Office for Product Safety & Standards

Resuming full conformity assessment of COVID-19 Personal Protective Equipment (PPE)

Guidance for large and small-scale manufacturers

December 2020

Contents

Guidance

1. Who is this guide for?

This guidance is for you if you are a manufacturer and you have changed, or want to change, your processes to make high volumes of Personal Protective Equipment (PPE) to protect users from COVID-19.

This guide is also 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.

In this guide, “manufacturer” includes large businesses, small businesses, organisations such as schools and universities, voluntary groups, and individuals.

This guidance does not cover general purpose face coverings or face visors 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 and face visors.

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 look at the procurement processes for the part of the UK's NHS that you want to supply to:

Further details on the competitive tendering processes for DHSC and NHS England are provided on GOV.UK.

For details on procurement for NHS Scotland, please visit:

https://www.nhsscotlandprocurement.scot.nhs.uk/

For details on procurement for NHS Wales, please visit:

https://nwssp.nhs.wales/ourservices/procurement-services/

For details on procurement for NHS Northern Ireland, please visit:

http://www.hscbusiness.hscni.net/services/1878.htm

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

The manufacture of PPE is highly regulated to ensure it is effective,and 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 Regulation still applies during the Transition Period and has been adopted in an amended form into UK law. Under the terms of the Protocol, the Regulation applies directly to Northern Ireland. In an amended form it applies directly to the Great Britain market after the end of the Transition Period on 31 December 2020.

EU Regulation 2016/425 is enforced in both Great Britain and Northern Ireland by the Personal Protective Equipment (Enforcement) Regulations 2018.

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".

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

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.

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.

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

Whichever of the standards or technical solutions you choose to use in the manufacture of your PPE, 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 an Approved Body in relation to the market in Great Britain, and a Notified Body in relation to the market in Northern Ireland.

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.

This assessment can only be undertaken by an Approved/ 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 in section 7.

The Type Approval and quality assurance procedures are set out in EU Regulation 2016/425.

The process by which new PPE intended to protect against COVID-19 was assessed for compliance with the essential health and safety requirements was temporarily changed while the UK followed EU Recommendation 2020/403. That Recommendation falls away in Great Britain (England, Scotland and Wales, “GB”) on 31 December 2020.

From 1 January 2021 full conformity assessment and conformity marking is required before PPE can be placed on the GB market by PPE manufacturers based in **Scotland**.

There are temporary arrangements in place for **COVID-19 related** PPE for use by manufacturers based in **England and in Wales** in relation to placing PPE on the GB market and by manufacturers in **Northern Ireland** in relation to placing PPE on the Northern Ireland market.

The arrangements for manufacturers in England and in Wales in relation to placing COVID-19 PPE on the GB market are in place until 31 March 2021 and in relation to supplying NHS England with COVID-19 related PPE until 30 June 2021. This is in response to a specific set of circumstances and the end dates will be kept under review.

From 1 April 2021 all PPE placed on the GB market or made for donation, and from 1 July 2021 all PPE offered for sale or donation to the NHS in England, Scotland and Wales, must undergo full conformity assessment (including conformity marking) as set out in Regulation 2016/425.

The arrangements in Northern Ireland are in place under EU Recommendation 2020/403 and will remain so until either the Recommendation is withdrawn, the UK agrees to bring the easements to an end or the people of Northern Ireland vote to end the arrangements in place pursuant to the Northern Ireland Protocol.

The next two sections of this guide tell you the route you must follow to ensure you can:

1. Supply COVID-19 related PPE for use by healthcare workers
2. Place on the market COVID-19 related PPE for any type of worker or user.

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 or other frontline workers?

If you are a PPE manufacturer based in **Scotland**, and intending to sell or donate COVID-19 related PPE to NHS Scotland, your PPE needs to complete full conformity assessment (including conformity marking) before you offer it to NHS Scotland, through their competitive tendering routes, set out above at the end of section 3 of this guide.

You should not sell directly or donate directly to healthcare or social care bodies (including hospitals, GP surgeries, care homes or other health or social care settings).

If you are a PPE manufacturer based in **England, Wales** or **Northern Ireland**, you can offer COVID-19 related PPE to NHS England, NHS Wales and NHS Northern Ireland respectively for purchase or donation, provided it meets **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 donation agreed by, or a purchase organised by the UK Government or NHS England, NHS Wales, or NHS Northern Ireland via a competitive tendering process. Evidence of this may be required by HSE as part of granting the product easement.
3. The products will only be made available for use by healthcare and other frontline workers in England, Wales or Northern Ireland.
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 relevant competitive tendering processes for NHS England, NHS Wales and NHS Northern Ireland respectively, as set out at the end of section 3 of this guide.

Your PPE will then be assessed by the Health and Safety Executive (and HSENI) to ensure it meets the essential safety requirements.

HSE would expect to see the following included as part of the application:

- 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, instructions and packaging;

- details of the tests carried out on the PPE;
- any relevant certificates;
- (if in process of being approved by a notified, or after 1 January 2021, an approved body) confirmation from the approved/ notified body that they have started the assessment procedure; and
- confirmation of where the products will be supplied.

HSE will assess the essential health and safety requirements and may communicate that its approval is subject to some limitations, for example, stating that the essential health and safety requirements will only be met if the packaging or instructions for using the PPE are altered.

