

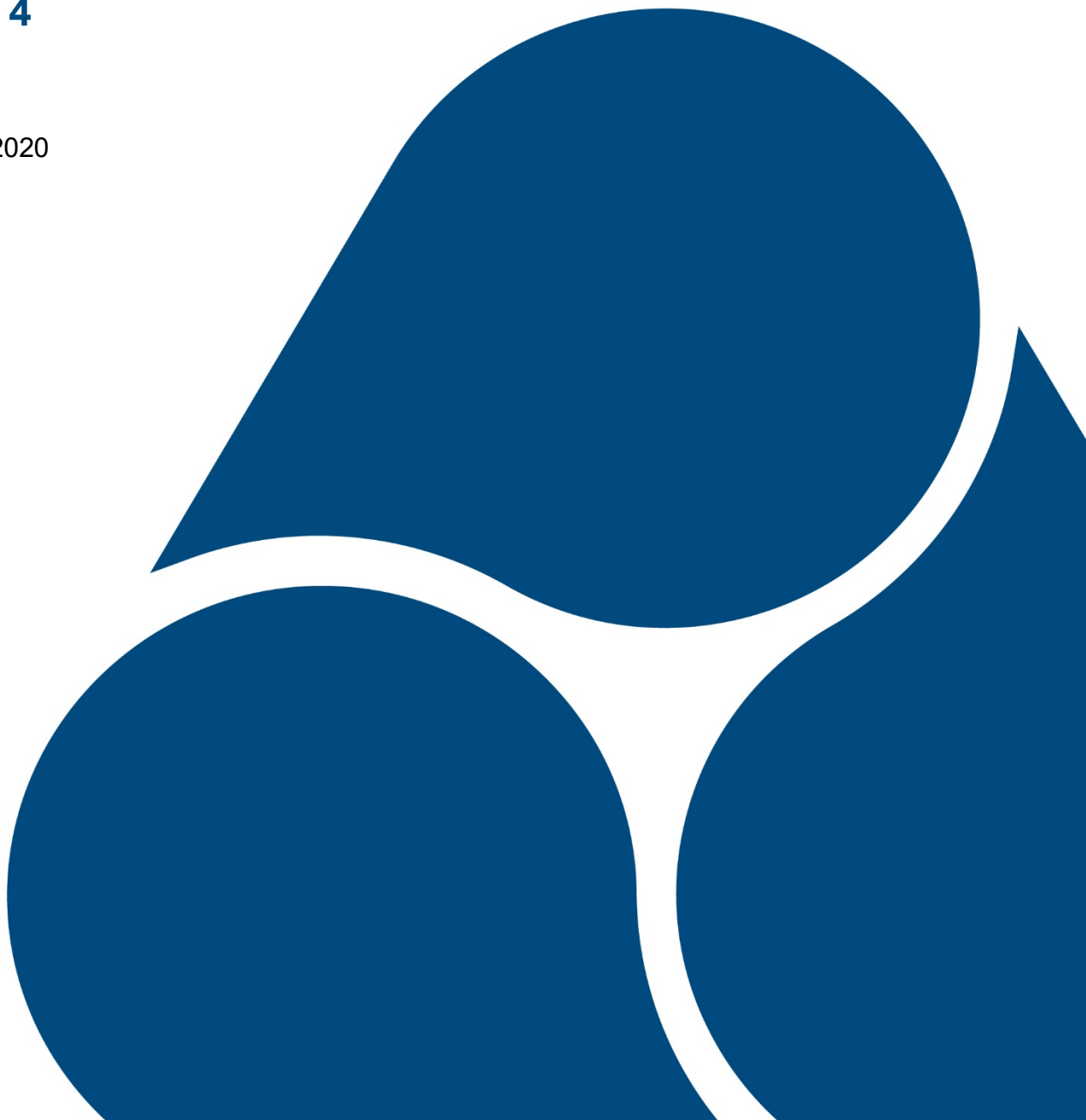


Office for Product
Safety & Standards

New Small-Scale Manufacturers of COVID-19 Personal Protective Equipment (PPE)

**Guidance for Businesses, Organisations and Individuals,
Version 4**

September 2020



Guide for small businesses and individuals wanting to manufacture personal protective equipment (PPE) that will protect against COVID-19

1. This guidance is designed to help any small businesses, organisations or other individuals wanting to produce personal protective equipment (PPE) aimed at protecting the health of the wearer during the COVID-19 outbreak.

If you are a large business and want to sell large volumes to the NHS, then you should refer to the guidance for [New high volume manufacturers of COVID-19 PPE](#).

2. To limit infection from COVID-19, PPE must be effective in guarding against specific risks, for example from contact with anything the virus is on or from infected breath, coughs or sneezes. It is your legal responsibility to ensure that any PPE you supply is effective in guarding against the risks it is designed for. This is known as meeting “essential health and safety requirements”. The details of these requirements are set out in [EU Regulation 2016/425](#).
3. This guidance does not cover general purpose face coverings which are not Personal Protective Equipment (PPE) or a medical device and are regulated under the General Product Safety Regulations 2005. [Please read the separate guidance for manufacturers and makers of face coverings](#).

Steps for new small-scale manufacturers or suppliers of PPE

Step 1 – Ensure you can make PPE that will protect against COVID-19.

