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BSI guide to masks and face coverings for use in the UK during the COVID-19 pandemic

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Introduction

As the UK moves to the stage of recovery from the COVID-19 pandemic, people are asking how they should protect themselves in situations where guidelines on social distancing are difficult to achieve. One of the most common forms of protection is a mask or face covering but, as there are different types of masks, it can be confusing to know what they are for and how they should be used. An inappropriate or poor design of mask or face covering may not protect the wearer adequately and may also lead to a false sense of protection.

This BSI guide summarizes the main characteristics of the four most common categories of mask and face covering available in the UK that health workers and the public may use.

If you are manufacturing PPE

Manufacturers of protective or medical face masks need to meet the requirements of the PPE Regulation, the Medical Device Directive or both and these products must feature the CE marking. This guide details some of the key technical specifications of which you need to be aware.

If you are involved in procuring PPE

To protect people effectively, it is important to select the appropriate type of PPE for the particular environment. It is also important to source PPE from a reputable supplier to ensure that it complies with the correct regulations. This guide contains information that you need to consider when purchasing PPE.

If you are a member of the public

Members of the public may use a face covering that is not classified as PPE or as a medical face mask. In this case, BSI has recommended that government should identify the level of protection that these coverings can give without being classified as PPE or a medical face mask and should set requirements for their design, including the need for independent assessment. Such an approach will provide a level of assurance to the public that the face protection they are using will be checked to have protective properties.

Overview of masks and face coverings

This paper gives a high level overview of the differences between the four main types of mask and face covering that are being used in the UK and throughout Europe to protect against the risk of coronavirus. Background information is also provided in the form of a taxonomy of common types of face masks, other personal safety equipment and other products such as face coverings.

Surgical masks to EN 14683:2019+AC:2019

Surgical face masks are intended to limit the transmission of infective agents.

Surgical face masks can also incorporate a microbial barrier that is designed to be effective in reducing the emission of infective agents from the nose and mouth of a carrier or a patient with clinical symptoms. Surgical masks are intended to be a barrier to infection of others though they do offer limited protection to the wearer.

Surgical face masks are classified into two main types;

Type I – these masks should only be used by 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 healthcare professionals in an operating room or in other medical settings with similar requirements.

Type II and Type IIR – these masks are principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements. Type II is further divided according to whether or not the mask is splash resistant. The R signifies splash resistance.

These products are certified under the European Medical Devices Regulation as a Class I device, so they must be CE marked based on the manufacturer's self-declaration unless they are supplied as sterile.

Protective masks to EN 149:2001+A1:2009

Protective masks are designed to protect against particulates such as dust particles and various viruses in the air. These masks, unlike surgical masks, protect the wearer from inhaling infectious agents or pollutants in the form of aerosols, droplets, or small solid particles. The wearer must be clean shaven for this type of mask to be effective and should be 'fit tested' to ensure that the wearer has the appropriate, specific mask. These masks can be used in domestic, industrial and healthcare applications.

The EN 149 standard defines three classes of filter efficiency for these masks;

- FFP1 – 80% filtering efficiency
- FFP2 – 94% filtering efficiency
- FFP3 – 99% filtering efficiency

In the current COVID-19 situation, the World Health Organization (WHO) is recommending the minimum of an FFP2 mask for offering protection. The NHS is stipulating FFP3 in high risk areas and FFP2 in lower risk areas.

In addition, masks are classified as single shift use only (marked NR on the product) or as re-usable i.e. more than one shift (marked R on the mask).

These products must comply with the European Personal Protective Equipment (PPE) Regulation and be certified by a Notified Body, such as BSI, and feature the CE marking. They are a Category III product under the PPE Regulation, so they must bear the CE Marking and a four-digit number identifying the Notified Body certifying it.

PPE mask for healthcare workers based on Recommendation 2020/403

In the current COVID-19 situation, the UK government is working to make PPE available to healthcare workers as fast as possible. BSI is helping in this initiative and has implemented a number of procedures to speed up the certification of masks, gowns, gloves and face shields for frontline healthcare workers. Given the urgency of the situation and the specific situation of healthcare workers, it has been agreed at European level that the full requirements of the PPE Regulation and Medical Device Directive need not be applied. Instead the European Commission has published a recommendation, Recommendation 2020/403 that invites Notified Bodies such as BSI to consider a minimum test requirement for the specific circumstances of healthcare workers.

To meet this, BSI has developed a stream-lined test specification for PPE suitable for use during the emergency, producing a special technical specification for COVID-19 use (see table on page five) to ensure PPE masks for healthcare workers meet a minimum FFP2 classification. In this specification, BSI has recommended retaining the test set out in the British Standard (BS EN 149), which calls for the use of paraffin oil as a test agent due to its small particle size - a reasonable simulation of the hazard posed by the coronavirus.

Masks meeting this specification are intended for use by healthcare workers in the context of COVID-19 only and are not for industrial or other applications. BSI will certify these products to the PPE Regulation and issue certificates to Module B and C2 to the PPE regulation. These masks will therefore qualify for the CE Marking for the duration of the pandemic under Recommendation 2020/403.

