A medical devices in Malaysia (see 3.10.1).

12.4 Clothing

12.4.1 Full-body and partial-body garments (other than surgical/isolation gowns)

MS ISO 13688:2020 is identical to the 2013 edition of ISO 13688 (an amendment to ISO 13688 was issued in 2021). The MS only specifies general requirements about (any type of) protective clothing and it supplements standards with requirements for specific protection. No MS could be identified similar to EN 14126 (protection against infective agents) but the latter seems to be accepted by the medical devices authority (MDA) in Malaysia. Table 12.5 shows the requirements for protective clothing in the Malaysian market compared to those of the EU and US markets.

Table 12.5: Comparison between EU, US, and Malaysian standards for protective clothing

Notes:

- For a more detailed comparison of EU and US standards (including test methods), see 4.4.1 of this guide.
- For simplicity, only requirements for materials and whole suits are included (that is, requirements for seams, joins, assemblages, and integral components, such as visors, are *not* included).
- For protection against infective agents only the following protection types, as defined in the standards, are considered here: Type 4 (spray-tight), Type PB [4] (partial-body protection—Type 4), Type 6 (limited protection against liquid chemicals) and Type PB [6] (partial-body protection—Type 6).

Color code:

- Green: Products made to the Malaysian standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Malaysian standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Malaysian standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

Market	**EU**	**Malaysia**	**US**	**COMPARISON/ COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
I. General requirements	**EN ISO 13688:2013+A1:2021**	**MS ISO 13688:2020**	**NFPA 1999:2018**	
Innocuousness	No harmful substances present No azo dyes present	No harmful substances present No azo dyes present		Similar to current ISO 13688+AMD 1 (MS contains fewer requirements, methods since revised)
Design and comfort	Acceptable (Annex C)	Acceptable Assessment in Annex C	Acceptable (section 6.1) *Note*: Design requirements only ≥650 g/(m²24 h) *Note*: In the US, for single-use garments/ ensembles "moisture vapor transmission rate" is specified (section 8.28 and ASTM E96) ≥450 W/m² *Note*: In the US, for multiple-use garments/ ensembles "total heat loss test" is specified (section 8.32 and ASTM F1868)	Similar to current ISO 13688+AMD 1

Market	EU	Malaysia	US	COMPARISON/ COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
II. Protection against infective agents	**EN 14126:2003 & EN 14605:2005+A1:2009 (for Types 4 and PB [4]) or EN 13034:2005+A1:2009 (for Types 6 and PB [6])**		**NFPA 1999:2018**	
1. Materials requirements				
a) Mechanical		**No requirements for mechanical properties**		
Abrasion resistance	Class 1 to 6 (highest) (cl. 4.4 of EN 14325 & EN ISO 12947-2)	n/a	Abrasion resistance is considered as a precondition to barrier performance of materials (ASTM D4157)	
Flex cracking resistance	Class 1 to 6 (highest) (cl. 4.5, 4.6 EN 14325 and EN ISO 7854, method B)	n/a	Flex fatigue is considered as a precondition to barrier performance of materials (ASTM F392)	
Trapezoidal tear resistance	Class 1 to 6 (highest) (EN 14325 and EN ISO 9073-4:1997)	n/a	Single-use: "Tear-resistance test two" ≥17 N (section 8.38 and ASTM D5733 for non-woven) Multiple-use: "Tear-resistance test one" ≥36 N (section 8.7 and ASTM D5587 for woven)	
Tensile strength	Class 1 to 6 (highest) (cl. 4.9 of EN 14325 and EN ISO 13934-1)	n/a	≥50 N (section 8.4 and ASTM D5034) Also bursting strength: ≥66N (single-use) ≥222.5N (multiple-use) (section 8.5 and ASTM D3787)	Bursting strength was eliminated in EU
Puncture resistance	Class 1 to 6 (highest) (cl. 4.10 of EN 14325 and EN 863)	n/a	≥12N (single-use) ≥25N (multiple-use) (section 8.6 and ASTM D2572)	
b) Chemical resistance		**No requirements for chemical resistance properties**		
Permeation by chemicals (applicable to Types 4 and PB [4])	Class 1 to 6 (highest) (EN ISO 6529, method A for liquids)	n/a		
Repellency to liquids (applicable to Types 6 and PB [6])	Class 1 to 3 (highest) (ISO 6530)	n/a	≤30% (section 8.31)	In the US, it is called "water- absorption resistance test"; applies only to multiple-use garments/ensembles
Penetration by liquids (applicable to Types 6 and PB [6])	Class 1 to 3 (highest) (ISO 6530)	n/a		
c) Flammability		**No requirements for flammability**		

Market	EU	Malaysia	US	COMPARISON/ COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Resistance to ignition or flame (more stringent)	Pass or min. class 1 (cl. 4.14 EN 14325 and EN 13274-4, method 3)	n/a	Flame spread time≥3.5 s (section 8.39 and ASTM D1230)	
d) Penetration by infective agents				
Contaminated liquids under hydrostatic pressure	Class 1 to 6 (highest) (cl. 4.1.4.1 of EN 14126, ISO 16603 and ISO 16604)	n/a	Pass *Note*: In the US, the "bio-penetration test one" applies (section 8.3 and ASTM F1671)	ISO 16603 and ISO 16604 have both been adopted as Malaysian Standards. However, there is no MS product standard referring to them
Mechanical contact with contaminated liquids (wet bacterial penetration)	Class 1 to 6 (highest) (cl. 4.1.4.2 of EN 14126 and EN ISO 22610)	n/a	n/a	ISO 22610:2006 has been adopted as a Malaysian Standard. However, there is no MS product standard referring to it
(Biologically) contaminated liquid aerosols	Class 1 to 3 (highest) (cl. 4.1.4.3 of EN 14126)	n/a	n/a	
Contaminated solid particles (dry microbial penetration)	As above (cl. 4.1.4.4 of EN 14126 and ISO 22612)	n/a	n/a	ISO 22612:2006 has been adopted as a Malaysian Standard. However, there is no MS product standard referring to it
2. Whole-suit requirements		**No requirements for whole suits**		
Mist test (Type 6)	Pass (EN ISO 17491-4 (method A) as modified by cl. 5.2 of EN 13034)	n/a	Pass (section 8.2) *Note*: In the US, the "liquid tight integrity test one" applies	
Liquid spray test (Type 4)	Pass (cl. 4.3.4.2 etc. of EN 14605 and EN ISO 17491-4 [method B])	n/a	Pass (section 8.2)	
Practical performance	Pass (EN 14605/EN 13034—"'seven movements" sequence while wearing the suit)	n/a	Demonstration of garment functionality is included as part of the liquid integrity testing applied to garments (ASTM F1154)	

12.4.2 Gowns

No standards for medical gowns in Malaysia have been identified. Therefore, no comparison table can be provided. For international gown standards accepted in Malaysia, see 3.10.2.

PART 13
PRODUCT-SPECIFIC COMPARISONS (SOUTH AFRICA)

13.1 Masks

13.1.1 Respirators

The applicable South African standard (SANS), SANS 50149:2003, "Respiratory protective devices—filtering half-masks to protect against particles—requirements, testing, marking," is identical to EN 149:2001 (without the amendment A1 that was issued in 2009). Several other EN standards on RPD have been adopted by the South African Bureau of Standards (SABS), such as SANS 50132 (EN 132—definition of terms and pictograms), SANS 50143 (EN 143—RPD-particle filters) and SANS 50133 (EN 133—classification of RPD). There is also a standalone national standard, SANS 10220:2010, "The selection, use, and maintenance of respiratory protective equipment." Table 13.1 shows the requirements for respirators in the South African market compared to those of the EU and US markets.

Table 13.1: Comparison between EU, US, and South African standards for respirators

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.1 of this guide.

Color code:

- Green: Products made to the South African standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the South African standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the South African standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU** **EN 149:2001 +A1:2009, Classes FFP2 and FFP3**	**South Africa** **SANS 50149:2003, Classes FFP2 and FFP3**	**US** **42 CFR Part 84, Series/Levels N95 and N99**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Practical performance	Pass (based on two subjects performing various tasks)	Pass (based on two subjects performing various tasks)	Fit testing before use (required by OSHA, not NIOSH)	
Total inward leakage	**FFP2** ≤ 11% (individual) ≤ 8% (mean)	**FFP2** ≤ 11% (individual) ≤ 8% (mean)	Not specified	
	FFP3 ≤ 5% (individual) ≤ 2 % (mean)	**FFP3** ≤ 5% (individual) ≤ 2 % (mean)	Not specified	

(Market) standard	EU EN 149:2001 +A1:2009, Classes FFP2 and FFP3	South Africa SANS 50149:2003, Classes FFP2 and FFP3	US 42 CFR Part 84, Series/Levels N95 and N99	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Filtering efficiency	**FFP2** ≥ 94% @ 95 L/min (NaCl and paraffin oil—EN 13274-7)	**FFP2** ≥ 94% @ 95 L/min (NaCl and paraffin oil)	**N95** ≥ 95% @ 85 L/min (NaCl only)	In South Africa, as in the EU, penetration of filtering material is specified (100%-filtering efficiency); some variations exist between the SANS 50149 and EN test method requirements: SANS 50149 requires testing according to EN 143, while testing specified by EN 149 (as amended in 2009) is according to EN 13274-7
	FFP3 ≥ 99% @ 95 L/min (NaCl and paraffin oil—EN 13274-7)	**FFP3** ≥ 99% @ 95 L/min (NaCl and paraffin oil)	**N99** ≥ 99% @ 85 L/min (NaCl only)	
Compatibility with skin	Pass	Pass	n/a	
Flammability	Pass	Pass	n/a	
Carbon dioxide content	Average ≤ 1% by volume in "dead space"	Average ≤ 1% by volume in "dead space"	n/a	
Field of vision	Pass (in the practical performance test)	Pass (in the practical performance test)	Pass	
Breathing resistance (inhalation)	**FFP2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min	**FFP2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min	**N95** ≤ 343 Pa @ 85 L/min	
	FFP 3 ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min	**FFP 3** ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min	**N99** ≤ 343 Pa @ 85 L/min	
Breathing resistance (exhalation)	**FFP2 and FFP3** ≤ 300 Pa @160 L/min	**FFP2 and FFP3** ≤ 300 Pa @160 L/min	**N95 and N99** ≤ 245 Pa @ 85 L/min	

13.1.2 Medical face masks

In South Africa, the relevant standard is SANS 1866-1:2018, "Medical devices—Part 1: Medical face masks," which draws heavily on the corresponding US standard, ASTM F2100, and the testing methods used in that standard. For completeness, it is mentioned that there is another part of the standard, SANS 1866-2: 2018, "Medical devices—Part 2: Medical respirators," which addresses respirators used in health care settings, that is, devices offering increased protection to the persons wearing them. This standard is also based on US standards, that is, ASTM testing standards and 42 Code of Federal Regulations (CFR) Part 84. In SANS 1866-2 essentially the same characteristics are specified as in SANS 1866-1 with the following main differences: there are stricter limits for filtration efficiency and splash resistance is not always required.

Table 13.2 shows the requirements for medical face masks in the South African market (using only SANS 1866-1) compared to those of the EU and US markets.

Table 13.2: Comparison between EU, US, and South African standards for medical face masks

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.1 and 4.1.2 of this guide.

