BSI Guide for personal protective equipment (PPE) products from non-PPE manufacturers

Due to the current COVID-19 pandemic, the UK Government wants to make sure that PPE products are available to health and social care workers ("healthcare workers") as fast as possible. This has resulted in a number of individuals and organizations taking the initiative to support the production of PPE with no previous experience in this field. BSI would like to help those initiatives with this guide, which is designed to explain step-by-step how PPE should be produced and tested, and obtain appropriate certification, to ensure it is safe and effective when being used in a health and social care environment.

If you are a school, university or other organization new to the manufacture of Personal Protective Equipment (PPE) you may find this document of use.

There is some guidance that has already been issued by the UK Government that complements this guide. Copy and paste the links below to access:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879498/Guidance-for-businesses-ppe-regulations-version-2.pdf

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879796/Guidance-for-businesses-high-volume-manufacture-of-ppe-version-2.pdf

The manufacturing and supply of PPE equipment is covered by relevant Regulations and Standards. Whatever route is applicable, it is the legal responsibility of anyone producing PPE to ensure that the PPE being made protects the healthcare worker and is fit for purpose. It is incorrect to state that any PPE is better than no PPE. Ineffective PPE may give a false sense of protection and put the wearer at greater risk.

BSI is making a number of relevant PPE product Standards freely available on the BSI website covering the full requirements for PPE gloves, filtering masks, clothing and eye protection. Click on the link below to access them:

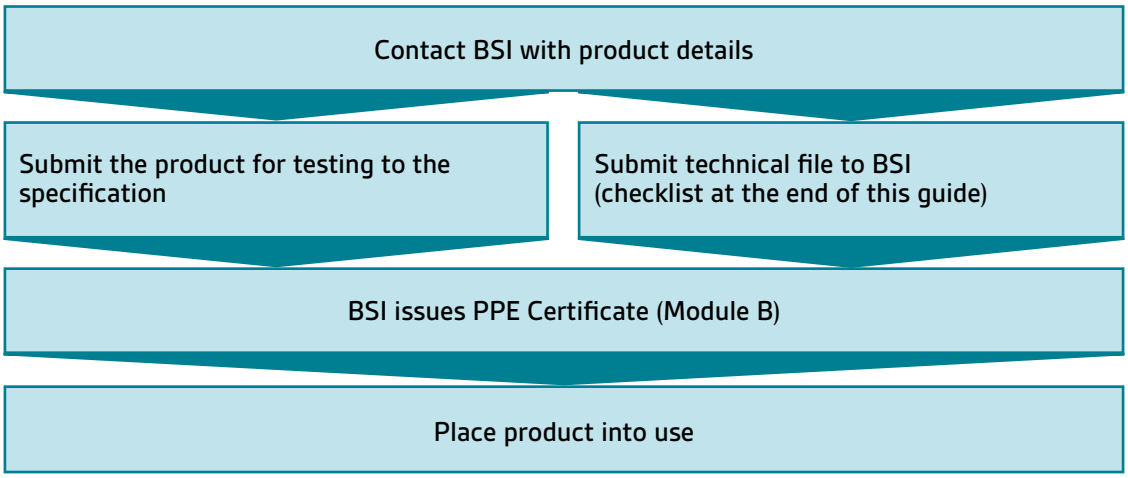
> Personal Protective Equipment Standards

Note that the normal procedure for testing and certification of PPE **for use in healthcare applications** has been streamlined so as to ensure that healthcare workers working on the front line of the COVID-19 crisis can receive it as quickly as possible.

Face shields and eye protection

This form of protection needs to be tested to ensure it offers the minimum level of protection for healthcare workers. A technical file is also required for certification purposes. For the requirements of a technical file, see the checklist at the end of this guide.