Technical testing specification for COVID-19 masks for use by healthcare workers

EN 149:2001+A1:2009 Performance requirement	EN 149:2001+A1:2009 Test method clause	Requirement
7.7 Practical performance The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections. 2 subjects As Received (AR)	Testing shall be done in accordance with 8.4	During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded: a. head harness comfort; b. security of fastenings; c. field of vision; d. any other comments reported by the wearer on request
7.9 Leakage **7.9.1 Total inward leakage** 5 subjects with samples As Received (AR)	Testing shall be done in accordance with 8.5	All individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, all arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2)
7.9 Leakage **7.9.2 Penetration of filter material** 3 samples As Received (AR) for NaCl and Paraffin oil 3min test	Testing shall be done in accordance with 8.11	6% for both Paraffin oil and NaCl
7.12 Carbon dioxide content of the inhalation air 3 samples As Received (AR)	Testing shall be done in accordance with 8.7	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume)
7.16 Breathing resistance 3 samples As Received (AR)	Testing shall be done in accordance with 8.9	The breathing resistances shall meet the requirements of: 30l/min – 0.7mbar (inhale) 95l/min – 2.4mbar (inhale) 160l/min – 3.0mbar (exhale) If achieves cl 7.9.2 FFP3 class: 30l/min – 1.0mbar (inhale) 95l/min – 3.0mbar (inhale) 160l/min – 3.0mbar (exhale)

Face coverings for use by the public

In many countries, local and national governments are requiring or recommending that members of the public wear some form of face covering when outside their homes, on public transport or in other situations. In the absence of formal standards for this application in the COVID-19 context, countries have developed their own requirements for this type of product and application.

Members of the public may use a face covering that is not classified as PPE or as a medical face mask. In this case, BSI has recommended that government should identify the level of protection that these coverings can give without being classified as PPE or a medical face mask and should set requirements for their design, including the need for independent assessment. Such an approach will provide a level of assurance to the public that the face protection they are using will be checked to have protective properties.

Technical testing specification for COVID-19 face coverings for use by the public

Performance requirement	Test method clause	Requirement
1. Leakage **Penetration of material** **Based on the requirements of** **EN 149:2001+A1:2009 clause 7.9.2 Penetration of filter material** **No. samples tested** Non-reusable devices - 3 samples in As Received (AR) state for NaCl and Paraffin oil 3min test Reusable devices – 3 samples in As Received (AR) state for NaCl and Paraffin oil after maximum cleaning and disinfecting cycle (suggest 5 as per clothing standards) according to the manufacturer's instructions 3 min test	Testing shall be done in accordance with 8.11 of EN 149:12001+A1:2009	Percentage breakthrough to be determined by the Cabinet Office/Department for Business, Energy and Industrial Strategy (BEIS)
2. Carbon dioxide content of the inhalation air **Based on the requirements of** **EN 149:2001+A1:2009 clause 7.12 Carbon dioxide content of the inhalation air** **No. samples tested** Non-reusable devices - 3 samples in As Received (AR) state for NaCl and Paraffin oil 3min test	Testing shall be done in accordance with 8.7 of EN 149:12001+A1:2009	Inhaled CO2 limit to be determined by the Cabinet Office/Department for Business, Energy and Industrial Strategy (BEIS) EN 149 limits (info only) The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume). Standard limit amongst Respiratory Protective Equipment
3.Breathing resistance **Based on the requirements of** **EN 149:2001+A1:2009 clause 7.16 Breathing resistance** **No. samples tested** 3 samples in As Received (AR) state	Testing shall be done in accordance with 8.9 of EN 149:12001+A1:2009	Breathing resistance limit to be determined by the Cabinet Office/Department for Business, Energy and Industrial Strategy (BEIS)

Taxonomy of personal safety equipment, masks and face coverings

The table below summarizes common types of face mask, other PPE designed to reduce the risk of transmission of the virus and other products such as face coverings. It includes intended users, the protection offered, the applicable regulations and the relevant UK regulator or enforcement authority.

Face masks

Name	Intended users	Who does it protect?	Applicable regulations	Regulator or enforcement authority
Surgical/medical face masks	Health care staff to limit passing on coronavirus and other germs to patients in medical settings	Patients	Class 1 - Medical Devices regulations	Medicines and Healthcare products Regulatory Agency (MHRA)
Respirator masks	Healthcare professionals	The wearer	Medical Devices regulations and PPE regulations	MHRA, Health and Safety Executive (HSE) (for business use) and Trading Standards (for consumer use)
General face masks	Health care staff to limit catching coronavirus and other germs from patients in medical settings	The wearer	PPE regulations	HSE (for business use) Trading Standards (for consumer use)

Other personal safety equipment

Name	Intended users	Who does it protect?	Applicable regulations	Regulator or enforcement authority
Gowns	Healthcare professionals and wearers	Wearers	Medical devices regulations and PPE regulations	MHRA, HSE (for business use) and Trading Standards (for consumer use)
Examination gloves, surgical gloves	Healthcare professionals	Patients	Medical Devices regulations: Class 1 - examination gloves Class IIa - surgical gloves	MHRA
Visors, eye shields, safety glasses	Healthcare professionals	The wearer	PPE regulations	HSE (for business use) and Trading Standards (for consumer use)
PPE gloves	The wearer (for example for use in laboratories or for other protective purposes)	The wearer	PPE regulations	HSE (for business use) and Trading Standards (for consumer use)
Dual use gloves	Healthcare professionals and wearers	Patients and wearers	PPE and Medical Devices regulations	MHRA, HSE (for business use) and Trading Standards (for consumer use)
Protective suits/coveralls	Healthcare professionals and wearers	Wearers	Category III – PPE regulations	HSE (for business use) and Trading Standards (for consumer use)

Taxonomy of personal safety equipment, masks and face coverings (continued)

Other products

Name	Intended users	Who does it protect?	Applicable regulations	Regulator or enforcement authority
Face covering i.e. not PPE or medical device	General public	Intended to reduce public not individual risk	General product safety regulations (product must be safe i.e. non-toxic, non-choking etc) The manufacturer/seller must not call it PPE or a medical device nor make any claim that the product will provide protection to any specific individual	Trading Standards - if product is unsafe or carries misleading claims

BSI/UK/1757/PC/0520/EN/GRP

For updates on standards and certification of personal protective equipment please visit: **bsigroup.com**

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