Color code:

- Green: Products made to the South African standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the South African standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the South African standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 14683:2019 Types I, II and IIR**	**South Africa SANS 1866-1 Levels 1, 2 and 3**	**US ASTM F2100–21 Levels 1, 2 and 3**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Bacterial filtration efficiency (BFE)	≥ 95% (Type I)	≥ 95% (Level 1)	≥ 95% (Level 1)	In the SANS, both EN and US methods for BFE are acceptable
	≥ 98% (Types II, IIR)	≥ 98% (Level 2,3) Using EN 14683 or ASTM F2101	≥ 98% (Levels 2,3) Using ASTM F2101	
Differential pressure	< 40 Pa/cm² (Type I, II) < 60 Pa/cm² (Type IIR) (Tested at 8L/min flowrate)	<39 Pa/cm² (Level 1) <58.8 Pa/cm² (Levels 2, 3) *Note* 1 Using EN 14683 or ASTM F2100	<49 Pa/cm² (Level 1) <58.8 Pa/cm² (Levels 2,3) Using EN 14683	In the SANS, both EN and US methods for breathing resistance (differential pressure) are acceptable *Note* 1: Limits in SANS specified as 4.0 and 5.0 mm H_2O/cm², respectively
Sub-micron particulate filtration efficiency	n/a	≥ 95% (Level 1) ≥ 98% (Levels 2,3) Both at 0.1 micron, using ASTM F2299	≥ 95% (Level 1) ≥ 98% (Levels 2,3) Both at 0.1 micron, using ASTM F2299	
Splash-resistance pressure	Not required (Types I, II) ≥ 16.0 kPa (Type IIR) Using ISO 22609:2004	≥ 10.7 kPa (Level 1) ≥16 kPa (Level 2) ≥21.4 kPa (Level 3) *Note* 2 Using ASTM F1862	≥ 10.7 kPa (Level 1) ≥16 kPa (Level 2) ≥21.4 kPa (Level 3) Using ASTM F1862	*Note* 2: Limits in SANS specified as 80, 120 and 160 mm Hg, respectively
Microbial cleanliness	≤ 30 CFU/g Using EN ISO 11737-1:2018	n/a	n/a	
Biocompatibility	Pass Using ISO EN 10993-1:2009	n/a	Pass Using ISO 10993-1	
Flame spread	n/a	SANS 50149 and 16 CFR 1610	Class 1 Using 16 CFR Part 1610	
Sterility	Validated sterilization process (optional requirement)	n/a	Validated sterilization process (optional requirement)	

13.1.3 Community face coverings

There is not yet a relevant standard for community face coverings in South Africa. SANS 2065,

"General use face mask—fabric type," is under development.[67]

67 January 2022. Communication with SABS.

13.2 Eye and face protection

The relevant standard, SANS 50166, is an identical adoption of EN 166 (for details, see 4.2.1). Similarly, testing method standards SANS 50167 (for optical test methods) and SANS 50168 (for non-optical test methods) are identical adoptions of EN 167 and EN 168, correspondingly. There is also SANS 1404:2009, "Eye protectors for industrial and non-industrial use," which contains similar requirements with SANS 50166, such as tests for protection against liquid droplets or liquid splashes. Table 13.3 shows the requirements for eye and face protection in the South African market, based on SAN 50166, compared to those of the EU and US markets.

Table 13.3: Comparison between EU, US, and South African standards for eye and face protection

Notes:

- In general, requirements for lenses (only) have not been included.
- For a more detailed comparison of EU and US standards (including test methods), see 4.2.1 of this guide.

Color code:

- Green: Products made to the South African standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the South African standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the South African standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 166:2001**	**South Africa SANS 50166:2018**	**US ANSI/ISEA Z87.1:2020**	**COMPARISON/ COMMENTS**
Characteristic/property	**Requirement/testing method**	**Requirement/ testing method**	**Requirement/testing method**	SANS 50166 is an identical adoption of EN 166
Construction and materials	Pass	Pass	Pass (ANSI Z80.1)	
Headband	Pass	Pass	n/a	
Basic (EU)/fundamental (US) requirements				
Field of vision	Pass (EN 168)	Pass (SANS 50168)		
Min. coverage area	Not a requirement, except for special uses	Not a requirement, except for special uses	Ellipse with axes ≥40 mm and ≥ 33 mm	
Transmittance of oculars without filtering action	> 74.4% (EN 167)	> 74.4% (SANS 50167)	≥ 85% (or ≥ 78% if relaxed optics)	
Haze	n/a	n/a	≤3% (ASTM D1003-13)	
Increased robustness	Pass (EN 168)	Pass (SANS 50168)	Pass	
Thermal stability	Pass (EN 168)	Pass (SANS 50168)	n/a	
Resistance to corrosion	Pass (EN 168)	Pass (SANS 50168)	Pass	
Resistance to ignition	Pass (EN 168)	Pass (SANS 50168)	Pass	

(Market) standard	EU EN 166:2001	South Africa SANS 50166:2018	US ANSI/ISEA Z87.1:2020	COMPARISON/ COMMENTS
Characteristic/property	**Requirement/testing method**	**Requirement/ testing method**	**Requirement/testing method**	SANS 50166 is an identical adoption of EN 166
Particular requirements (EU)				
Droplets and splashes of liquid	No color present for goggles Face shields pass the area coverage test (EN 168)	No color present for goggles Face shields pass the area coverage test (SANS 50168)	No color present for goggles Face shields pass the area coverage test	
Lateral protection (optional)	Pass (EN 168)	Pass (SANS 50168)	Pass	
Optional requirements (EU)				
Resistance to fogging (only for oculars, not complete eye protectors)	Time without fogging ≥ 8 s (EN 168)	Time without fogging ≥ 8 s (SANS 50168)	Time without fogging ≥ 8 s	US requirement added in the 2020 edition

13.3 Gloves

13.3.1 Medical examination gloves

The relevant standard is SANS 11193-1:2010 (for gloves made of rubber/latex), identical to ISO 11193-1:2008 (last revised in 2020). There appears not to be a corresponding standard for gloves made of PVC, for example, an adoption of ISO 11193-2. For details on the ISO standards, see 4.3.1.1.

Also, there is SANS 50455 series of standards, adopting the EN 455 series as follows:

- SANS 50455-1:2019 adopting EN 455-1:2000, "Medical gloves for single-use—Part 1: Requirements and testing for freedom from holes" (not the latest version)
- SANS 50455-2:2019 adopting EN 455-2:2015, "Medical gloves for single-use—Part 2: Requirements and testing for physical properties" (current)
- SANS 50455-3:2019 adopting EN 455-3:2015, "Medical gloves for single-use—Part 3: Requirements and testing for biological evaluation" (current)
- SANS 50455-4:2019 adopting EN 455-4:2009, "Medical gloves for single-use—Part 4: Requirements and testing for shelf-life determination" (current).

These South African standards apply to both surgical gloves and medical examination gloves. This situation is true in the EU/UK as well, while it differs from the approach taken in ISO or ASTM standards, where distinct standards apply for the two uses and different standards cover various materials of construction.

For completeness, the standalone SANS 416:2021, "Chemical resistant gloves," is also mentioned but it will not be further detailed.

Table 13.4 shows the requirements for medical examination gloves in the South African market, based only on SANS 11193-1, compared to those of the EU and US markets.

Table 13.4: Comparison between EU, US, and South African standards for medical examination gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.1.3 of this guide.

Color code:

- Green: Products made to the South African standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the South African standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the South African standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 455 series**	**South Africa Material specific SANS 11193-1:2010 (rubber)**	**US ASTM—material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	SANS 11193-1:2010 is an adoption of ISO 11193-1:2008 (since revised)
Freedom from holes	AQL =1.5 (EN 455-1:2020)	AQL =2.5	AQL =2.5 (ASTM D5151)	
Force at break (N) / Tensile strength (MPa), elongation at break (%) (Also, after ageing/challenge)	Non-thermoplastic materials ≥6.0N Thermoplastic materials (PVC, PE) ≥ 3.6N (EN 455-2 :2015, method A of ISO 23529:2010)	AQL = 4.0 For rubber ≥ 6.0 N Elongation ≥ 500% (Type 1) and ≥ 400% (Type 2)	AQL = 4.0 Nitrile ≥ 14MPa/ elongation ≥400% Latex (natural) ≥ 14MPa / Elongation ≥ 500% Polychloroprene ≥ 14MPa/elongation ≥ 400% PVC ≥ 11MPa/elongation ≥ 300% (ASTM D412, ASTM D573 [ageing])	In the EU, instead of AQL, the median of 13 samples is used In general, the tensile properties and their limits specified in the Indian standards are an amalgam of the EU/US ones SANS and EN standards specify minimum absolute force (N) for samples taken from the glove (varies with thickness); ASTM specifies in terms of tensile strength
Biocompatibility	Pass (EN ISO 10993-5 and -10)	No explicit requirements	Pass (FDA regulations)	
Powder residue content	≤ 2.0mg/glove (EN 455-3, EN ISO 21171:2006)	n/a	≤ 2.0mg/glove (powder-free gloves) ≤ 10 mg/dm² (powdered gloves) (ASTM D6124)	The requirement was first introduced in the 2020 edition of ISO 11193-1
Aqueous soluble protein content	"Manufacturer shall monitor the content in natural rubber latex gloves and shall try to minimize it" (EN 455-3)	n/a	≤ 200 µg/dm² Only for rubber gloves (ASTM D5712)	

(Market) standard	EU EN 455 series	South Africa Material specific SANS 11193-1:2010 (rubber)	US ASTM—material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	SANS 11193-1:2010 is an adoption of ISO 11193-1:2008 (since revised)
Extractable antigenic protein content	Optional	n/a	≤ 10 µg/dm² Only for rubber gloves (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	If gloves are sterilized, the nature of the sterilization process shall be disclosed on request	Pass (US Pharmacopeia)	

13.3.2 Surgical gloves

The relevant standard, SANS 68:2003, is equivalent to ISO 10282:2002, though there is a later (2014) version of ISO 10282 (a minor revision; for details on the ISO standard, see 4.3.2.1). Table 13.5 shows the requirements for surgical gloves in the South African market compared to those of the EU and US markets.