Certification process for eyewear



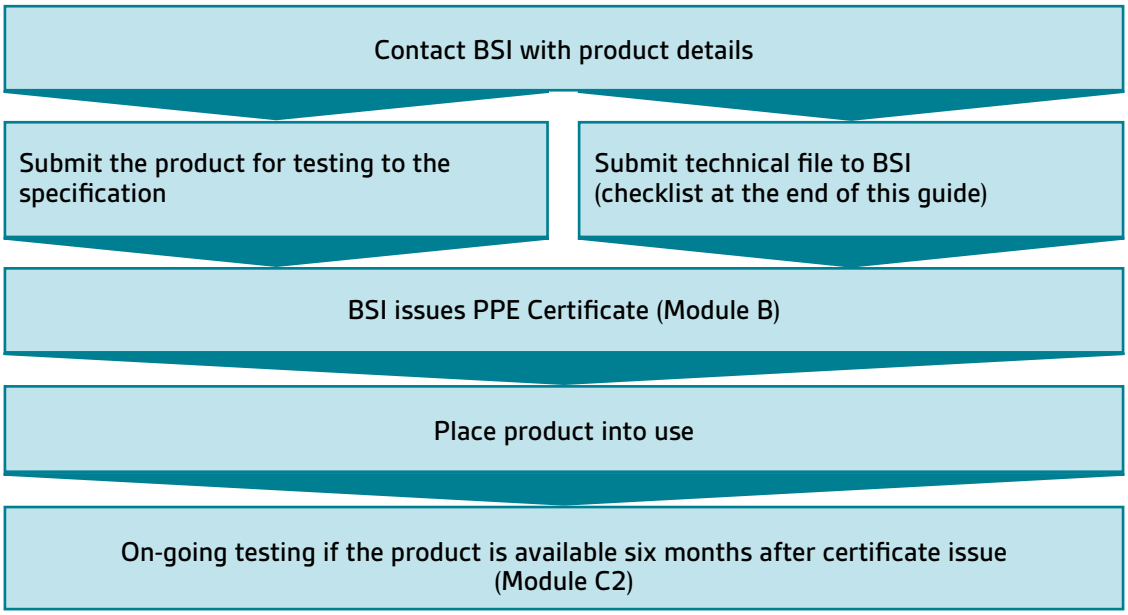
Eyewear technical specification (what the product is tested to) specific to Covid-19 requirements for healthcare workers:

Clauses from EN 166:2001 requirement	Explanation We are not testing fully to the standard but have selected hazards that may be encountered in a healthcare environment
6.1 General construction	Eye-protectors shall be free from projections, sharp edges or other defects which are likely to cause discomfort or injury during use.
6.2 Materials	No parts of the eye-protector which are in contact with the wearer shall be made of materials which are known to cause any skin irritation.
6.3 Headbands (where applicable)	Headbands, when used as the principal means of retention, shall be at least 10 mm wide over any portion which may come into contact with the wearer's head. Headbands shall be adjustable or self-adjusting.
7.1.1 Field of vision	Eye-protectors shall exhibit a minimum field of vision
7.1.2.2 Spherical. Astigmatic & prismatic refractive powers	The visor must not affect the wearers vision or strain their eyes
7.1.3 Quality of material and surface	Except for a marginal area 5 mm wide, the visors shall be free from any significant defects likely to impair vision in use, such as bubbles, scratches, inclusions, dull spots, pitting, mould marks, scouring, grains, pocking, scaling and undulation.
7.2.4 Protection against droplets and splashes of liquids	Face shields cover a prescribed eye-region rectangle fully
7.2.8 Lateral protection	The face shield protects from at least 10mm at the corner of the eyes

Filtering face masks

This form of protection needs to be tested to ensure that the masks offer the minimum level of protection for healthcare workers to levels recommended by the World Health Organization (WHO) and the NHS. A technical file is also required for certification purposes. For the requirements of the technical file, please see the checklist at the end of this guide. If production continues there will be some form of on-going testing once the initial certificate is issued, this will take place after six months.

Certification process for filtering face masks



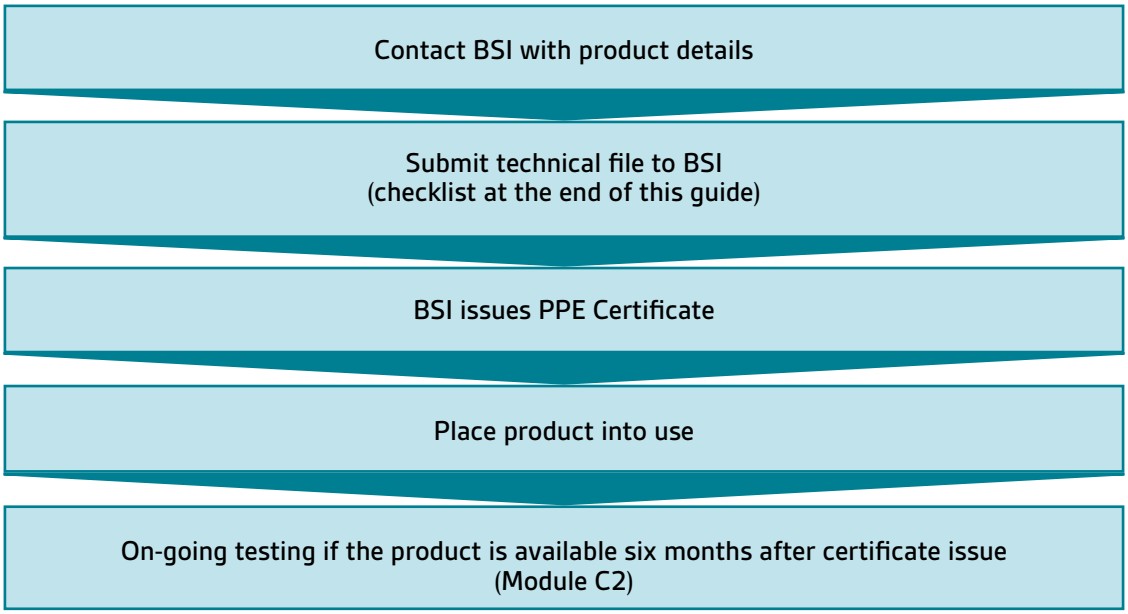
Filtering face mask technical specification (what the product is tested to).

