



Office for Product  
Safety & Standards

# **New High-Volume Manufacturers of COVID-19 Personal Protective Equipment (PPE)**

**Guidance for Businesses, Version 6**

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# Guidance

## 1. Who is this guide for?

This guidance is for you if you are a manufacturer and you want to change your processes to make high volumes of Personal Protective Equipment (PPE) to protect users from COVID-19. This guidance is not intended to cover small scale home production or manufacturing of PPE although its principles can be applied to these processes too.

## 2. What is PPE in the context of protection of users from COVID-19?

For the purpose of this guide, PPE is:

1. equipment designed and manufactured to be worn or held by workers for protection against one or more risks from COVID-19, e.g. gloves, face-masks, gowns;
2. interchangeable components for equipment referred to above which are essential for its protective function;
3. connexion systems for equipment referred to above that are not held or worn but that are designed to connect that equipment to an external device or to a reliable anchorage point, that are not designed to be permanently fixed and that do not require fastening works before use.

Some types of products that appear to be similar to PPE may actually be regulated as medical devices if their main purpose is to protect others from the user (like a surgical face mask).

A gown, for example, is a medical device if it is to protect the patient from the healthcare worker. If it is to protect the healthcare worker from the patient, it is PPE. A product that serves both purposes is regulated both as a medical device and as PPE and must meet the requirements for both.

[Further information about the regulation and safety of medical devices](#) is provided on GOV.UK.

## 3. What COVID-19 related PPE can you make?

Read this guide first to understand the factors you need to consider in deciding whether you are able to make PPE to the essential health and safety requirements (*see next section*) so that it is effective in protecting users from COVID-19.

PPE that doesn't meet the essential health and safety requirements should not be supplied and won't be used, as it could not be ensured to protect against the risk of infection.

If you are thinking of making and selling to the NHS high volumes of PPE that meets the essential health and safety requirements, please note the Government PPE offers portal has now closed. As a result of the huge response from UK manufacturers and the success of the PPE drive, the Government is not currently seeking additional new manufacturers or suppliers through the government portal, but has moved to competitive tendering.

[Further details on the competitive tendering processes](#) for DHSC and NHS England are provided on GOV.UK.

#### **4. What are the essential health and safety requirements for PPE intended to protect against COVID-19?**

The manufacture of PPE is normally governed by product safety legislation. The relevant legislation is [EU Regulation 2016/425](#) on Personal Protective Equipment. Even though the UK left the European Union on 31 January 2020, this still applies during the Implementation Period and has been adopted in an amended form into UK law so that it continues to apply to the UK market after the Implementation Period has ended on 31 December 2020. EU Regulation 2016/425 is enforced in the UK by the [Personal Protective Equipment \(Enforcement\) Regulations 2018](#).

You can find the essential health and safety requirements that apply to PPE in Annex II to [EU Regulation 2016/425](#).

For PPE intended to protect against COVID-19 the process by which new PPE will be assessed for compliance with the essential health and safety requirements has been changed.

To ensure you meet the essential health and safety requirements, you should manufacture the PPE either:

1. in line with a relevant European Standard;
2. in accordance with a standard referenced in the WHO guidelines; or
3. to an alternative technical solution that meets the essential health and safety requirements and delivers adequate safety.

[Standards relevant to PPE for COVID-19](#) are available free from the British Standards Institution and there are also [WHO guidelines](#) on COVID-19.

The Health and Safety Executive (HSE) and the Medicines and Healthcare products Regulatory Agency (MHRA) have produced [simplified essential technical specifications](#) for gowns, surgical face masks, respirator masks, eye protection, visors and gloves which you can use to make high volumes of PPE for the NHS.

#### **5. Do I as a manufacturer need to have the COVID-19 related PPE conformity assessed?**

Normally, yes, and this includes Type Approval and quality assurance procedures as set out in EU Regulation 2016/425. However, for COVID-19 related PPE, these have been eased, depending on how you are placing your PPE on the market.

There are two different groups of users for whom this guide is intended to help you manufacture safe PPE.

The way your PPE will be able to reach the UK market, the way it must be conformity assessed and the responsibilities on you as a manufacturer differ for each user group.