Table 13.5: Comparison between EU, US, and South African standards for surgical gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.2.3 of this guide

Color code:

- Green: Products made to the South African standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the South African standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the South African standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	EU EN 455 series	South Africa SANS 68:2003 Type 1: Natural rubber Type 2: Synthetic rubber	US ASTM D3577-19 Type 1: Natural rubber Type 2: Synthetic rubber	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/ testing method**	
Freedom from holes	AQL = 0.65 (EN 455-1:2020)	AQL = 1.5	AQL = 1.5 (ASTM D5151)	
Force at break (N) Tensile strength (MPa), elongation (%) (Also, after ageing/challenge)	All materials ≥ 9.0N (EN 455-2 :2015, method A of ISO 23529:2010)	AQL = 4.0 Type 1: Latex (natural) ≥18MPa/elongation ≥560% Type 2: Synthetic rubber ≥12Mpa/ elongation ≥490%	AQL = 4.0 Type 1: Latex (natural) ≥18MPa/ elongation ≥560% Type 2: Synthetic rubber ≥12Mpa/ elongation ≥490% (ASTM D412, ASTM D573 (ageing))	EU standard does not specify AQL EU standards specify minimum absolute force (N) for samples taken from the glove (varies with thickness); ASTM and SANS standards specify in terms of tensile strength (MPa—force per unit area)

(Market) standard	EU EN 455 series	South Africa SANS 68:2003 Type 1: Natural rubber Type 2: Synthetic rubber	US ASTM D3577-19 Type 1: Natural rubber Type 2: Synthetic rubber	COMPARISON/COMMENTS
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/ testing method**	
Biocompatibility	Pass (EN ISO 10993-5 and -10)	Pass	Pass (FDA regulations)	SANS specifies generally similar testing methodology with EU/US
Powder residue content	≤ 2.0 mg/glove (EN 455-3, EN ISO 21171:2006)	n/a	≤ 2.0mg/glove (ASTM D6124)	
Aqueous soluble protein content	"Manufacturer shall monitor the content in NRL gloves and shall try to minimize it" (EN 455-3, Annex A)	n/a	≤ 200 µg/dm² (ASTM D5712)	
Extractable antigenic protein content	Optional (EN 455-3, Annex B)	n/a	≤ 10 µg/dm² (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	Gloves shall be sterilized; the nature of the sterilization process shall be disclosed on request	Pass (US Pharmacopeia)	

13.4 Clothing

13.4.1 Full-body and partial-body garments (other than surgical/isolation gowns)

The following standards were identified:

- SANS 434:2018, "General protective clothing," includes requirements on materials, workmanship, size, and make of various types of suits, coats, and overalls. This will not be further analyzed as the regulatory agency SAHPRA references compliance to ISO 13688:2013,[68] "Protective clothing—general requirements" (not yet adopted in South Africa)

- SANS 54325:2019, "Protective clothing against chemicals—test methods and performance classification of chemical protective clothing materials, seams, joins, and assemblages" is an adoption of EN 14325:2018 (current). On the other hand, EN 14126, the standard for protection against infective agents and which makes reference to EN 14325, has not been adopted in South Africa.

As a result of the above, no comparison between South African and EU/US standards for protective clothing can be made.

13.4.2 Gowns

The relevant South African standard, SANS 53795:2015, "Surgical drapes, gowns, and clean air suits,

used as medical devices for patients, clinical for manufacturers, processors, and products,

test methods, performance requirements, and performance levels," is an adoption of EN 13795:2011+A1, since superseded by EN 13795-1 (performance requirements and test methods for surgical gowns and drapes) and EN 13795-2 (same, for clean air suits). For details on EN 13795-1, the standard that is relevant to the scope of this guide, see 4.4.2.1. Table 13.6 shows the requirements for gowns in the South African market compared to those of the EU and US markets.

68 January 2022. Communication with SABS.

Table 13.6: Comparison between EU, US, and South African standards for gowns

Notes:

- For a more detailed comparison of EU and US standards (including test methods), see 4.4.2.3 of this guide.
- For simplicity, only requirements related to barrier performance of gown materials and seams are specified.

Color code:

- Green: Products made to the South African standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the South African standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the South African standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 13795-1:2019 Surgical gowns**	**South Africa SANS 53795:2015 Surgical gowns**	**US ANSI/AAMI PB70:2012 (all gowns) ASTM F2407-20 (surgical gowns) and ASTM F3352-19 (isolation gowns)**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	SANS 53795 is an adoption of EN 13795 (since replaced by EN 13795-1)
Resistance to dry microbial penetration	≤ 300 CFU (less critical areas) *Note*: For critical product areas, wet bacterial penetration limits apply instead EN ISO 22612:2005	≤ 300 CFU (less critical areas) *Note*: For critical product areas, wet bacterial penetration limits apply instead EN ISO 22612	n/a	The Association for the Advancement of Medical Instrumentation (AAMI) PB 70 standard specifically excludes dry microbial penetration from its scope
Resistance to wet bacterial penetration	I_B ≥ 2.8 (critical areas, standard performance) I_B = 6.0 (critical areas, high performance) EN ISO 22610:2006	I_B ≥ 2.8 (critical areas, standard performance) I_B = 6.0 (critical areas, high performance) EN ISO 22610	n/a	US requires (only for Level 4) a stricter characteristic (viral penetration; see next row in table)
Viral penetration	n/a	n/a	Pass (AQL 4%, RQL=20%) (AAMI Level 4) ASTM F1671	
Cleanliness microbial/ bioburden	≤ 300 CFU/100 cm² EN ISO 11737-1:2018	≤ 300 CFU/100 cm² EN ISO 11737-1	n/a	
Particle release	Log_{10} (lint count) ≤ 4.0 EN ISO 9073-10:2004	Log_{10} (lint count) ≤ 4.0 IPM ≤3.5 EN ISO 9073-10		Optional in the US In EN 13795-1, the Index for Particulate Matter (IPM) and the lint count have been combined

(Market) standard	**EU EN 13795-1:2019 Surgical gowns**	**South Africa SANS 53795:2015 Surgical gowns**	**US ANSI/AAMI PB70:2012 (all gowns) ASTM F2407-20 (surgical gowns) and ASTM F3352-19 (isolation gowns)**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	SANS 53795 is an adoption of EN 13795 (since replaced by EN 13795-1)
Water resistance (hydrostatic pressure)	≥ 20 cm H_2O (critical areas, std. performance) ≥ 100 cm H_2O (critical areas, high performance) ≥ 10 cm H_2O (less critical areas) EN ISO 811:2018	≥ 20 cm H_2O (critical areas, std. performance) ≥ 100 cm H_2O (critical areas, high performance) ≥ 10 cm H_2O (less critical areas) EN 20811	≥ 20 cm H_2O (AAMI Level 2) ≥ 50 cm H_2O (AAMI Level 3) (AQL 4%, RQL=20%) AATC 127	For critical areas/zones, US limits are the same as EU/South African ones (for standard performance) or lower (for high performance); limits in the US apply only to critical zone components (akin to critical areas in the EU/South Africa); EU/South African and US methods are similar
Water resistance (impact penetration)	n/a	n/a	≤ 4.5 g (AAMI Level 1) ≤ 1.0 g (AAMI Level 2 and 3) (AQL 4%, RQL=20%) AATC 42 or NWSP 80.3	Limits in the US apply only to critical zone components (akin to critical areas in the EU/South Africa)
Bursting strength (dry) (wet)	≥ 40 kPa ≥ 40 kPa (critical areas) EN ISO 13938:1:1999	≥ 40 kPa ≥ 40 kPa (critical areas) EN ISO 13938:1		
Tensile strength (dry) (wet)	≥ 20 N ≥ 20 N (critical areas) EN 29073-3:1992	≥ 20 N ≥ 20 N (critical areas) EN 29073-3	≥ 30 N ASTM D5034	Higher limit in the US compared to the EU/South Africa. Additionally, limits are set for tear strength (≥ 10 N per ASTM D5587 or D5733) and seam strength (≥ 30 N per ASTM D1683/ D1683M). Physical property limits are Same for all barrier levels per AAMI
Biocompatibility	Pass EN ISO 10993-1:2009	n/a	Pass ANSI/AAMI BE78 or ISO 10993-10	
Sterility	Packaging for terminally sterilized medical devices is recommended according to EN ISO 11607 series	Validated manufacturing and processing procedures shall be used	Assurance level of sterilization process: at least 10^{-6}	
Flammability	Manufacturer to provide fire risk information	No explicit requirements	Class 1 16 CFR 1610	
Other criteria to consider	Comfort (depends on a variety of properties)	Comfort (depends on a variety of properties)	Optional: - Water vapor transmission rate (ASTM D6701) - Evaporative resistance (ASTM F1868, Part B) - etc.	

PART 14
PRODUCT-SPECIFIC COMPARISONS (UK)

As of December 31, 2021, British (BS EN) standards, which are "designated" under the PPE Regulation and the Medical Device Directive (as applicable in the UK), are identical to the EN "harmonized" ones. This situation may diverge in the future due to the exit of the UK from the EU (see 3.12). At present, however, comparison tables against EU/US requirements are relatively straightforward.

14.1 Masks

14.1.1 Respirators

Table 14.1 shows the requirements for respirators in the UK market compared to those of the EU and US markets.

Table 14.1: Comparison between EU, US, and UK standards for respirators

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.1 of this guide.

Color code:

- Green: Products made to the UK standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the UK standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the UK standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU** **EN 149:2001 +A1:2009, Classes FFP2 and FFP3**	**UK** **BS EN 149:2001 +A1:2009, Classes FFP2 and FFP3**	**US** **42 CFR Part 84, Series/Levels N95 and N99**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	British standard is currently a national adoption of EN 149
Practical performance	Pass	Pass	Pass	
Total inward leakage	**FFP2** ≤ 11% (individual) ≤ 8% (mean)	**FFP2** ≤ 11% (individual) ≤ 8% (mean)	n/a	
	FFP3 ≤ 5% (individual) ≤ 2 % (mean)	**FFP3** ≤ 5% (individual) ≤ 2 % (mean)	n/a	

(Market) standard	**EU EN 149:2001 +A1:2009, Classes FFP2 and FFP3**	**UK BS EN 149:2001 +A1:2009, Classes FFP2 and FFP3**	**US 42 CFR Part 84, Series/Levels N95 and N99**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	British standard is currently a national adoption of EN 149
Filtering efficiency	**FFP2** ≥ 94% @ 95 L/min (NaCl and paraffin oil— EN 13274-7)	**FFP2** ≥ 94% @ 95 L/min (NaCl and paraffin oil— BS EN 13274-7)	**N95** ≥ 95% @ 85 L/min (NaCl only)	
	FFP3 ≥ 99% @ 95 L/min (NaCl and paraffin oil— EN 13274-7)	**FFP3** ≥ 99% @ 95 L/min (NaCl and paraffin oil—BS EN 13274-7)	**N99** ≥ 99%@ 85 L/min (NaCl only)	
Compatibility with skin	Pass	Pass	n/a	
Flammability	Pass	Pass	n/a	
Carbon dioxide content	Average ≤ 1% by volume in "dead space"	Average ≤ 1% by volume in "dead space"	n/a	
Field of vision	Pass	Pass	Pass	
Breathing resistance (inhalation)	**FFP2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min	**FFP2** ≤ 70 Pa @ 30 L/min ≤ 240 Pa @ 95 L/min	**N95** ≤ 343 Pa @ 85 L/min	
	FFP 3 ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min	**FFP 3** ≤ 100 Pa @ 30 L/min ≤ 300 Pa @ 95 L/min	**N99** ≤ 343 Pa @ 85 L/min	
Breathing resistance (exhalation)	**FFP2 and FFP3** ≤ 300 Pa @160 L/min	**FFP2 and FFP3** ≤ 300 Pa @160 L/min	**N95 and N99** ≤ 245 Pa @ 85 L/min	

Respirators are regulated as Category III PPE in the UK.

14.1.2 Medical face masks

The UK standard for medical face masks, BS EN 14683:2009, is identical to EN 14683 (for details, see 4.1.2.1). Table 14.2 shows the requirements for medical face masks in the UK market compared to those of the EU and US markets.

Table 14.2: Comparison between EU, US, and UK standards for medical face masks

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.2 of this guide.