Clauses from EN 149:2001+A1:2009 Performance requirement	**Explanation We are not testing fully to the standard but have selected hazards that may be encountered in a healthcare environment**
7.7 Practical performance	The mask is worn and 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	The mask is worn by a person and tested to make sure it filters correctly
7.9 Leakage 7.9.2 Penetration of filter material	The mask material is tested to make sure it filters correctly
7.12 Carbon dioxide content of the inhalation air	Make sure there isn't a build-up of CO2 in the mask
7.16 Breathing resistance	Ensure that the mask can be easily breathed through

Protective gowns and clothing

PPE protective gowns and clothing offering protection against biohazards BSI does not have testing facilities for clothing, so the manufacturer will have to seek testing from a specialist testing laboratory and then provide the test reports needed in the technical file themselves. The technical file is required for certification purposes. For the requirements of the technical file, please see the checklist at the end of this guide. If production continues there will be some form of on-going testing once the initial certificate is issued, this will take place after six months.

Certification process for protective gowns and clothing



Clothing Standards in use with healthcare products

EN 13034:2005+A1:2009
Protective clothing against liquid chemicals

EN 14126:2003
Protective clothing against infective agents

EN ISO 13688:2013
Protective clothing – general requirements

Type 1 EN 943-1:2015
Protective clothing against dangerous solid, liquid and gaseous chemicals, inc liquid & solid aerosols

Type 2 EN 943-2:2019 or EN 943-2:2002
Protective clothing against dangerous solid, liquid and gaseous chemicals

Type 3 EN 14605:2005+A1:2009
Protective clothing against liquid chemicals

Type 4 EN 14605:2005+A1:2009
Protective clothing against liquid chemicals

Types 1-4 and 6 ISO 16602:2007+A1:2012
Protective clothing for protection against chemicals

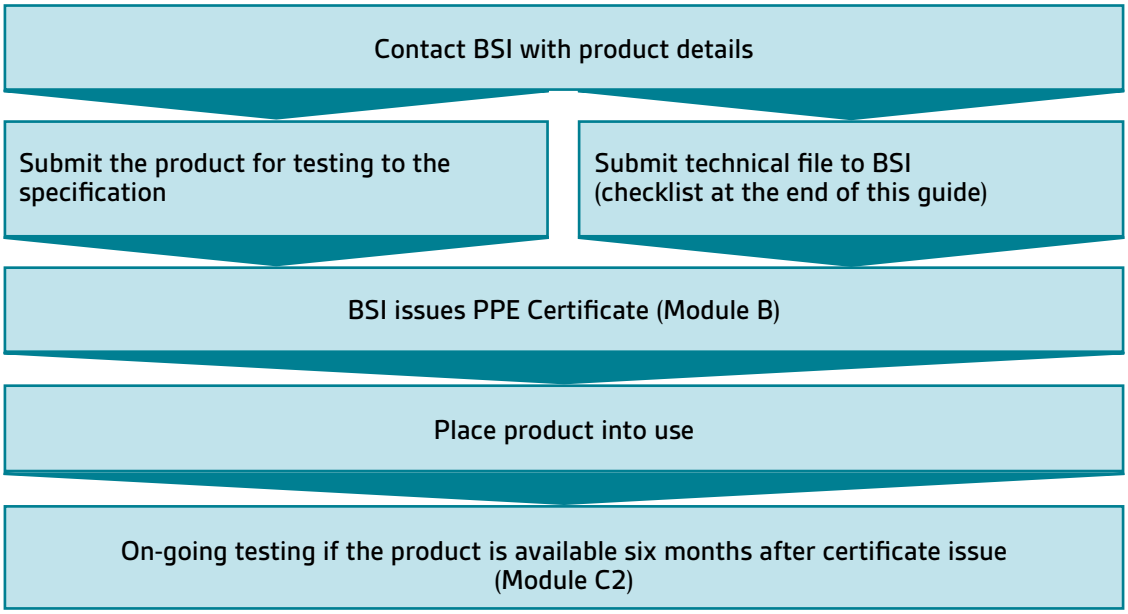
Type 5 EN ISO 13982-1:2004+A1:2010
Protective clothing for use against solid particulates