These are temporary arrangements. The assessments of COVID-19 related PPE will end on 30 June 2021 in England and in Wales. They end in Northern Ireland when Recommendation 2020/403 is withdrawn by the EU or the UK government in respect of Northern Ireland, or when the people of Northern Ireland withdraw from the arrangements under the Northern Ireland Protocol, whichever comes first.

From 1 July 2021, PPE manufacturers based in England and in Wales can only offer PPE to NHS England and NHS Wales respectively, via their competitive tendering processes, that has completed full conformity assessment, including conformity marking.

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?

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.

For PPE manufacturers based in **Scotland** intending to place COVID 19 PPE on the GB market, PPE must have completed full conformity assessment, and be UKCA marked (or until 31 December 2021, CE marked), before it can be placed on the GB market.

For PPE manufacturers based **Northern Ireland** intending to place PPE on the NI market, PPE must either have completed full conformity assessment and be CE marked (or CE and UKNI marked if the manufacturer uses a UK Approved Body for conformity assessment), or (COVID-19 related PPE only) have been assessed in line with the regulatory easements in EU Recommendation 2020/403 by the relevant Market Surveillance Authority, before being placed on the NI market.

For PPE manufacturers based in **England and in Wales** intending to place on the GB market, PPE must either have completed full conformity assessment and be UKCA marked (or until 31 December 2021, CE marked), or (**COVID-19 related PPE only**) have been assessed and approved by HSE **before 31 March 2021** in line with the arrangements in the Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (England) Regulations 2020 (“the 2020 PPE Regulations”), and The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Wales) Regulations 2020, before being placed on the GB market.

If you are using the temporary arrangements, you should start the conformity assessment process by making a formal application to a relevant Approved Body (England and Wales) or Notified Body (Northern Ireland). An email will **not** suffice. Your COVID-19 PPE product must be formally accepted into the process of conformity assessment with that Approved/Notified Body. You can use any of the Approved/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 the conformity assessment process or been conformity 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 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 conformity 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 EEA market when the conformity assessment process is complete and the product has been CE marked.

If the product is deemed by your chosen Approved/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.

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;

- any relevant certificates;
- (if in process of being approved by a notified, or after 1 January 2021, an approved body) confirmation from the approved/ notified body that they have started the assessment procedure; and
- confirmation of where the products will be supplied.

HSE will assess the essential health and safety requirements and may communicate that its approval is subject to some limitations, for example, stating that the essential health and safety requirements will only be met if the packaging or instructions for using the PPE are altered.

Applications will only be considered by HSE up to 31 March 2021. You will want to factor that into your planning. From 1 April 2021, all PPE must complete full conformity assessment and conformity marking.

Contact details for UK Notified Bodies[1] 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: leicester.reports@intertek.com Website: www.intertek.com Notified Body number: 0362

[1] At the time of writing these bodies are being invited by the Government to become UK Approved Bodies

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 Fax: +44 1483 302230 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[2]:

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 and/or Approved/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.

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

9. Importers' obligations in light of the temporary arrangements

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

PPE being imported into England, Wales or Northern Ireland that has not yet completed conformity assessment can only be placed on the GB or NI markets once it has been assessed and certified by the relevant UK market surveillance authority. PPE being imported into Scotland or Wales must have completed full conformity assessment and conformity marking.

While the temporary arrangements are in place, this means that an importer based in England, Wales or Northern Ireland 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 (before 30 June 2021) as meeting the essential health and safety requirements. PPE supplied through this process cannot be made available to the general GB or NI markets.

  or

- A manufacturer wishing to supply COVID-19 PPE to the general GB or NI markets has applied to an Approved/ Notified Body for conformity assessment, has had their application accepted, and has had their PPE assessed by the UK Market Surveillance Authority (before 31 March 2021) as meeting the essential health and safety requirements, even though the formal conformity assessment procedures have not been completed.

10. Transitional arrangements (GB market)

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

The arrangements for PPE being supplied to NHS healthcare workers as part of a Government or NHS procurement will come to an end in England and Wales on 30 June 2021. From 1 July 2021 HSE will no longer assess or approve COVID-19 PPE. Therefore, if you wish to supply on a longer term basis or to place your product on the GB or EEA markets (i.e. selling it outside of NHS or UK Government procurement for healthcare workers), you should seek full conformity assessment through an Approved Body for the GB market and an EU-recognised body for the EEA market. From 1 January 2021, new batches of PPE supplied to NHS Scotland will need to have completed full conformity assessment, including conformity marking.

Do I need to take PPE off the GB market from 1 April 2021 where it has not completed full conformity assessment or is not conformity marked?

Any equipment placed on the GB market without conformity marking before 31 March 2021 on assessment and certification by a UK market surveillance authority, 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 requirements including conformity marking and labelling.

If full conformity assessment has not been completed or is still in process with a Notified Body, and the HSE's approval has not been given by 31 March 2021 for placing on the market in England or Wales, full conformity assessment and conformity marking is required before PPE can be placed on the GB market.

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

The UK has left the EU and the Transition Period has ended, so you are no longer an importer within the EEA market. You can only export to the EEA any PPE you have. It must fully comply with EU Regulation 2016/425, including CE marking.

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Office for Product Safety and Standards

Department for Business, Energy and Industrial Strategy
4th Floor, Cannon House, 18 The Priory Queensway, Birmingham B4 6BS
https://www.gov.uk/government/organisations/office-for-product-safety-and-standards