Please make sure that you understand which group you plan to produce PPE for:

1. Healthcare workers, where you intend to sell/ donate the PPE only to the NHS/UK Government.

[Further details on the competitive tendering processes](#) for DHSC and NHS England are provided on GOV.UK.

2. All workers or other users, where you intend to sell/ donate the PPE to distributors, retailers or directly.

## **6. What do I as the manufacturer need to do to have my COVID-19 related PPE approved for sale or donation to the Government to be used by NHS healthcare workers?**

For COVID-19 related PPE to be purchased by or donated to the Government/ NHS via the [competitive tendering processes](#) to be used by healthcare workers, it must meet **ALL** the following criteria:

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 health and safety requirements.
2. The products must be part of a purchase organised by or donation agreed by the UK Government or the NHS via a competitive tendering process.
3. The products will only be made available for healthcare workers.
4. The products will only be made available for the duration of the outbreak of COVID-19.
5. The products will not enter regular distribution channels and will not be made available to other users.

Once you are sure that your product meets these requirements you can enter the Department of Health and Social Care (DHSC) competitive tendering processes for the NHS.

[Further details on the competitive tendering processes](#) are provided on GOV.UK.

## **7. What do I as the manufacturer need to do to have my COVID-19 related PPE approved for sale or donation to any users in the UK, if it is not being purchased by or donated via a Government or NHS competitive tendering process?**

This section has been amended in the light of revised guidance from the European Commission published on 10 July 2020.

To place PPE intended to protect UK workers in any environment from COVID-19 on the UK market, it must meet the essential health and safety requirements in Annex II of Regulation (EU) 2016/425.

COVID-19 related PPE legally requires third party assessment by a recognised Notified Body. In that case, it must either have completed full conformity assessment and be CE marked or have been assessed in line with the regulatory easements in [EU Recommendation 2020/403 by the relevant Market Surveillance Authority](#).

You should start the conformity assessment process by making a formal application to a relevant Notified Body (an email will not suffice). Your COVID-19 PPE product must have been accepted into the process of conformity assessment with that Notified Body. You can use any of the Notified Bodies mentioned in the table below but please note which PPE products they are able to assess.

If you wish to place your product on the market before it has completed this process or been CE marked, you can do so provided that the relevant Market Surveillance Authority (HSE or HSENI) has agreed that it meets the essential health and safety requirements of EU Regulation 2016/425.

If you have already placed equipment on the market without CE marking under previous arrangements, please see section 10 on Transitional Arrangements for further advice.

If the Market Surveillance Authority confirms the product meets essential health and safety requirements, you can begin selling it, provided you make sure that:

1. All COVID-19 related PPE bears a type and serial or batch number, or other element allowing its identification, including your name, registered trade name or registered trademark and postal address. Where the size or nature of the PPE does not allow this then it may be provided on the packaging or accompanying documentation. This is so that there is traceability and if the PPE is later found not to meet essential health and safety requirements, you can be contacted and can identify and correct any design, process or system flaws and the product can be located and withdrawn.
2. The COVID-19 related PPE is accompanied by instructions and safety information as set out in point 1.4 of Annex II to the EU Regulation 2016/425, which is clear, legible and in easily understandable English.
3. The Declaration of Conformity is completed with as much detail as possible, including the details of the Notified Body to which you have submitted your PPE for conformity assessment, so that you can demonstrate that you have begun conformity assessment procedures.
4. You recognise that this is for a limited period while you complete full conformity assessment and CE marking for your product in the usual way. This easement is only allowable during the health crisis. You should also recognise that the product is only for sale in the UK; you can only place your product on the wider EU market when the conformity assessment process is complete and the product has been CE marked.

If the product is deemed by your chosen Notified Body or by the Market Surveillance Authority as not meeting the essential health and safety requirements it will tell you why, and it will then be up to you to address any issues and reapply for assessment.

Manufacturers can send their applications to HSE via their market surveillance E-mail address: [MarketSurvPPE@hse.gov.uk](mailto:MarketSurvPPE@hse.gov.uk).