Color code:

- Green: Products made to the UK standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the UK standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the UK standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 14683:2019 Types I, II and IIR**	**UK BS EN 14683:2021 Types I, II and IIR**	**US ASTM F2100–21 Levels 1, 2 and 3**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	British standard is currently a national adoption of EN 14683
Bacterial filtration efficiency (BFE)	≥ 95% (Type I) ≥ 98% (Types II, IIR)	≥ 95% (Type I) ≥ 98% (Types II, IIR)	≥ 95% (Level 1) ≥ 98% (Levels 2,3) Using ASTM F2101	
Differential pressure	< 40 Pa/cm² (Types I, II) < 60 Pa/cm² (Type IIR) (Tested at 8L/min flowrate)	< 40 Pa/cm² (Types I, II) < 60 Pa/cm² (Type IIR) (Tested at 8L/min flowrate)	<49 Pa/cm² (Level 1) <58.8 Pa/cm² (Levels 2, 3) Using EN 14683	
Sub-micron particulate filtration efficiency	n/a	n/a	≥ 95 (Level 1) ≥ 98 (Levels 2,3) Both at 0.1 micron, using ASTM F2299	
Splash-resistance pressure	Not required (Types I, II) ≥ 16.0 kPa (Type IIR) Using ISO 22609:2004	Not required (Types I, II) ≥ 16.0 kPa (Type IIR) Using ISO 22609:2004	≥ 10.7 kPa (Level 1) ≥16 kPa (Level 2) ≥21.4 kPa (Level 3) Using ASTM F1862	
Microbial cleanliness	≤ 30 CFU/g Using EN ISO 11737-1:2018	≤ 30 CFU/g Using BS EN ISO 11737-1:2018	n/a	
Biocompatibility	Pass Using ISO EN 10993-1:2009	Pass Using BS EN ISO 10993-1:2009	Pass Using ISO 10993-1	
Flame spread	n/a	n/a	Class 1 Using 16 CFR Part 1610	

Medical face masks are regulated as medical devices in the UK; see part 3.12.3.

14.1.3 Community face coverings

In the UK, the specification BSI Flex 5555, Version 2.1 (April 2021), "Community face coverings—specification," was adapted from the relevant CEN Workshop Agreement (CWA) 17553:2020. Table 14.3 shows the requirements for community face coverings in the UK market compared to those of the EU and US markets.

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.3.3 of this guide

Table 14.3: Comparison between EU, US, and UK standards for community face coverings

Color code:

- Green: Products made to the UK standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the UK standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the UK standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU CWA 17553:2020**	**UK BSI Flex 5555, Version 2.1, April 2021**	**US ASTM F3502-21**	**COMPARISON/ COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Breathing Resistance	EN 14683:2019, Annex C (≤ 70 Pa/cm²) EN 13274-3 (inhalation resistance of 2.4 mbar; exhalation resistance 3 mbar)	Differential pressure ≤60 Pa/cm² (BS EN 14683:2019, Annex C) or Inhalation resistance of 2.4 mbar; exhalation resistance of 3 mbar (BS EN 13274-3:2001, Clause 6, method 1 using a constant flow of 95 l/min)	Subpart K of 42 CFR Part 84, modified by §8.2 (Level 1 ≤ 15 mm H_2O Level 2 ≤ 5 mm H_2O)	For EU, either breathing resistance or air permeability is measured
Air permeability	EN ISO 9237 (≥ 96 l/s/m² @ 100 Pa)	n/a	n/a	
Particle filtration efficiency (PFE)	EN 13274-7:2019 or EN ISO 16890-2 or EN ISO 21083-1:2018, or measure BFE (see below) (Level 90% ≥ 90%; Level 70% ≥ 70%) Particle size 3 (± 0.5) µm	≥ 70% In accordance with the NaCl test method in BS EN 13274-7:2019, Clause 6 with a flow of 95 l/min, Particle size 3 (± 0.5) µm or	Subpart K of 42 CFR Part 84, modified by §8.1 (Level 1 ≥20%; Level 2 ≥ 50%)	For EU and UK, either PFE or BFE is measured For PFE, the CWA provides for alternative methods
Bacterial filtration efficiency (BFE)	EN 14683:2019 Level 90% ≥ 90% Level 70% ≥ 70%	≥ 95% BS EN 14683:2019, Annex B	Manufacturer may choose to provide the BFE results (as per ASTM F 2101) along with PFE	UK exceeds the requirements in EU

14.2 Eye and face protection

The relevant British Standard, BS EN 166, is currently a national adoption of EN 166 (for details, see 4.2.1). Table 14.4 shows the requirements for eye and face protection in the UK market compared to those of the EU and US markets.

Table 14.4: Comparison between EU, US, and UK standards for eye and face protection

Notes:

- In general, requirements for lenses (only) have not been included.
- For a more detailed comparison of EU and US standards (including test methods), see 4.2.1 of this guide.

Color code:

- Green: Products made to the UK standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the UK standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the UK standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 166:2001**	**UK BS EN 166:2001**	**US ANSI/ISEA Z87.1:2020**	**COMPARISON/ COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	British standard is currently a national adoption of EN 166
Construction and materials	Pass	Pass	Pass (ANSI Z80.1)	
Headband	Pass	Pass	n/a	
Basic (EU)/ fundamental (US) requirements				
Field of vision	Pass (EN 168)	Pass (BS EN 168)		
Min. coverage area	Not a requirement, except for special uses	Not a requirement, except for special uses	Ellipse with axes ≥40 mm and ≥ 33 mm	
Transmittance of oculars without filtering action	> 74.4% (EN 167)	> 74.4% (BS EN 167)	≥ 85% (or ≥ 78% if relaxed optics)	
Haze	n/a	n/a	≤3% (ASTM D1003-13)	
Increased robustness	Pass (EN 168)	Pass (BS EN 168)	Pass	
Thermal stability	Pass (EN 168)	Pass (BS EN 168)	n/a	
Resistance to corrosion	Pass (EN 168)	Pass (BS EN 168)	Pass	
Resistance to ignition	Pass (EN 168)	Pass (BS EN 168)	Pass	
Particular requirements (EU)				
Droplets and splashes of liquid	No color present for goggles Face shields pass the area coverage test (EN 168)	No color present for goggles Face shields pass the area coverage test (BS EN 168)	No color present for goggles Face shields pass the area coverage test	

(Market) standard	EU EN 166:2001	UK BS EN 166:2001	US ANSI/ISEA Z87.1:2020	COMPARISON/ COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	British standard is currently a national adoption of EN 166
Lateral protection (optional)	Pass (EN 168)	Pass (BS EN 168)	Pass	
Optional requirements (EU)				
Resistance to fogging (only for oculars, not complete eye protectors)	Time without fogging ≥ 8 s (Acc to EN 168)	Time without fogging ≥ 8 s (BS EN 168)	Time without fogging ≥ 8 s	US requirement added in the 2020 edition

14.3 Gloves

The relevant British Standards are currently national adoptions of EN 455 series (four parts); for details see 4.3.1.1. These standards apply to both medical examination gloves and surgical gloves.

14.3.1 Medical examination gloves

Table 14.5 shows the requirements for medical examination gloves in the UK market compared to those of the EU and US markets.

Table 14.5: Comparison between EU, US, and UK standards for medical examination gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.1 of this guide.

Color code:

- Green: Products made to the UK standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the UK standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the UK standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	EU EN 455 series	UK BS EN 455 series	US ASTM – material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)	COMPARISON/COMMENTS
Characteristic/ Property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	British Standards are currently national adoptions of the EN 455 series
Freedom from holes	AQL =1.5 (EN 455-1:2020)	AQL =1.5 (BS EN 455-1:2020)	AQL =2.5 (ASTM D5151)	

(Market) standard	**EU EN 455 series**	**UK BS EN 455 series**	**US ASTM – material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)**	**COMPARISON/COMMENTS**
Characteristic/ Property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	British Standards are currently national adoptions of the EN 455 series
Force at break (N) / Tensile strength (Mpa), elongation at break (%) (Also, after ageing/challenge)	Non-thermoplastic materials ≥6.0N Thermoplastic materials (PVC, PE) ≥ 3.6N (EN 455-2 :2015, method A of ISO 23529:2010)	Non-thermoplastic materials ≥6.0N Thermoplastic materials (PVC, PE) ≥ 3.6N (BS EN 455-2 :2015, method A of ISO 23529:2010)	AQL = 4.0 Nitrile ≥ 14Mpa/ elongation ≥400% Latex (natural) ≥ 14Mpa / Elongation ≥ 500% Polychloroprene ≥ 14Mpa/elongation ≥ 400% PVC ≥ 11Mpa/elongation ≥ 300% (ASTM D412, ASTM D573 [ageing])	UK and EU standards specify minimum absolute force (N) for samples taken from the glove (varies with thickness); ASTM specifies in terms of tensile strength (Mpa— force per unit area)
Biocompatibility	Pass (EN ISO 10993-5 and -10)	Pass (BS EN ISO 10993-5 and -10)	Pass (FDA regulations)	
Powder residue content	≤ 2.0 mg/glove (EN 455-3, EN ISO 21171:2006)	≤ 2.0 mg/glove (BS EN 455-3, BS EN ISO 21171:2006)	≤ 2.0mg/glove (powder-free gloves) ≤ 10 mg/dm² (powdered gloves) (ASTM D6124)	
Aqueous soluble protein content	"Manufacturer shall monitor the content in natural rubber latex gloves and shall try to minimize it" (EN 455-3)	"Manufacturer shall monitor the content in natural rubber latex gloves and shall try to minimize it" (BS EN 455-3)	≤ 200 µg/dm² Only for rubber gloves (ASTM D5712)	
Extractable antigenic protein content	Optional	Optional	≤ 10 µg/dm² Only for rubber gloves (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	BS EN 455-4 refers to BS EN ISO 11607 (sterile barrier integrity during shelf-life)	Pass (US Pharmacopeia)	

Medical examination gloves are regulated as Class I medical devices in the UK (see 3.12.1).

14.3.2 Surgical gloves

Table 14.6 shows the requirements for surgical gloves in the UK market compared to those of the EU and US markets.

Table 14.6: Comparison between EU, US, and UK standards for surgical gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.2 of this guide.

Color code:

- Green: Products made to the UK standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the UK standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the UK standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 455 series**	**UK BS EN 455 series**	**US ASTM D3577-19 Type 1: Natural rubber Type 2: Synthetic rubber**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/ testing method**	**Requirement/testing method**	British standards are currently national adoptions of the EN 455 series
Freedom from holes	AQL = 0.65 (EN 455-1:2020)	AQL = 0.65 (BS EN 455-1:2020)	AQL = 1.5 (ASTM D5151)	
Force at break (N) / Tensile strength (Mpa), elongation (%) (Also, after ageing/challenge)	All materials ≥ 9.0N (EN 455-2 :2015, method A of ISO 23529:2010)	All materials ≥ 9.0N (BS EN 455-2 :2015, method A of ISO 23529:2010)	AQL = 4.0 Type 1: Latex (natural) ≥18Mpa/elongation ≥560% Type 2: Synthetic rubber ≥12Mpa/elongation ≥490% (ASTM D412, ASTM D573 (ageing))	BS and EN standards specify minimum absolute force (N) for samples taken from the glove (varies with thickness); ASTM specifies in terms of tensile strength (Mpa—force per unit area)
Biocompatibility	Pass (EN ISO 10993-5 and -10)	Pass (BS EN ISO 10993-5 and -10)	Pass (FDA regulations)	
Powder residue content	≤ 2.0 mg/glove (EN 455-3, EN ISO 21171:2006)	≤ 2.0 mg/glove (BS EN 455-3, BS EN ISO 21171:2006)	≤ 2.0mg/glove (ASTM D6124)	
Aqueous soluble protein content	"Manufacturer shall monitor the content in NRL gloves and shall try to minimize it" (EN 455-3, Annex A)	"Manufacturer shall monitor the content in NRL gloves and shall try to minimize it" (BS EN 455-3, Annex A)	≤ 200 µg/dm² (ASTM D5712)	
Extractable antigenic protein content	Optional (EN 455-3, Annex B)	Optional (BS EN 455-3, Annex B)	≤ 10 µg/dm² (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	BS EN 455-4 refers to BS EN ISO 11607 (sterile barrier integrity during shelf-life)	Pass (US Pharmacopeia)	

Surgical gloves are regulated as Class I medical devices in the UK (see 3.12.1)

14.4 Clothing

14.4.1 Full-body and partial-body garments (other than surgical/isolation gowns)

The relevant British standards are currently national adoptions of EN ISO 13688, EN 14126, EN 14605, and EN 13034. Table 14.7 shows the requirements for protective clothing in the UK market compared to those of the EU and US markets.

