



Office for Product
Safety & Standards

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

**Guidance for Businesses, Organisations and Individuals,
Version 1**

May 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 who are responding to the call for a national effort 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 can switch your production to make thousands of masks/visors/aprons/gloves every week, then you should complete the webform at <https://www.gov.uk/coronavirus-support-from-business> and 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](#).

Steps for new small-scale manufacturers or suppliers of PPE

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

3. 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.
4. 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.
5. 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. Please do not offer any PPE for sale or donation to the NHS that does not meet essential health and safety requirements as it will not be able to be used and may put healthcare workers at risk.

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

6. 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.

7. 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.
8. We have eased the administrative requirements for third party assessment so that PPE can be donated or sold more quickly. 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; and
 - c) the Notified Body agrees that your product meets the essential health and safety requirements.
9. The only exception is for PPE that is organised by the UK Government for use by the NHS or other healthcare workers where assessments will be undertaken by the HSE. To ensure maximum supply to the NHS and best use of resources this route of assessment by HSE is only available to large-scale manufacturers

Who to contact?

10. If you believe you are able to follow the two steps above and want to sell or donate to the NHS, please register your interest on the webform at <https://www.gov.uk/coronavirus-support-from-business>.

Please do not contact individual NHS Trusts with offers of PPE unless it has been assessed as meeting the essential health and safety requirements, as set out in Step Two, as even small-scale supplies must be assured as safe. The Government is currently prioritising purchase of large-scale supplies for the NHS as that will have the most impact on frontline staff.

Frequently asked questions

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.

I've got the raw materials to make PPE but can't make it to the required standard

If you already have raw materials that can be used to make PPE, but your business cannot make PPE to the required standards, you should register at <https://www.gov.uk/coronavirus-support-from-business>.

If possible, you should look to sell the raw materials to a UK company who can use them to make PPE for the NHS or other frontline healthcare workers.

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

You may be able to do so, but please speak to your Local Authority Trading Standards department about what you are selling/ giving away, what regulations apply to it and how you intend to describe what it is that you are selling. They can help you ensure your product is safe and does not mislead your buyers into thinking it provides protection against COVID-19 infection.

What Notified Bodies can I contact?

<p>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</p> <p style="text-align: right;">Notified Body number: 0086</p>
<p>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</p> <p style="text-align: right;">Notified Body number: 1105</p>
<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> <p style="text-align: right;">Notified Body number: 0194</p>
<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> <p style="text-align: right;">Notified Body number: 0362</p>
<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> <p style="text-align: right;">Notified Body number: 0321</p>

<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> <p style="text-align: right;">Notified Body number: 0120</p>
<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> <p style="text-align: right;">Notified Body number: 0338</p>
<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> <p style="text-align: right;">Notified Body number: 0518</p>
<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> <p style="text-align: right;">Notified Body number: 0843</p>

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			✓	✓	✓		✓

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

SATRA	✓		✓	✓	✓	✓	✓
SGS United Kingdom Limited	✓	✓		✓	✓		
Shirley Technologies Limited, trading as BTTG	✓	✓	✓	✓	✓	✓	✓
SIRA CERTIFICATION SERVICE						✓	
UL INTERNATIONAL (UK) LTD	✓				✓	✓	✓

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