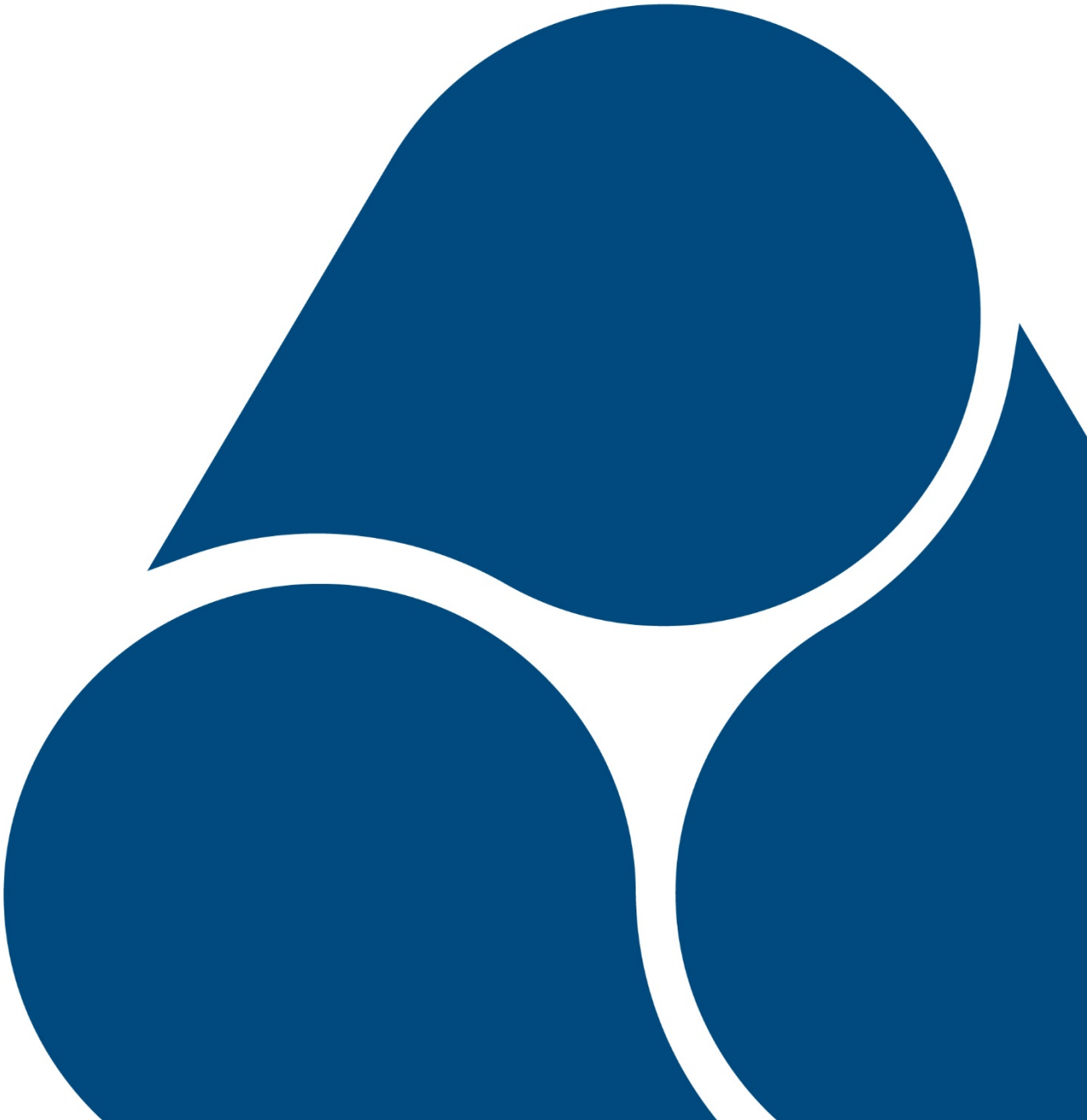
Office for Product Safety & Standards

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

Guidance for Businesses, Version 5

July 2020



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Guidance

1. Who is this guide for?

This guide 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 for users although its principles can be applied to these processes too.

2. What is Personal Protective Equipment (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 for protection against one or more risks from COVID-19 to their health or safety, 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 equipment if their main purpose is to protect others from the user (like a surgical face mask).

A medical gown 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.

Further information about the regulation and safety of medical devices is provided on GOV.UK.

3. What 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 were 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 is moving to competitive tendering.

Further details on the competitive tendering processes are provided on GOV.UK.

4. What are the essential 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 Transition Period and has been adopted in an amended form into UK law so that it continues to apply to the UK market after the Transition Period has ended. 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 requirements has been changed.

To ensure you have met 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 technical specifications for gowns, surgical face masks, respirator masks, eye protection 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 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 directly.

   Further details on the competitive tendering processes are provided on GOV.UK.

2. All workers, 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 PPE approved for sale or donation to the Government to be used by NHS healthcare workers?

Before COVID-19 related PPE can 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 safety requirements.
2. The products must be part of a purchase organised by or donation agreed by the UK Government or the National Health Service 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 current 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 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 National Health Service competitive tendering process?