Applications will only be considered by HSE if they include a **minimum** of:

- Photographs of the PPE showing the product;
- Details of the manufacturer, product types and serial/model numbers of the PPE;
- Details of the Standard or any other technical solution the product claims to be made to;
- Copies/photos of product labels and instructions;
- Details of the tests carried out on the PPE; and
- Any relevant certificates and
- (if in process of being approved by a notified body) – confirmation from the notified body that they have started the assessment procedure.

Contact details for UK Notified Bodies which can assess COVID-19 PPE can be found here:

<p><b>BSI Assurance UK Ltd</b> Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP Phone: +44 (0) 8450 809000 Fax: +44 (0) 8450 809000 Email: <a href="mailto:product.certification@bsigroup.com">product.certification@bsigroup.com</a> Website: <a href="http://www.bsigroup.com">www.bsigroup.com</a> Notified Body number: 0086</p>
<p><b>CCQS UK LTD</b> Level 2, 5 Harbour Exchange Square, London E14 9GE Phone: +44(0)20 7868 1509 Email: <a href="mailto:info@ccqs.co.uk">info@ccqs.co.uk</a> Website: <a href="http://www.ccqs.co.uk">www.ccqs.co.uk</a> Notified Body number: 1105</p>
<p><b>INSPEC International Ltd.</b> 56 Leslie Hough Way, Salford, Greater Manchester M6 6AJ Phone: +44 (0) 161 737 0699 Fax: +44 (0) 161 736 0101 Email: <a href="mailto:certification@inspec-international.com">certification@inspec-international.com</a> Website: <a href="http://www.inspec-international.com">www.inspec-international.com</a> Notified Body number: 0194</p>
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<p><b>SGS United Kingdom Limited</b> Unit 202B, Worle Parkway, Weston-super-Mare, Somerset BS22 6WA Phone: +44 (0)1934 522917 Fax: +44 (0)1934 522137 Email: <a href="mailto:globalmedical@sgs.com">globalmedical@sgs.com</a> / <a href="mailto:sgsprodcert@sgs.com">sgsprodcert@sgs.com</a> (for 89/686/EEC; 92/42/EEC) Website: <a href="http://www.uk.sgs.com">www.uk.sgs.com</a> Notified Body number: 0120</p>

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<p><b>UL INTERNATIONAL (UK) LTD</b>                  Wonersh House Building C, The Guildway, Old Portsmouth Road, Guildford GU3 1LR                  Phone: +44 1483 302130                  Fax: +44 1483 302230                  Email: <a href="mailto:Inform.NB@uk.ul.com">Inform.NB@uk.ul.com</a>                  Website: <a href="http://www.ul-europe.com">http://www.ul-europe.com</a>                  Notified Body number: 0843</p>

The type of PPE they assess is set out in the table below<sup>1</sup>:

Notified Bodies	Types of PPE Assessed						
	1	2	3	4	5	6	7
<b>BSI Assurance UK Ltd</b>	✓	✓		✓	✓	✓	✓
<b>CCQS UK Ltd</b>		✓	✓	✓	✓	✓	✓
<b>INSPEC International Ltd</b>		✓		✓	✓	✓	✓
<b>ITS Testing Services (UK) Ltd</b>			✓	✓	✓		✓
<b>SATRA</b>	✓		✓	✓	✓	✓	✓
<b>SGS United Kingdom Limited</b>	✓	✓		✓	✓		
<b>Shirley Technologies Limited, trading as BTTG</b>	✓	✓	✓	✓	✓	✓	✓

<sup>1</sup> This table has been created from information available on [the NANDO database](#).



<b>SIRA CERTIFICATION SERVICE</b>						✓	
<b>UL INTERNATIONAL (UK) LTD</b>	✓				✓	✓	✓

## 8. What else must I do as a manufacturer to fulfil my obligations?

In addition to ensuring that the PPE is designed and manufactured in accordance with the applicable essential health and safety requirements, you must:

1. Keep the technical documentation for 10 years after the PPE has been purchased.
2. Ensure that procedures are in place for series production to remain as approved by the Market Surveillance Authority or Notified Body. You must adequately take into account changes in the design or characteristics of the PPE and changes in the harmonised standards or in other technical specifications by reference to which you state that the PPE meets the essential health and safety requirements.
3. Thinking about the risks presented by PPE, protect the health and safety of users, carry out sample testing of PPE made available for purchasing, investigate, and, if necessary, keep a register of complaints, of PPE which does not meet the essential health and safety requirements/ protect the user from COVID-19, and PPE recalls, and keep the purchaser and distributors informed of any such monitoring.

