Office for Product Safety & Standards

Guidance for new high volume manufacturers of COVID-19 Personal Protective Equipment

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1. Who is this guide for?

This guide is for you if you want to change your processes to make high volumes of Personal Protective Equipment (PPE) to protect users from COVID19.

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 COVID19?

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.

For information about medical devices, please look at this information on medical devices regulation and safety - https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety - and the Medicines and Healthcare products Regulatory Agency website - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

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 COVID19.

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, once you have read the guide, you decide you may be able to make high volumes of PPE that meets the essential health and safety requirements, contact gcfcovid19enquiries@cabinetoffice.gov.uk to find out how you can help.

4. What are the essential safety requirements for PPE intended to protect against COVID19?

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.

The essential health and safety requirements that apply to PPE are listed in Annex II of EU Regulation 2016/425. You can find them 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 essential requirements has been changed.

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

a) in line with a relevant European Standard,
b) in accordance with a standard referenced in the WHO guidelines or
c) to an alternative technical solution that meets the essential health and safety requirements and delivers adequate safety

There are Standards relevant to PPE for COVID-19 available free from the British Standards Institution.

There are also WHO guidelines.

5. Do I 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.

The extent to which the conformity assessment rules have been eased depends on whether you are manufacturing COVID-19 related PPE for Government/NHS purchase or are more generally placing it on the market.

6. Who is the customer for your PPE?

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

The way that your PPE will be able to reach the UK market, the way that it must be conformity assessed, and the responsibilities on you as a manufacturer will differ for each user group so please make sure that you understand which group you plan to produce PPE for :

1. Healthcare workers, where you only intend to sell the PPE directly to the UK government

2. Other key workers in, the public and private healthcare companies, where you intend to sell PPE to distributors, retailers or directly.

7. What do I need to do to have my PPE approved for sale to the Government to be used by NHS healthcare workers?

Before COVID-19 related PPE is purchased by the Government/ NHS to be used by NHS 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,

   and

   the cross-Government Decision Making Committee, comprising representatives from Department Health and Social Care, Medicines and Healthcare products Regulatory Agency, Health and Safety Executive (the Market surveillance Authority), Office for Product Safety and Standards, and other experts as required have assessed the product via the route outlined below, against the standard(s) or technical solution you have chosen;

2. The products must be part of a purchase organised by the UK Government or the National Health Service

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.

To enable the cross-Government Committee to assess your COVID-19 related PPE, you should supply to gcfcovid19enquiries@cabinetoffice.gov.uk relevant documentation, including any test reports, that shows 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.

Your PPE will then be reviewed against essential health and safety requirements, including any physical testing necessary, and you will receive feedback on whether it has met them.

If your PPE is not approved as meeting the essential health and safety requirements they will tell you why, and it will then be up to you to address any issues and reapply should you wish.

Once your PPE has been approved by the relevant authorities as meeting the essential health and safety requirements applicable to COVID-19 PPE for use by NHS workers, the Government/ NHS PPE purchaser will be back in contact with you.

8. 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 the Government/ NHS for NHS use?

Before PPE intended to protect UK workers in any environment from COVID19 can be placed 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. Your product must be **in the process** of conformity assessment with a Notified Body, you can choose any mentioned in the table below and
2. The Notified Body must attest that your product **would pass** the conformity assessment process if it was to complete the process.

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.

The Notified Body after its assessment, which will include simplified product testing, will inform 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.

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

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	**SGS United Kingdom Limited** Unit 202B, Worle Parkway **SGS United Kingdom Limited**, Weston-super-Mare, Somerset, BS22 6WA Phone : +44 (0)1934 522917 Fax : +44 (0)1934 522137 Email : globalmedical@sgs.com; sgsprodcert@sgs.com (for 89/686/EEC; 92/42/EEC) Website : www.uk.sgs.com

	Notified Body number : 0120
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	**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
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	**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
ITS Testing Services (UK) Ltd Centre Court Meridian Business Park Leicester 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	**UL INTERNATIONAL (UK) LTD** Wonersh House Building C The Guildway Old Portsmouth Road Guildford GU3 1LR Phone : +44 1483 302130 Fax : +44 1483 302230 Email : Inform.NB@uk.ul.com Website : http://www.ul-europe.com Notified Body number : 0843
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	

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

Notified Body	*Protective equipment against harmful biological agents*	*Equipment providing respiratory system protection* *For example, Face Masks*	*Equipment providing chest and groin protection* *For example, Specialist Clothing*	*Equipment providing hand and arm protection* *For example, medical grade gloves*	*Equipment providing general body protection (clothing)* *For example, coveralls or limited life clothing*	*Equipment providing face protection* *For example, visors or face shields*	*Equipment providing eye protection* *For example safety spectacles or goggles*
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	✓▪				✓▪	✓▪	✓▪

9. 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 cross-Government Committee or Notified Body. You will adequately take into account changes in the design or characteristics of the PPE and changes in the

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

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 UK healthcare workers, 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 COVID19, and PPE recalls, and keep the purchaser and distributors informed of any such monitoring.

4. Ensure that all 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.

5. Ensure that the 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.

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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