4. There are two ways you can do this:
 - a. **Follow a relevant BS/EU Standard.** [Standards relevant to PPE for COVID-19](#) are now available to download at no cost. If you follow the standard exactly, it will be presumed that your PPE will comply with essential health and safety requirements and offers the protections the standard is designed to deliver.
 - b. **Follow another technical solution** (for example a US standard or a standard referenced in the [WHO guidelines](#)). This route is most suitable for experienced manufacturers.
5. Please read the relevant BS/EU standards. The Health and Safety Executive (HSE) has produced [simplified technical specifications](#) for relevant PPE. Although these are designed for PPE being supplied to healthcare workers as part of a centralised high-volume Government purchase, you may find them helpful as a reference.
6. If you do not think you can make PPE to the safety levels required, then your PPE will not be suitable for protecting against COVID-19.

Step 2 – Arrange for a third party to guide you and assess your PPE as safe

7. Whichever of the above routes you choose in Step 1, your PPE will need to be assessed as safe, (i.e. as meeting the essential health and safety requirements) by a third-party assessor, called a Notified Body. If having read the standards, you believe that you can make PPE to the required safety levels, then you should arrange to have your PPE assessed.

8. This assessment can only be undertaken by a Notified Body appointed by the Government to test and assess products against the requirements of product safety legislation. These are listed in the table below.
9. We have eased the administrative requirements for third party assessment so that PPE can be donated or sold in advance of full conformity assessment being completed and CE marking being applied. If you are satisfied that you can demonstrate that your PPE meets the essential health and safety requirements, you can sell or donate it as soon as you:
 - a) have started the third-party assessment process by making an application to a Notified Body;
 - b) the Notified Body confirms it has accepted your PPE product into the conformity assessment process;
 - c) the Notified Body agrees that your product meets the essential health and safety requirements, and
 - d) your product has been approved by the relevant Market Surveillance Authority (HSE or HSENI; if PPE is designed solely for private consumption on domestic premises, then Local Authority Trading Standards are the Market Surveillance Authority) has agreed that it meets the essential safety requirements.
10. Please note that you will need to ensure that your PPE is traceable and if it is placed on the market before the full conformity assessment by the Notified Body is completed then it is only for the UK.

If you have already placed equipment on the market without CE marking under previous arrangements, please see the FAQs on page 5 for further advice.

Supplying the general UK market

11. If the product is deemed by the Market Surveillance Authority as meeting essential safety requirements, you can begin selling or donating it, provided you make sure that:
 - a) 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 it is traceable - 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.
 - b) 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.
 - c) 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.

- d) You recognise that this is for a limited period of the health crisis, for the UK market only, 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.

Supplying the NHS

12. If you believe you are able to follow the two steps above and want to sell to the NHS, [please read the competitive tendering details](#).

Please do not contact individual NHS Trusts with offers of PPE unless it has been assessed as meeting the essential health and safety requirements by the Market Surveillance Authority, as even small-scale supplies must be assured as safe.

Please note that the Government's 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 manufactures or suppliers through the government portal, but has moved to competitive tendering.

Frequently asked questions

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?

PPE placed on the UK market without CE marking on clearance of a Notified Body (in line with earlier guidance), must complete full conformity assessment. Any subsequent batches should be CE marked in line with normal procedures. Market Surveillance Authority clearance is now required for these and any new COVID-19 related PPE if these have not yet completed the conformity assessment procedures.

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 clearance of a Notified Body (in line with earlier guidance), does not need to be recalled but conformity assessment must be completed as soon as possible to allow subsequent batches to be placed in the market. These must meet the Personal Protective Equipment Regulation including the CE marking and required markings and labelling. If full conformity assessment has not been completed or is still in process with a Notified Body, the Market Surveillance Authority's approval is now required for any subsequent batches placed on the market.

My equipment 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 equipment. If you need to place the equipment on the market in advance of this, you should contact the MSA for approval to do so. They will want to confirm that it meets the essential health and safety requirements that apply to it.

My equipment 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 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 market (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 can make gowns/ aprons/ masks/ face visors/ gloves. What are the specifications for COVID-19 related PPE?

BSI standards are available for free here: [Standards relevant to PPE for COVID-19](#)

If I share my designs for PPE with others and my product is assessed as compliant, will theirs automatically be compliant?

All products need to be assessed as meeting essential health and safety requirements. However, if you use a design that already has type approval the route to market is likely to be quicker. You should discuss your proposal with a Notified Body as soon as possible.

Can I put a 'no liability' claim on what I am selling/ donating to cover myself if it doesn't work?

If you are making PPE, it must meet essential health and safety requirements and if you supply it to others you are responsible for making sure it is safe for them to use. Including a "no liability" disclaimer does not exclude you from meeting your legal obligations nor protect you against claims should anyone be harmed by your product.

Can I make face masks for sale/ donation to the ordinary public and not sell/ donate it as PPE?

General purpose face coverings are not Personal Protective Equipment (PPE) or a medical device and are regulated under the General Product Safety Regulations 2005. Please [read the guidance for manufacturers and makers of face coverings](#), telling you what you need to know to make face coverings that are safe.

What Notified Bodies can I contact?

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

<p>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</p>	Notified Body number: 0194
<p>ITS Testing Services (UK) Ltd; Centre Court, Meridian Business Park, Leicester LE19 1WD Phone: +44 (0) 116 263 0330; Fax: +44 (0) 116 26 03 11/12 Email: marc.gaten@intertek.com / tina.ball@intertek.com; Website: www.intertek.com</p>	Notified Body number: 0362
<p>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</p>	Notified Body number: 0321
<p>SGS United Kingdom Limited, Unit 202B, Worle Parkway, 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</p>	Notified Body number: 0120
<p>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</p>	Notified Body number: 0338
<p>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</p>	Notified Body number: 0518
<p>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</p>	Notified Body number: 0843

The type of PPE they assess is set out in the table below¹:

Notified Bodies	Types of PPE Assessed						
	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	✓				✓	✓	✓

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

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