Table 14.7: Comparison between EU, US, and UK standards for protective clothing

Notes:

- For a more detailed comparison of EU and US standards (including test methods), see 4.4.1 of this guide.
- For simplicity, only requirements for materials and whole suits are included (that is, requirements for seams, joins, assemblages, and integral components, such as visors, are not included).
- For protection against infective agents only the following protection types, as defined in the standards, are considered here: Type 4 (spray-tight), Type PB [4] (partial-body protection—Type 4), Type 6 (limited protection against liquid chemicals), and Type PB [6] (partial-body protection—Type 6).

Color code:

- Green: Products made to the UK standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the UK standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the UK standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

Market	**EU**	**UK**	**US**	**COMPARISON/ COMMENTS**
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
I. General requirements	**EN ISO 13688:2013+A1:2021**	**BS EN ISO 13688:2013+A1:2021**	**NFPA 1999:2018**	
Innocuousness	No harmful substances present No azo dyes present	No harmful substances present No azo dyes present	No specific requirements	
Design and comfort	Acceptable (Annex C)	Acceptable (Annex C)	Acceptable (Section 6.1) *Note*: Design requirements only ≥650 g/(m²24 h) *Note*: In the US for single-use garments/ensembles "moisture vapor transmission rate" is specified (section 8.28 and ASTM E96) ≥450 W/m² *Note*: In the US for multiple-use garments/ensembles "total heat loss test" is specified (section 8.32 and ASTM F1868)	

Market	EU	UK	US	COMPARISON/ COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
II. Protection against infective agents	**EN 14126:2003 & EN 14605:2005+A1:2009 (for Types 4 and PB [4]) or EN 13034:2005+A1:2009 (for Types 6 and PB [6])**	**BS EN 14126:2003 & BS EN 14605:2005+A1:2009 (for Types 4 and PB [4]) or BS EN 13034:2005+A1:2009 (for Types 6 and PB [6])**	**NFPA 1999:2018**	
1. Materials requirements				
a) Mechanical				
Abrasion resistance	Class 1 to 6 (highest) (cl. 4.4 of EN 14325 & EN ISO 12947-2)	Class 1 to 6 (highest) (cl. 4.4 of BS EN 14325 & BS EN ISO 12947-2)	Abrasion resistance is considered as a precondition to barrier performance of materials (ASTM D4157)	
Flex cracking resistance	Class 1 to 6 (highest) (cl. 4.5, 4.6 EN 14325 & EN ISO 7854, method B)	Class 1 to 6 (highest) (cl. 4.5, 4.6 BS EN 14325 & BS EN ISO 7854, method B)	Flex fatigue is considered as a precondition to barrier performance of materials (ASTM F392)	
Trapezoidal tear resistance	Class 1 to 6 (highest) (EN 14325 & EN ISO 9073-4:1997)	Class 1 to 6 (highest) (BS EN 14325 & BS EN ISO 9073-4:1997)	Single-use: "Tear-resistance test two" ≥17 N (section 8.38 and ASTM D5733 for non-woven) Multiple-use: "Tear-resistance test one" ≥36 N (section 8.7 and ASTM D5587 for woven)	
Tensile strength	Class 1 to 6 (highest) (cl. 4.9 of EN 14325 & EN ISO 13934-1)	Class 1 to 6 (highest) (cl. 4.9 of BS EN 14325 & BS EN ISO 13934-1)	≥50 N (section 8.4 and ASTM D5034) Also bursting strength: ≥66N (single-use) ≥222.5N (multiple-use) (section 8.5 & ASTM D3787)	Bursting strength was eliminated in EU and UK
Puncture resistance	Class 1 to 6 (highest) (cl. 4.10 of EN 14325 & EN 863)	Class 1 to 6 (highest) (cl. 4.10 of BS EN 14325 & BS EN 863)	≥12N (single-use) ≥25N (multiple-use) (section 8.6 and ASTM D2572)	
b) Chemical resistance				
Permeation by chemicals (applicable to Types 4 and PB [4])	Class 1 to 6 (highest) (EN ISO 6529, method A for liquids)	Class 1 to 6 (highest) (BS EN ISO 6529, method A for liquids)		
Repellency to liquids (applicable to Types 6 and PB [6])	Class 1 to 3 (highest) (ISO 6530)	Class 1 to 3 (highest) (ISO 6530)	≤30% (Section 8.31)	In the US it is called "water-absorption resistance test"; it applies only to multiple-use garments/ensembles
Penetration by liquids (applicable to Types 6 and PB [6])	Class 1 to 3 (highest) (ISO 6530)	Class 1 to 3 (highest) (ISO 6530)		
c) Flammability				
Resistance to ignition or flame (more stringent)	Pass or min. class 1 (cl. 4.14 EN 14325 & EN 13274-4, method 3)	Pass or min. class 1 (cl. 4.14 BS EN 14325 & BS EN 13274-4, method 3)	Flame spread time≥3.5 s (section 8.39 and ASTM D1230)	

Market	EU	UK	US	COMPARISON/ COMMENTS
Characteristic/ property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
d) Penetration by infective agents				
Contaminated liquids under hydrostatic pressure	Class 1 to 6 (highest) (cl. 4.1.4.1 of EN 14126, ISO 16603 and ISO 16604)	Class 1 to 6 (highest) (cl. 4.1.4.1 of BS EN 14126, ISO 16603 and ISO 16604)	Pass *Note*: In the US the "bio-penetration test one" applies (section 8.3 and ASTM F1671)	
Mechanical contact with contaminated liquids (wet bacterial penetration)	Class 1 to 6 (highest) (cl. 4.1.4.2 of EN 14126 and EN ISO 22610)	Class 1 to 6 (highest) (cl. 4.1.4.2 of BS EN 14126 and BS EN ISO 22610)	n/a	
(Biologically) contaminated liquid aerosols	Class 1 to 3 (highest) (cl. 4.1.4.3 of EN 14126)	Class 1 to 3 (highest) (cl. 4.1.4.3 of BS EN 14126)	n/a	
Contaminated solid particles (dry microbial penetration)	As above (cl. 4.1.4.4 of EN 14126 and ISO 22612)	As above (cl. 4.1.4.4 of BS EN 14126 and ISO 22612)	n/a	
2. Whole-suit requirements				
Mist test (Type 6)	Pass (EN ISO 17491-4 (method A) as modified by cl. 5.2 of EN 13034)	Pass (BS EN ISO 17491-4 (method A) as modified by cl. 5.2 of BS EN 13034)	Pass (Section 8.2) *Note*: In the US the "liquid tight integrity test one" applies	
Liquid spray test (Type 4)	Pass (cl. 4.3.4.2 etc. of EN 14605 and EN ISO 17491-4 (method B))	Pass (cl. 4.3.4.2 etc. of BS EN 14605 and BS EN ISO 17491-4 [method B])	Pass (Section 8.2)	
Practical performance	Pass (EN 14605/EN 13034—"seven movements" sequence while wearing the suit)	Pass (BS EN 14605/BS EN 13034—"seven movements" sequence while wearing the suit)	Demonstration of garment functionality is included as part of the liquid integrity testing applied to garments (ASTM F1154)	

14.4.2 Gowns

The relevant British standard, BS EN 13795-1, is currently a national adoption of EN 13795-1 (for details on the EN, see 4.4.2.1). Table 14.8 shows the requirements for gowns in the UK market compared to those of the EU and US markets.

Table 14.8: Comparison between EU, US, and UK standards for gowns

Notes:

- For a more detailed comparison of EU and US standards (including test methods), see 4.4.2.3 of this guide.
- For simplicity, only requirements related to barrier performance of gown materials and seams are specified.

Color code:

- Green: Products made to the UK standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the UK standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the UK standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU** **EN 13795-1:2019** **Surgical gowns**	**UK** **BS EN 13795-1:2019** **Surgical gowns**	**US** **ANSI/AAMI PB70:2012 (all gowns)** **ASTM F2407-20 (surgical gowns) and ASTM F3352-19 (isolation gowns)**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/ testing method**	British standard is currently a national adoption of EN 13795-1
Resistance to dry microbial penetration	≤ 300 CFU (less critical areas) *Note*: For critical product areas, wet bacterial penetration limits apply instead EN ISO 22612:2005	≤ 300 CFU (less critical areas) *Note*: For critical product areas, wet bacterial penetration limits apply instead BS EN ISO 22612:2005	n/a	The Association of the Advancement of Medical Instrumentation (AAMI) PB 70 standard specifically excludes dry microbial penetration from its scope
Resistance to wet bacterial penetration	I_B ≥ 2.8 (critical areas, standard performance) I_B = 6.0 (critical areas, high performance) EN ISO 22610:2006	I_B ≥ 2.8 (critical areas, standard performance) I_B = 6.0 (critical areas, high performance) BS EN ISO 22610:2006	n/a	US requires (only for Level 4) a stricter characteristic (viral penetration; see next row in table)
Viral penetration	n/a	n/a	Pass (AQL 4%, RQL=20%) (AAMI Level 4) ASTM F1671	
Cleanliness microbial/ bioburden	≤ 300 CFU/100 cm² EN ISO 11737-1:2018	≤ 300 CFU/100 cm² BS EN ISO 11737-1:2018	n/a	
Particle release	Log_{10} (lint count) ≤ 4.0 EN ISO 9073-10:2004	Log_{10} (lint count) ≤ 4.0 BS EN ISO 9073-10:2004		Optional in the US
Water resistance (hydrostatic pressure)	≥ 20 cm H_2O (critical areas, std. performance) ≥ 100 cm H_2O (critical areas, high performance) ≥ 10 cm H_2O (less critical areas) EN ISO 811:2018	≥ 20 cm H_2O (critical areas, std. performance) ≥ 100 cm H_2O (critical areas, high performance) ≥ 10 cm H_2O (less critical areas) BS EN ISO 811:2018	≥ 20 cm H_2O (AAMI Level 2) ≥ 50 cm H_2O (AAMI Level 3) (AQL 4%, RQL=20%) AATC 127	For critical areas/zones, US limits are the same as EU/UK ones (for standard performance) or lower (for high performance); limits in the US apply only to critical zone components (akin to critical areas in the EU/UK); EU/UK and US methods are similar

