

## How can BSI help:



### For PPE

From 21 April 2018 onwards, any organization placing Protective Gloves on the market in the EU has a legal requirement to meet the PPE Regulation (EU) 2016/425. As a notified body for the PPE Regulation (EU) 2016/425 BSI has the expertise to help with this.

To meet the requirements of EN ISO 21420 manufacturers must get their Module B certificate updated to reflect the latest state of the art. And if your gloves fall into category III PPE, we can also provide notified body services to Module C2 or Module D.



The BSI Kitemark is the ultimate mark of quality, safety and trust and only available from BSI. When you want to differentiate your products, enhance your reputation and boost customer confidence Kitemark certification is the logical choice. Kitemark certification can also be used to meet the requirements of Module B, C2 or D of the PPE Regulation simultaneously.

### For medical gloves

If you produce medical as well as PPE gloves working with BSI could save you time and money as BSI is also a notified body designated to certify against the Medical Devices Regulation.

## Our glove testing capabilities

We have a comprehensive range of glove testing including:

Standard	Description
BS EN 388:2016+A1:2018	Protective gloves against mechanical risks
BS EN ISO 374-2:2019	Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration
BS EN ISO 374-4:2019	Protective gloves against chemicals and microorganisms. Determination of resistance to degradation by chemicals
BS EN 455-2:2015	Medical gloves for single use. Requirements and testing for physical properties
BS EN 455-1:2020	Medical gloves for single use - Requirements and testing for freedom from holes

## Why BSI?



For over a century BSI has championed what good looks like and driven best practice in organizations around the world. As one of the founding members of ISO, we help make sure international standards developed address today and tomorrow's business and social needs, while delivering real benefits to an organization and all its stakeholders.

We work closely with leading manufacturers to ensure their products meet the latest Regulations to gain market access. We focus on delivering a testing and certification partnership underpinned by quality, safety, reliability and accuracy aligned to your product development requirements. That's why we're best placed to help you understand standards and to meet the requirements.

From shaping collective best practice with our knowledge solutions to product testing, certification, and environmental health and safety professional services, are we are committed to innovating and collaborating with our clients to build a safer more resilient tomorrow – one that protects buildings, assets, the environment and most importantly people.

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# EN ISO 21420:2020 Protective gloves. General requirements and test methods.

**ISO standard provides better protection for wearers**



# Introducing EN ISO 21420

Manufacturers of PPE need to ensure that the materials from which their products are made do not adversely affect the health or safety of users. The publication of the new glove standard, EN ISO 21420 which replaces EN 420 builds on this and responds to the growing trend in standardization to address the topic of "innocuousness".

It takes into consideration the requirements of the EU PPE Regulation as ISO 21420 helps address the Essential Health and Safety aspects of Annex II, where PPE must be made so that its free of inherent risks and nuisance factors and must not be made from materials that can adversely affect the health and safety of users.

As a manufacturer or distributor of protective gloves you need to be aware of these changes and prepare now. BSI can help you to understand your obligations.

## BS EN ISO 21420 – a summary

The new ISO 21420:2020 brings a new limit level of DMFa (dimethylformamide) in polyurethane-coated (PU) gloves; it also provides further alignment with the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) legislation on hazardous substances or substances of very high concern.

Protective gloves are frequently manufactured with the use of dozens of chemicals and it is the manufacturer's responsibility to ensure the products they place on the market are safe. This could prove challenging not only

to the manufacturer but also to the body testing and approving the particular PPE, in trying to determine whether it satisfies the provisions of the PPE Regulation.

For this reason, the new standard pays close attention to alignment with REACH, by adding requirements for nickel release, the presence of phthalates, the content of polycyclic aromatic hydrocarbons (PAHs), undetectable carcinogenic amines in azodyes and the aforementioned DMFa content.

## Key changes manufacturers need to be aware of include:

- Introduction of a new pictogram for electrostatic properties EN 16350
- Removal of the protein content test in natural rubber gloves
- Introduction of date of manufacture markings
- Removal of minimal glove length requirements, unless required by a specific standard i.e. welding gloves
- Other subtle changes concerning information for users, additional information on donning/doffing, product integrity checks before use

## Other key requirements covered by EN ISO 21420 include:

Gloves shall be designed and manufactured to provide protection when used in accordance with manufacturer's instructions, without harm to the end user.

Protective gloves shall not adversely affect health and hygiene of the end user (innocuousness).

Chromium VI content in leather no more than 3mg/kg (Test method EN 17075).

Any metallic materials that could come into contact with the skin shall not release nickel in more than 0.5µg/cm<sup>2</sup> per week (Test method EN 1811).

Azo colorants which release carcinogenic amines shall not be detectable (Test method ISO 17234-1 leather or ISO 14362-1 textile).

pH value shall be between 3.5-9.5 (Test method ISO 4045 leather or ISO 3071 textile).

DMFa (dimethylformamide) shall not exceed 0.1% weight/weight (Test method prEN 16778).

Selected polycyclic aromatic hydrocarbons (PAHs) shall not exceed 1 mg/kg (0,0001% by mass, for the rubber or plastic materials intended to come in direct contact with the skin.

Phthalates content, the sum of four phthalates (DEHP, DBP, BBP and DIBP) to be no greater than 0.1% by mass of plasticised material, as required by the REACH Regulation (EC) 1907/2006 Annex XVII Entry 51.

The levels of performance should be based on the lowest results obtained before and after cleaning cycles (consideration of care instructions for testing).

For gloves worn in ATEX environments, the electrostatic properties shall be tested (Test method EN 16350).

## Important changes covering glove marking\*

Each protective glove shall be marked with:

- Manufacturer's name and postal address
- Glove designation
- Size designation
- Date of manufacturing (month and year)

- Relevant pictograms and corresponding level(s) of protection
- The CE and/or UKCA marking

\*If marking on glove is not possible, due to the characteristics of the product then the marking shall be affixed to the first packaging enclosure.

## New EN ISO 21420 Protective Gloves Pictograms include:



EN 388  
Mechanical Risks



EN 1082  
Cuts and stabs by hand knives



EN 421  
Ionizing radiation



EN 381  
Chainsaw Protection



EN 511  
Cold Protection



EN 407  
Heat and Flame



EN 421  
Radioactive contamination



EN ISO 374-1  
Dangerous chemicals



EN 16350  
Electrostatic properties



EN ISO 374-5  
Microorganisms including Virus



EN 659  
Fire Fighters' Gloves