In order to place PPE intended to protect UK workers in any environment from COVID-19 on the UK market, it must meet the essential safety requirements under 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. However:

1. You must have submitted a formal application to a Notified Body (a simple email will not suffice) and your COVID-19 PPE product must have been **accepted into the process** of conformity assessment with that Notified Body. You can choose any mentioned in the table below.

   and

2. The Notified Body must have confirmed that your product has an adequate level of health and safety in accordance with the essential requirements laid down for that product.
3. You must be able to produce confirmation of 1. and 2.

All relevant UK Notified Bodies have been informed of this procedure and the Notified Body that you choose should guide you through the fast track process of conformity assessment.

Following its assessment of your PPE, as part of Notified Body involvement referred to in point 2 above, which will include simplified product testing, the Notified Body will inform you whether your product meets the essential requirements or not.

If the product is deemed by the Notified Body as meeting essential safety requirements, you can begin selling it, provided you make sure that:

4. 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 if the PPE is later found not to meet essential 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.
5. 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.
6. 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.
7. You recognise that this is for a limited period of the health crisis and you continue with the Notified Body to seek full conformity for your product (in the time that the Notified Body is able to complete the conformity process) in the usual way.

If the product is deemed by your chosen Notified Body not to be capable of meeting essential safety requirements it will tell you why, and it will then be up to you to address any issues and reapply for assessment to that Notified Body.

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

BSI Assurance UK Ltd Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP Phone: +44 (0) 8450 809000 Fax: +44 (0) 8450 809000 Email: product.certification@bsigroup.com Website: www.bsigroup.com Notified Body number: 0086
CCQS UK LTD Level 2, 5 Harbour Exchange Square, London E14 9GE Phone: +44(0)20 7868 1509 Email: info@ccqs.co.uk Website: www.ccqs.co.uk Notified Body number: 1105

INSPEC International Ltd. 56 Leslie Hough Way, Salford, Greater Manchester M6 6AJ Phone: +44 (0) 161 737 0699 Fax: +44 (0) 161 736 0101 Email: certification@inspec-international.com Website: www.inspec-international.com Notified Body number: 0194
ITS Testing Services (UK) Ltd Centre Court, Meridian Business Park, Leicester LE19 1WD Phone: +44.116 263.0330 Fax: +44.116.263.03.11/12 Email: marc.gaten@intertek.com / tina.ball@intertek.com Website: www.intertek.com Notified Body number: 0362
SATRA SATRA Technology Centre Ltd, Wyndham Way, Telford Way, Kettering, Northamptonshire NN16 8SD Phone: +44 (0)1536 410000 Fax: +44 (0)1536 410626 Email: info@satra.co.uk Website: www.satra.co.uk Notified Body number: 0321
SGS United Kingdom Limited Unit 202B, Worle Parkway, Weston-super-Mare, Somerset BS22 6WA Phone: +44 (0)1934 522917 Fax: +44 (0)1934 522137Email: globalmedical@sgs.com / sgsprodcert@sgs.com (for 89/686/EEC; 92/42/EEC) Website: www.uk.sgs.com Notified Body number: 0120
Shirley Technologies Limited, trading as BTTG Unit 6, Wheel Forge Way, Trafford Park, Manchester M17 1EH Phone +44 (0)161 876 4211 Fax: +44 (0)161 872 0294 Email: onestopshop@bttg.co.uk Website: www.bttg.co.uk Notified Body number: 0338
SIRA CERTIFICATION SERVICE Unit 6 Hawarden Industrial Park, Hawarden, Deeside CH5 3US Phone: +44 (0)1244 670900 Fax: +44 (0) 1244 681330 Email: UK_NotifiedBody@csagroup.org Website: www.csagroupuk.org Notified Body number: 0518

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

The type of PPE they assess is set out in the table below[1]:

Notified Bodies	**Types of PPE Assessed** **1** Protective equipment against harmful biological agents **2** Equipment providing respiratory system protection, for example face masks **3** Equipment providing chest and groin protection, for example specialist clothing **4** Equipment providing hand and arm protection, for example medical grade gloves **5** Equipment providing general body protection (clothing), for example coveralls or limited life equipment **6** Equipment providing face protection, for example visors or face shields **7** Equipment providing eye protection, for example safety spectacles or goggles

	1	**2**	**3**	**4**	**5**	**6**	**7**
BSI Assurance UK Ltd	✓	✓		✓	✓	✓	✓
CCQS UK Ltd		✓	✓	✓	✓	✓	✓
INSPEC International Ltd		✓		✓	✓	✓	✓
ITS Testing Services (UK) Ltd			✓	✓	✓		✓
SATRA	✓		✓	✓	✓	✓	✓
SGS United Kingdom Limited	✓	✓		✓	✓		
Shirley Technologies Limited, trading as BTTG	✓	✓	✓	✓	✓	✓	✓
SIRA CERTIFICATION SERVICE						✓	
UL INTERNATIONAL (UK) LTD	✓				✓	✓	✓

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.

[1] This table has been created from information available on the NANDO database.

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.

A key obligation under the Regulations is that as the importer, you must ensure that the manufacturer has carried out the appropriate conformity assessment.

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

1. 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 as meeting the essential health and safety requirements, even though the formal conformity assessment procedures have not been completed.

   or

2. 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.

This publication is available at https://www.gov.uk/guidance/opss-coronavirus-covid-19-guidance-for-business-and-local-authorities

Contact us if you have any enquiries about this publication, including requests for alternative formats, at: OPSS.enquiries@beis.gov.uk

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