(Market) standard	**EU** **EN 13795-1:2019** **Surgical gowns**	**UK** **BS EN 13795-1:2019** **Surgical gowns**	**US** **ANSI/AAMI PB70:2012 (all gowns)** **ASTM F2407-20 (surgical gowns) and ASTM F3352-19 (isolation gowns)**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/ testing method**	British standard is currently a national adoption of EN 13795-1
Water resistance (impact penetration)	n/a	n/a	≤ 4.5 g (AAMI Level 1) ≤ 1.0 g (AAMI Levels 2 and 3) (AQL 4%, RQL=20%) AATC 42 or NWSP 80.3	Limits in the US apply only to critical zone components (akin to critical areas in the EU/UK)
Bursting strength (dry) (wet)	≥ 40 kPa ≥ 40 kPa (critical areas) EN ISO 13938:1:1999	≥ 40 kPa ≥ 40 kPa (critical areas) BS EN ISO 13938:1:1999		
Tensile strength (dry) (wet)	≥ 20 N ≥ 20 N (critical areas) EN 29073-3:1992	≥ 20 N ≥ 20 N (critical areas) BS EN 29073-3:1992	≥ 30 N ASTM D5034	Higher limit in the US compared to the EU/UK. Additionally, limits are set for tear strength (≥ 10 N per ASTM D5587 or D5733) and seam strength (≥ 30 N per ASTM D1683/ D1683M). Physical property limits are same for all barrier levels per AAMI
Biocompatibility	Pass EN ISO 10993-1:2009	Pass BS EN ISO 10993-1:2009	Pass ANSI/AAMI BE78 or ISO 10993-10	
Sterility	Packaging for terminally sterilized medical devices is recommended according to EN ISO 11607 series	Packaging for terminally sterilized medical devices is recommended according to BS EN ISO 11607 series	Assurance level of sterilization process: at least 10^{-6}	
Flammability	Manufacturer to provide fire risk information	Manufacturer to provide fire risk information	Class 1 16 CFR 1610	
Other criteria to consider	Comfort (depends on a variety of properties)	Comfort (depends on a variety of properties)	Optional: - Water vapor transmission rate (ASTM D6701) - Evaporative resistance (ASTM F1868, Part B) - etc.	

Surgical gowns are regulated as medical devices in the UK; see 3.12.3.

PART 15 PRODUCT-SPECIFIC COMPARISONS (VIETNAM)

15.1 Masks

15.1.1 Respirators

There is currently no Vietnamese equivalent to EN 149 or to 42 Code for Federal Regulations (CFR) Part 84 for respirators. TCVN 12325:2018, "Requirements and test methods for dust filters," is derived from EN 143:2000 but is not directly relevant. The test methods of TCVN 7312:2003, "Personal respiratory protective devices—dust masks with filter," are specified in TCVN 8389-1 (see section on face masks below) but TCVN 7312 is not explicitly mentioned in any COVID-19-related Vietnamese announcements. Therefore, no comparison table to EU/US requirements can be provided.

15.1.2 Face masks

In Vietnam the categorization of face masks is not the same as in the EU or the United States. Vietnam has two relevant standards, as follows:

- TCVN 8389-1:2010, "Medical face masks—Part 1: Normal medical face masks," combine some of the characteristics of respirators and surgical masks according to the EU/US classifications. Additional requirements in Vietnam, not commonly found in other standards, are tests for the absence of heavy metals and for the field of vision (according to TCVN 3159)

- TCVN 8389-2:2010, "Medical face masks—Part 2: Medical face masks preventing bacteria," includes all the requirements of "normal" masks but also requires masks to have a bactericide on their external surface, thus giving them a bacterial filtration efficiency (BFE) of almost 100 percent (but measured in a much simpler way than in the EU/United States). They are also sterile.

Table 15.1 shows the requirements for medical face masks in the Vietnamese market compared to those of the EU and US markets.

Table 15.1: Comparison between EU, US, and Vietnam standards for medical face masks

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.1 and 4.1.2 of this guide.

Color code:

- Green: Products made to the Vietnamese standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Vietnamese standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Vietnamese standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU EN 14683:2019 Types I, II and IIR**	**Vietnam TCVN 8389-1 and -2, Normal and antibacterial**	**US ASTM F2100–21 Levels 1, 2 and 3**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Bacterial filtration efficiency (BFE)	≥ 95% (Type I)	Not required for masks per TCVN 8389-1	≥ 95% (Level 1)	Testing method for Vietnam is different (simpler) than for EU and US
	≥ 98% (Types II, IIR)	>99.99% for masks per TCVN 8389-2 (with antibacterial surface); tested at 10L/min flowrate	≥ 98% (Levels 2,3) Using ASTM F2101	
Differential pressure	< 40 Pa/cm² (Types I, II) < 60 Pa/cm² (Type IIR) (Tested at 8L/min flowrate)	89 Pa (specified as 9mm H_2O) Using TCVN 7312 with a flowrate of @ 30 l/min	<49 Pa/cm² (Level 1) <58.8 Pa/cm²– (Levels 2,3) using EN 14683	Units of measurement for acceptance criteria and test methods differ significantly from those in the EU and US
Sub-micron particulate filtration efficiency	n/a	≥ 90% Using TCVN 7312 with a flowrate of 30 l/min	≥ 95% (Level 1) ≥ 98% (Levels 2,3) Both at 0.1 micron, using ASTM F2299	
Splash-resistance pressure	Not required (Types I, II)	n/a	≥ 10.7 kPa (Level 1)	
	≥ 16.0 kPa (Type IIR) Using ISO 22609:2004	n/a	≥16 kPa (Level 2) ≥21.4 kPa (Level 3) Using ASTM F1862	
Microbial cleanliness	≤ 30 CFU/g Using EN ISO 11737-1:2018	Not required for "simple" masks; see sterility requirement for antibacterial masks	n/a	
Biocompatibility	Pass Using ISO EN 10993-1:2009	n/a	Pass Using ISO 10993-1	
Flame spread	n/a	n/a	Class 1 Using 16 CFR Part 1610	
Heavy metals	n/a	Limits specified for As, Pb, Hg, Sb and Cd	n/a	
Sterility	Validated sterilization process (optional requirement)	Requirement only for antibacterial masks; using Vietnamese Pharmacopeia	Validated sterilization process (optional requirement)	
Field of vision	n/a	≥ 94% Using TCVN 3159	n/a	

"Antibacterial" masks are regulated in Vietnam as medical devices; see 3.13.3. The situation for "normal" masks is not clear-cut.

15.1.3 Community face coverings

No directly relevant standard for community face coverings in Vietnam has been identified. However, a technical regulation (decision No. 8720/QD-BYT dated March 12, 2020, on temporary technical guidelines for fabric anti-droplet and bacteria prevention face masks) provides relevant specifications and makes reference to standards TCVN 8389-1:2010 and TCVN 8389-2:2010 for medical masks.

Table 15.2 shows the requirements for community face coverings in the Vietnamese market compared to those of the EU and US markets.

Table 15.2: Comparison between EU, US, and Vietnam standards for community face coverings

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.1.3 of this guide.

Color code:

- Green: Products made to the Vietnamese standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Vietnamese standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Vietnamese standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU CWA 17553:2020**	**Vietnam Decision No. 870/ QD-BYT**	**US ASTM F3502-21**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/ Testing method**	**Requirement/ Testing method**	**Requirement/ Testing method**	
Breathing resistance	EN 14683:2019, Annex C (≤ 70 Pa/cm²) EN 13274-3 (inhalation resistance of 2.4 mbar; exhalation resistance 3 mbar)	≤9 mm H_2O	Subpart K of 42 CFR Part 84, modified by §8.2 (Level 1 ≤ 15 mm H_2O Level 2 ≤ 5 mm H_2O)	
Air permeability	EN ISO 9237 (≥ 96 l/s/m² @ 100 Pa)	n/a	n/a	
Particle filtration efficiency (PFE)	EN 13274-7 EN ISO 16890-2 EN ISO 21083-1:2018, (Level 90% ≥ 90%; Level 70% ≥ 70%) Particle size 3 (± 0.5) µm	≥ 90%; @ 40L/min using oil mist	Subpart K of 42 CFR Part 84, modified by §8.1 (Level 1 ≥20%; Level 2 ≥ 50%)	
Bacterial filtration efficiency (BFE)	EN 14683:2019 (Level 90% ≥ 90%; Level 70% ≥ 70%)	n/a	Manufacturer may choose to provide the BFE results (as per ASTM F 2101) along with PFE	
Heavy metals	n/a	Limits specified for As, Pb, Hg, Sb, and Cd	n/a	

15.2 Eye and face protection

No standards for eye and face protection in Vietnam have been identified. Therefore, no comparison table to the EU/US ones can be provided.

15.3 Gloves

15.3.1 Medical examination gloves

The relevant standards are TCVN 6343-1:2007 (for gloves made of rubber/latex), identical to ISO 11193-1:2002 with A1:2007 (last revised in 2020) and TCVN 6343-2:2007 (made of PVC), identical to ISO 11193-2:2006 (current). For details on the ISO standards, see 4.3.1.1.

For completeness, the standard TCVN 12326-5:2018, "Protective gloves against dangerous chemicals and micro-organisms—Part 5: Terminology and performance requirements for micro-organisms risks," identical to ISO 374-5:2016 (current), is also mentioned. As it has been analyzed in section 4.3.1.1 on EU requirements for examination gloves, standards on "protective gloves" as opposed to "medical gloves" will not be further detailed

Table 15.3 shows the requirements for medical examination gloves in the Vietnamese market compared to those of the EU and US markets.

Table 15.3: Comparison between EU, US, and Vietnam standards for medical examination gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.1.3 of this guide.

Color code:

- Green: Products made to the Vietnamese standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Vietnamese standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Vietnamese standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU** **EN 455 series**	**Vietnam** **TCVN 6343-1:2007 (rubber)** **TCVN 6343-2:2007 (PVC)**	**US** **ASTM—material specific** **D6319 (nitrile)** **D3578 (rubber)** **D5250 (PVC)** **D6977 (polychloroprene)**	**COMPARISON/ COMMENTS**
Characteristic/property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Freedom from holes	AQL =1.5 (EN 455-1:2020)	AQL =2.5	AQL =2.5 (ASTM D5151)	

(Market) standard	**EU EN 455 series**	**Vietnam TCVN 6343-1:2007 (rubber) TCVN 6343-2:2007 (PVC)**	**US ASTM—material specific D6319 (nitrile) D3578 (rubber) D5250 (PVC) D6977 (polychloroprene)**	**COMPARISON/ COMMENTS**
Characteristic/property	**Requirement/ testing method**	**Requirement/testing method**	**Requirement/testing method**	
Force at break (N) / Tensile strength (MPa), elongation at break (%) (Also, after ageing/challenge)	Non-thermoplastic materials ≥6.0N Thermoplastic materials (PVC, PE) ≥ 3.6N (EN 455-2 :2015, method A of ISO 23529:2010)	AQL = 4.0 For rubber ≥ 6.0 N Elongation ≥ 500% (Type 1), 400% (Type 2) For PVC ≥ 7.0 N Elongation ≥ 350%	AQL = 4.0 Nitrile ≥ 14MPa/ elongation ≥400% Latex (natural) ≥ 14MPa / Elongation ≥ 500% Polychloroprene ≥ 14MPa/elongation ≥ 400% PVC ≥ 11MPa/elongation ≥ 300% (ASTM D412, ASTM D573 [ageing])	In general, the tensile properties and their limits specified in the Vietnamese standards are an amalgam of the EU/ US ones Vietnamese and EU standards specify minimum absolute force (N) for samples taken from the glove (varies with thickness); ASTM specifies in terms of tensile strength (MPa—force per unit area)
Biocompatibility	Pass (EN ISO 10993-5 and -10)	No explicit requirements	Pass (FDA regulations)	
Powder residue content	≤ 2.0mg/glove (EN 455-3, EN ISO 21171:2006)	n/a	≤ 2.0mg/glove (powder-free gloves) ≤ 10 mg/dm² (powdered gloves) (ASTM D6124)	
Aqueous soluble protein content	"Manufacturer shall monitor the content in NRL gloves and shall try to minimize it" (EN 455-3)	n/a	≤ 200 µg/dm² Only for rubber gloves (ASTM D5712)	
Extractable antigenic protein content	Optional	n/a	≤ 10 µg/dm² Only for rubber gloves (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	If gloves are sterilized, the nature of the sterilization process shall be disclosed on request	Pass US Pharmacopeia	

15.3.2 Surgical gloves

The relevant standard, TCVN 6344:2007, is equivalent to ISO 10282:2002, though there is a later (2014) version of ISO 10282 (for details on the ISO standard, see 4.3.2.1). Table 15.4 shows the requirements for surgical gloves in the Vietnamese market compared to those of the EU and US markets.