Type 5 ISO 16602:2007+A1:2012
Protective clothing for protection against chemicals

Gloves

PPE gloves protecting against viruses and biohazards. This form of protection needs to be tested to ensure that the gloves offer genuine protection for healthcare workers. A technical file is also required for certification purposes. For the requirements of the technical file, please see the checklist at the end of this guide. If production continues there will be some form of on-going testing once the initial certificate is issued, this will take place after six months.

Certification process for gloves



Standards that are applicable to PPE gloves in healthcare environments (what the product is tested to)

EN (ISO) 374 Protective gloves against dangerous chemicals and micro-organisms - consists of the following:

BS EN ISO 374-1:2016
Terminology and performance requirements for chemical risks.

BS EN 374-2:2014
Determination of resistance to penetration.

BS EN 374-4:2013
Determination of resistance to degradation by chemicals.

BS EN ISO 374-5:2016
Terminology and performance requirements for micro-organisms risks.

BS EN 16523-1:2015
Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact.

What the modules mean

BSI will be issuing certificates to the European PPE Regulation to cover the products being certified.

Module B certificates – they are issued to the product and verify that they meet the requirements.

Module C2 certificates – gloves, clothing and masks need on-going tests in 6 months after the certification is given if the product is in the market.

The PPE technical file

As part of the BSI certification process, we need a technical file giving details of the product, if you submit the following 12 pieces of information we will review.

- Completed BSI Application form
- File Contents List - what is in the technical file
- Amendment record Sheet - record of any changes if applicable
- Product Description - what the product is designed to protect against and where and how is it used
- Visual Identification of product - Photograph / Schematics / Drawings
- Details of components
- Details of materials used to make up the PPE
- For 3D printed products data file information
- Test Reports if applicable
- Declaration of Conformity
- Marking that will appear on the product
- User Information that will accompany the product

We have a range of blogs that you can read that help with PPE activities

> BSI Personal Protective Equipment Blog

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UK Government guidance in supplying PPE to the NHS and non-NHS

What do I need to do to have my PPE approved for sale or donation to the Government to be used by NHS healthcare workers?	What do I need to do to have my COVID-19 related PPE approved for sale to other users in the UK, if it is not being purchased by or donated to the Government/NHS for NHS use?
1. The products are manufactured in accordance with either: a. a relevant harmonised European standard, or b. any of the standards referred to in the WHO guidelines or, c. any other non-EU standard or technical solution, provided that the chosen standard or technical solution ensures an adequate level of safety in respect to the essential safety requirements 2. The products have been assessed against the standard(s) or technical solution you have chosen by the cross-Government Decision Making Committee, which comprises the Health and Safety Executive (the Market Surveillance Authority), the Department for Health and Social Care, the Medicines and Healthcare products Regulatory Agency, the Office for Product Safety and Standards, and other experts as required. 3. The products must be part of a purchase organized by or donation agreed by the UK Government or the National Health Service. 4. The products will only be made available for healthcare workers. 5. The products will only be made available for the duration of the current outbreak of COVID-19. 6. The products will not enter regular distribution channels and will not be made available to other users.	Before PPE intended to protect UK workers against the COVID-19 virus can be placed on the UK market, it must meet the essential safety requirements required by current UK law, which is the EU Regulation 2016/425 (see Annex II) and be assessed in line with the regulatory easements in EU Recommendation 2020/403 This means that your product does not need to complete formal conformity assessment procedures including Type approval by a Notified Body (organizations such as BSI), however: a. Your product must be **in the process** of conformity assessment with a Notified Body and b. The Notified Body must confirm that your product has an adequate level of health and safety in accordance with the essential requirements laid down for that product

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