## 9. Importers' obligations in light of the easements

The importer has a number of obligations under the PPE Regulations. These are set out in section 7 of the [OPSS PPE Legislation Guidance](#).

The European Commission issued updated guidance on 10 July in relation to Recommendation 2020/403 to the effect that PPE that has not yet completed conformity assessment must be approved by the relevant Member State's Market Surveillance Authority before it can be placed on that Member State's market.

This means that PPE being imported into the UK that has not yet completed conformity assessment must be approved by the UK's Market Surveillance Authority before it can be placed on the UK market.

It also means PPE being imported into the UK that has not yet completed conformity assessment cannot be placed on the EU market. Only PPE that has completed conformity assessment and has been CE marked can be placed on the EU market.

While the easements are in place, this means that an importer must have documentary proof that either:

Where a manufacturer has contracted to supply the Government or NHS with COVID-19 PPE via a competitive tendering process, that the PPE has been designed and manufactured in line with a relevant European Standard, a standard referenced in the WHO guidelines, or an alternative technical solution that delivers adequate safety, and has been reviewed as meeting the essential health and safety requirements. PPE supplied through this process cannot be made available to the general market.

**or**

A manufacturer wishing to supply COVID-19 PPE to the general UK market has applied to a Notified Body for conformity assessment, has had their application accepted, and has had their PPE assessed by the UK Market Surveillance Authority as meeting the essential health and safety requirements, even though the formal conformity assessment procedures have not been completed.

## 10. Transitional arrangements

### **My PPE is supplied to the NHS without CE marking as part of a central procurement, do I now need full conformity assessment/CE marking?**

There are no changes to the easement for PPE being supplied to NHS healthcare workers as part of a Government or NHS procurement at present. However, you should be aware that the easement will only apply for the duration of the Covid-19 crisis. Therefore, if you wish to supply on a longer term basis or to place your product on the UK or EU markets (i.e. selling it outside of NHS or UK Government procurement for healthcare workers), you should seek full conformity assessment through a Notified Body.

### **I have placed my PPE on the UK market without CE marking but with clearance by a Notified Body. Do I now need Market Surveillance Authority approval?**

Any PPE already placed on the UK market without CE marking on approval of a Notified Body (in line with earlier guidance), should by now have completed full conformity assessment and any subsequent batches should be CE marked in line with normal procedures. If any equipment placed on the market in this way has not yet completed full conformity assessment, this should be completed ideally within a few days or Market Surveillance Authority clearance will be required and this should be obtained not later than 21 September.

### **Do I need to take PPE off the UK market where it has not completed full conformity assessment or is not CE marked and it has only been cleared by the Notified Body?**

Any equipment placed on the UK market without CE marking before 7 September 2020 on approval of a Notified Body (in line with earlier guidance), does not need to be recalled but conformity assessment should be completed ideally within a few days and not later than 21 September or MSA approval will be required.

Notified Bodies should not approve any new equipment to be placed on the UK market for the first time unless full conformity assessment has been completed or the MSA has approved it.

### **My PPE is currently undergoing conformity assessment with a Notified Body. Can they still clear it to be placed on the market before the process is completed?**

No. You should complete full conformity assessment and CE mark your PPE. If you need to place the PPE on the market in advance of this, you should contact the Market Surveillance Authority for approval to do so. They will want to confirm that it meets the essential health and safety requirements that apply to it.

**I have imported PPE to be placed on the EU market. It has not completed conformity assessment and is not CE marked. What do I do?**

You cannot place the PPE on the EU market until it has completed conformity assessment and has been CE marked. Provided the Member State is still accepting PPE under paragraph 7 of Recommendation 2020/403, you could place it on an individual Member State's market (it should not be for wider distribution outside that Member State), provided it has been approved by that Member State's Market Surveillance Authority, and provided the product completes conformity assessment and is CE marked ideally within a few days from its placing on that Member State's market.

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