Table 15.4: Comparison between EU, US, and Vietnam standards for surgical gloves

Note: For a more detailed comparison of EU and US standards (including test methods), see 4.3.2.3 of this guide.

Color code:

- Green: Products made to the Vietnamese standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Vietnamese standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Vietnamese standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

(Market) standard	**EU** **EN 455 series**	**Vietnam** **TCVN 6344:2007** **Type 1: Natural rubber** **Type 2: Synthetic rubber**	**US** **ASTM D3577-19** **Type 1: Natural rubber** **Type 2: Synthetic rubber**	**COMPARISON/COMMENTS**
Characteristic/ property	**Requirement/testing method**	**Requirement/testing method**	**Requirement/testing method**	
Freedom from holes	AQL = 0.65 (EN 455-1:2020)	AQL = 1.5	AQL = 1.5 (ASTM D5151)	
Force at break (N) Tensile strength (MPa), elongation (%) (Also, after ageing/challenge)	All materials ≥ 9.0N (EN 455-2 :2015, method A of ISO 23529:2010)	AQL = 4.0 Type 1: Latex (natural) ≥18MPa/elongation ≥560% Type 2: Synthetic rubber ≥12Mpa/elongation ≥490%	AQL = 4.0 Type 1: Latex (natural) ≥18MPa/elongation ≥560% Type 2: Synthetic rubber ≥12Mpa/elongation ≥490% (ASTM D412, ASTM D573 [ageing])	EU standard does not specify AQL EU standards specify minimum absolute force (N) for samples taken from the glove (varies with thickness); ASTM and TCVN standards specify in terms of tensile strength (MPa—force per unit area)
Biocompatibility	Pass (EN ISO 10993-5 and -10)	Pass	Pass (FDA regulations)	TCVN specifies generally similar testing methodology with EU/ US
Powder residue content	≤ 2.0 mg/glove (EN 455-3, EN ISO 21171:2006)	n/a	≤ 2.0mg/glove (ASTM D6124)	
Aqueous soluble protein content	"Manufacturer shall monitor the content in NRL gloves and shall try to minimize it" (EN 455-3, Annex A)	n/a	≤ 200 µg/dm² (ASTM D5712)	
Extractable antigenic protein content	Optional (EN 455-3, Annex B)	n/a	≤ 10 µg/dm² (ASTM D6499)	
Sterility	EN 455-4 refers to EN ISO 11607 (sterile barrier integrity during shelf-life)	Gloves shall be sterilized; the nature of the sterilization process shall be disclosed on request	Pass US Pharmacopeia	

15.4 Clothing

15.4.1 Full-body and partial-body garments (other than surgical/isolation gowns)

The only standard that could be identified is TCVN 6689:2021, identical to ISO 13688:2013 +AMD1:2021 (current). TCVN 6689 only specifies general requirements about (any kind of) protective clothing and it supplements standards with requirements for specific protection. No TCVN could be identified that is similar to EN 14126 (against infective agents) but the latter is accepted by authorities in Vietnam. Table 15.5 shows the requirements for protective clothing in the Vietnamese market compared to those of the EU and US markets.

Table 15.5: Comparison between EU, US, and Vietnam standards for protective clothing

Notes:

- For a more detailed comparison of EU and US standards (including test methods), see 4.4.1 of this guide.
- For simplicity, only requirements for materials and whole suits are included (that is, requirements for seams, joins, assemblages, and integral components, such as visors, are not included).
- For protection against infective agents only the following protection types, as defined in the standards, are considered here: Type 4 (spray-tight), Type PB [4] (partial-body protection— Type 4), Type 6 (limited protection against liquid chemicals) and Type PB [6] (partial-body protection—Type 6).

Color code:

- Green: Products made to the Vietnamese standard are likely to meet or exceed the EU or US standard
- Yellow: Products made to the Vietnamese standard might not meet the European or US standard but are similar. Additional testing may be required if conformity to the EU or US standard is to be claimed
- Red: Significantly different criteria—products made to the Vietnamese standard are not likely to meet the EU or US standard and/or additional testing will be required
- Blue: Differences in criteria and/or test methods mean it is not possible to make a direct comparison

Note: Testing standard is only mentioned if it is not defined in the product specification.

Market	**EU**	**Vietnam**	**US**	**COMPARISON/COMMENTS**
Characteristic/ Property	**Requirement/ Testing method**	**Requirement/ Testing method**	**Requirement/ Testing method**	
I. General requirements	**EN ISO 13688:2013+A1:2021**	**TCVN 6689:2021**	**NFPA 1999:2018**	No TCVN standard could be identified that is similar to EN 14126 (protection against infective agents) but EN 14126 seems to be accepted in Vietnam, as well
Innocuousness	No harmful substances present No azo dyes present	No harmful substances present No azo dyes present	No specific requirements	TCVN is identical to ISO 13688 + AMD1

Market	EU	Vietnam	US	COMPARISON/COMMENTS
Characteristic/ Property	**Requirement/ Testing method**	**Requirement/ Testing method**	**Requirement/ Testing method**	
Design and comfort	Acceptable (Annex C)	Acceptable Assessment in Annex C	Acceptable (section 6.1) *Note*: Design requirements only ≥650 g/(m²24 h) *Note*: In the US for single-use garments/ ensembles "moisture vapor transmission rate" is specified (section 8.28 and ASTM E96) ≥450 W/m² *Note*: In the US for multiple-use garments/ ensembles "total heat loss test" is specified (section 8.32 and ASTM F1868)	
II. Protection against infective agents	**EN 14126:2003 & EN 14605:2005+A1:2009 (for Types 4 and PB [4]) or EN 13034:2005+A1:2009 (for Types 6 and PB [6])**	**No requirements**	**NFPA 1999:2018**	
1. Materials requirements				
a) Mechanical		**No requirements for mechanical properties**		
Abrasion resistance	Class 1 to 6 (highest) (cl. 4.4 of EN 14325 & EN ISO 12947-2)	n/a	Abrasion resistance is considered as a precondition to barrier performance of materials (ASTM D4157)	
Flex cracking resistance	Class 1 to 6 (highest) (cl. 4.5, 4.6 EN 14325 & EN ISO 7854, method B)	n/a	Flex fatigue is considered as a precondition to barrier performance of materials (ASTM F392)	
Trapezoidal tear resistance	Class 1 to 6 (highest) (EN 14325 & EN ISO 9073-4:1997)	n/a	Single-use: "Tear-resistance test two" ≥17 N (section 8.38 and ASTM D5733 for non-woven) Multiple-use: 'tear resistance test one' ≥36 N (Section 8.7 & ASTM D5587 for woven)	
Tensile strength	Class 1 to 6 (highest) (cl. 4.9 of EN 14325 & EN ISO 13934-1)	n/a	≥50 N (section 8.4 and ASTM D5034) Also bursting strength: ≥66N (single-use) ≥222.5N (multiple-use) (section 8.5 and ASTM D3787)	Bursting strength was eliminated in EU

Market	**EU**	**Vietnam**	**US**	**COMPARISON/COMMENTS**
Characteristic/ Property	**Requirement/ Testing method**	**Requirement/ Testing method**	**Requirement/ Testing method**	
Puncture resistance	Class 1 to 6 (highest) (cl. 4.10 of EN 14325 & EN 863)	n/a	≥12N (single-use) ≥25N (multiple-use) (section 8.6 and ASTM D2572)	
b) Chemical resistance		**No requirements for chemical resistance properties**		
Permeation by chemicals (applicable to Types 4 and PB [4])	Class 1 to 6 (highest) (EN ISO 6529, method A for liquids)	n/a		
Repellency to liquids (applicable to Types 6 and PB [6])	Class 1 to 3 (highest) (ISO 6530)	n/a	≤30% (section 8.31)	In the US it is called "water-absorption resistance test"; it applies only to multiple-use garments/ensembles
Penetration by liquids (applicable to Types 6 and PB [6])	Class 1 to 3 (highest) (ISO 6530)	n/a		
c) Flammability		**No requirements for flammability**		
Resistance to ignition or flame (more stringent)	Pass or min. class 1 (cl. 4.14 EN 14325 & EN 13274-4, method 3)	n/a	Flame spread time ≥3.5 s (section 8.39 and ASTM D1230)	
d) Penetration by infective agents		**Requirement/ testing method**		
Contaminated liquids under hydrostatic pressure	Class 1 to 6 (highest) (cl. 4.1.4.1 of EN 14126, ISO 16603 and ISO 16604)	n/a	Pass *Note*: In the US the "bio-penetration test one" applies (section 8.3 and ASTM F1671)	
Mechanical contact with contaminated liquids (wet bacterial penetration)	Class 1 to 6 (highest) (cl. 4.1.4.2 of EN 14126 and EN ISO 22610)	n/a	n/a	
(Biologically) contaminated liquid aerosols	Class 1 to 3 (highest) (cl. 4.1.4.3 of EN 14126)	n/a	n/a	
Contaminated solid particles (dry microbial penetration)	As above (cl. 4.1.4.4 of EN 14126 and ISO 22612)	n/a	n/a	ISO 22612:2006 has been adopted as TCVN 11539:2016; there is, however, no TCVN product standard referring to it
2. Whole-suit requirements		No requirements for whole suits		
Mist test (Type 6)	Pass (EN ISO 17491-4 (method A) as modified by cl. 5.2 of EN 13034)	n/a	Pass (section 8.2) *Note*: In the US the "liquid tight integrity test one" applies	

Market	EU	Vietnam	US	COMPARISON/COMMENTS
Characteristic/ Property	**Requirement/ Testing method**	**Requirement/ Testing method**	**Requirement/ Testing method**	
Liquid spray test (Type 4)	Pass (cl. 4.3.4.2 etc. of EN 14605 and EN ISO 17491-4 [method B])	n/a	Pass (section 8.2)	
Practical performance	Pass (EN 14605/EN 13034—"seven movements sequence" while wearing the suit)	n/a	Demonstration of garment functionality is included as part of the liquid integrity testing applied to garments (ASTM F1154)	

15.4.2 Gowns

No standards for medical gowns in Vietnam have been identified. Therefore, no comparison table can be provided. For international gown standards accepted in Vietnam, see 3.13.2.

ANNEX A
OTHER CONSIDERATIONS FOR MANUFACTURERS AND PURCHASERS OF COVID-19-RELATED PPE

A1 Sustainability of PPE

The increased global use of PPE during the COVID-19 pandemic has brought with it considerable risk to the environment. Many national administrations have mandated the use of PPE (primarily face coverings) as part of front-line measures to prevent the spread of the virus. Non-woven (polymer-based) single-use face coverings are the PPE of choice for many users given their convenience, price, and ease of access.

This global uptake in the use and disposal of single-use PPE (masks, gloves, gowns, aprons, and so on) has compromised solid waste management strategies at municipal and national levels in many countries, as waste management administrations and facilities grapple with the sheer volume of discarded PPE and medical waste more generally. The issue is further compounded by increased consumption of other single-use commodities used in the battle against COVID-19 and the fact that recommended practice PPE disposal requirements call for specialist processing that is not available in sufficient capacity at many waste management facilities.

In its recent report "Innovation in Manufacturing Personal Protective Equipment—Toward Sustainability and Circularity," [69] IFC estimates that since the start of the pandemic, the amount of plastic waste generated globally has been 1.6 million tons per day. It is further estimated that 3.4 billion single-use face masks and shields are being discarded every day. [70] These numbers alone are a clear indicator that PPE manufacturers, users/consumers, and governments need to collaborate and strive to be more ecologically conscious when using and disposing of PPE.

PPE sustainability and its impact on global pollution levels are urgent priorities that need to be addressed along the PPE lifecycle of resin-to-recycling. This approach will require a rethinking of fundamental strategies around PPE materials, production processes and technology, transportation and distribution, utilization and disposal.

Each of these themes is not without its own set of complexities and challenges. And although the analysis of these issues is not the primary focus of this guide, attention does need to be drawn to the critical role that global standards can play toward realizing PPE sustainability objectives. All relevant stakeholders should discuss ways in which sustainability aspects can be incorporated into existing and new PPE standards.

69 https://www.ifc.org/wps/wcm/connect/industry_ext_content/ifc_external_corporate_site/manufacturing/resources/innovation+in+manufacturing+personal+protective+equipment.

70 https://www.sciencedirect.com/science/article/pii/S2405844021004485.

During the event hosted by the British Standards Institution (BSI) in 2021 to celebrate the 75th anniversary of the International Organization for Standardization (ISO),[71] representatives of all 163 national ISO Members signed the "London Declaration." [72] The development of this declaration was led by BSI, with the stated intention of considering climate science in every new standard that is created and retrospectively for all existing standards as they are revised.

This is precisely where the focus of sustainability in PPE should be directed—making sure that the necessary "sustainable product policy framework" is in place across different governments, "reinventing" or significantly improving the key value chains, and finally, but no less importantly, educating and empowering users. Providing better information to consumers leads to better-informed purchasing and this can certainly be achieved through standards. To do so, sustainability and material efficiency aspects must be included in PPE-related legislation and standardization. Governments should focus on establishing and harmonizing certain policy and standardization must-haves that would enable PPE products to move toward more sustainable options, allowing for their reusability.

This technical guide shows that standards and certification for PPE products have so far focused on requirements for safety, health functions, and conformity with the relevant legislation, without containing much data on circularity, reuse, or reprocessing. There is a need to focus on embedding product requirements related to durability, use/reuse, and recyclability into the policies and standards, as well as developing the corresponding testing methods.

Sustainability in PPE must be achieved by following common circular economy principles that have proven effective in other sectors (that is, designing products so that the resources needed in their manufacture are kept to a minimum and the life of those resources is extended for as long as possible via reuse, recycling and remanufacture). These principles and approaches should guide future policy development for PPE management after the current pandemic and in the case of any future pandemic.

Future standards must, to the extent possible, include aspects on:

- Sustainability and material efficiency
- Defining performance requirements for the PPE products in a way that manufacturers can offer innovative products that achieve both the necessary protection for users and durability/reusability
- Instructions on how to care for reusable products (clear cleaning and maintenance instructions, maximum use time, and similar)
- Clear waste and disposal procedures.

A2 Diversity and inclusion in PPE

In most health care systems, 75—80 percent of staff are women. According to the recent Women in Global Health report, [73] "women [make up] 90 percent of nurses and have been the vast majority of health care workers in patient-facing roles in the pandemic [...] Therefore, if medical PPE is not fit for women, it is not fit for the majority of the health workforce."

Most PPE that is available is based on generic anthropometric data. Generally, for those who fall outside the data that are considered to represent 5—95 percent of various user segments, the hope of finding anything to fit them is low, regardless of gender. Additionally, anthropometric data is limited to only a few metrics and does not provide a complete anatomically accurate picture. During the pandemic, health care workers from non-Caucasian populations faced additional challenges with mask fit due to diverse face shapes, whether they may be smaller or larger depending on gender and race. The COVID-19 pandemic further highlighted

71 https://www.bsigroup.com/en-GB/about-bsi/uk-national-standards-body/what-is-the-national-standards-body/iso-week-2021/.

72 https://www.bsigroup.com/en-GB/about-bsi/uk-national-standards-body/london-declaration/.

73 https://www.womeningh.org/fitforwomen.

major challenges in governance and inequalities particularly among those from black, Asian, and minority ethnic groups. Simply making something a bit bigger or a bit smaller does not address diversity needs.

Notwithstanding some efforts from ISO to address such issues for the case of respiratory protection devices with the ISO 16976 series of standards, [74]the next challenge to address is that standards written for PPE often fail to take into account a diverse group of end users. With ever more diversity in the workforce, there has been an effort to expand the sizes offered in various types of PPE, and companies are producing PPE such as goggles and coveralls for a larger range of body shapes and sizes. While available information on the degree of design efforts in creating these products is limited, suppliers suggest a growing demand for "diversely sized PPE". However, producing diversely sized PPE is only the first step. There are other barriers such as problems with supply chains, lack of promotion of diversely sized PPE, a lack of awareness among employers, procurement officials and others of the need for alternative PPE and economics of costs vs. return. The provision of a suitable selection of PPE to meet all sizes and genders is market driven. Historically there was no money to be made by producing customized PPE for a diverse minority of the workforce. [75]All these factors hinder getting diversely sized PPE from the manufacturer to the workers who need it.

Standards need to play a crucial role in helping the industry deliver on this challenge and make the necessary efforts to develop better methods and processes for ensuring that PPE is more inclusive and diverse. ISO in particular has recognized the need for gender responsive and inclusive standards and aims to create adequate tools for technical committees that ensure standards address these concerns. Launched in 2019, the ISO Gender Action Plan outlines five priority areas that focus on collecting data, creating a network to share best practice and raising awareness of standards in support of gender equality and women's empowerment.

Notwithstanding some efforts by ISO, historically many standardization technical committees have often been made up mostly of men, who have not always considered the specific needs of women or minorities when developing standards. Therefore, promoting diversity in the committees themselves is a step in the right direction. This will ensure that the needs, experiences and concerns of all end users are an integral part of the design and performance of the product, process, or service being standardized.

A3 Approaches to conformity assessment and accreditation

According to the standard ISO/IEC 17000,[76] conformity assessment is "a demonstration that specified requirements are fulfilled." This can involve, among other things, testing, inspection, and certification of products as well as management system certification. The associated laboratories, inspection agencies and certification bodies are collectively referred to as "conformity assessment bodies" (CABs), and the requirements to be fulfilled are typically defined in regulations, standards, or purchasing specifications.

Depending on the regulatory framework covering PPE in a specific market, conformity assessment may sometimes be carried out by the manufacturer itself (resulting in a 'supplier's declaration of conformity') but in other cases can necessitate the use of an independent third-party conformity assessment body designated by the regulatory authority. The conformity assessment body is typically chosen by the manufacturer from a list provided by the regulator (called 'notified bodies' in the EU – see 3.1.3). Choosing a suitable conformity assessment body can be sometimes a daunting task, especially in developing economies where there may not be many that are active and/or recognized in any given field.

The meaning of "accreditation" in the conformity assessment context is different from that of "hospital accreditation." The formal definition is "third-party attestation related to a conformity assessment body, conveying formal demonstration of its competence, consistent operation, and impartiality in performing specific conformity assessment activities."

74 https://www.iso.org/committee/291088/x/catalogue/p/1/u/1/w/0/d/0.

75 BSI. "Diversity in PPE." White paper.

76 ISO/IEC 17000:2020. "Conformity assessment—vocabulary and general principles."

There is typically only one formally recognized national accreditation body in each country[77] (see Part 3 of this guide). These operate within a global network to facilitate trade across borders. Multilateral recognition arrangements between accreditation bodies are overseen at the global level by the International Laboratory Accreditation Cooperation (ILAC) via its Mutual Recognition Arrangements (MRAs) and the International Accreditation Forum (IAF) via its Multilateral Recognition Arrangements (MLAs)[78] and, at the regional level, by organizations such as the Interamerican Accreditation Cooperation, European Accreditation Cooperation, and others. These arrangements are underpinned by peer evaluations against the requirements of the international standard for the operation of accreditation bodies (ISO/IEC 17011) which ensure a consistent approach to accreditation. In this way confidence and trust can be placed in the conformity assessment of products that are manufactured or purchased by organizations located in different parts of the world.

Claims made by conformity assessment bodies that they are accredited (and therefore can be relied on to provide valid attestations of conformity) should be verified by consulting the ILAC and IAF websites[79] to confirm that the conformity assessment body's accreditation body is a signatory of the relevant multilateral recognition arrangements and then by confirming via the accreditation body's website that the conformity assessment body has an appropriate accreditation scope for the services it is providing.

Accredited third-party conformity assessment is not the only way to demonstrate conformity, though. Standards such as ASTM F3050[80] and ISO/IEC 17067[81] define different types of conformity assessment approaches that can be applied to PPE, ranging from self-declaration by the supplier (supplier's declaration of conformity) to formal product certification by an accredited third-party certification body.

The cost of conformity assessment services needed for entry into specific markets depends greatly on the scope of the activities to be performed. These might need to include accredited certification of the supplier's quality management system (based on ISO 9001 for general PPE, or on ISO 13485 for PPE that are covered by medical device regulations), testing of a product sample in an accredited laboratory, or full product certification. It is not realistic to try to provide cost estimates in this guide, because the starting point and the efforts involved are likely to be different for every potential supplier of PPE (taking into consideration any previous experience in manufacturing similar products for other markets and any pre-existing certifications).

It is also important also to keep in mind that one important component of the overall cost relates to the internal development costs incurred by the manufacturer itself, to establish reliable systems and processes that ensure the product will consistently meet the relevant requirements over time. These costs can often significantly outweigh the costs of the associated conformity assessment procedures.

77 One notable exception is the United States, where several accreditation bodies operate within a competitive environment.

78 The IAF MLA and the ILAC MRA are based on the same concept, though the terminology used is slightly different.

79 https://ilac.org/signatory-search/ and https://iaf.nu/en/recognised-abs/.

80 ASTM F3050-21. "Standard guide for conformity assessment of personal protective clothing and equipment."

81 ISO/IEC 17067:2013. "Conformity assessment—fundamentals of product certification and guidelines for product certification schemes."

About IFC

IFC—a member of the World Bank Group—is the largest global development institution focused on the private sector in emerging markets. We work in more than 100 countries, using our capital, expertise, and influence to create markets and opportunities in developing countries. In fiscal year 2021, we invested $31.5 billion in total commitments, including $23.3 billion in long-term finance and $8.2 billion in short-term finance,to private companies and financial institutions in emerging and developing economies, leveraging the power of the private sector to end extreme poverty and boost shared prosperity. For more information, visit www.ifc.org.

bsi.

IFC International Finance Corporation
WORLD BANK GROUP

Creating Markets, Creating Opportunities