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trading standards law explained

# Manufacturers of PPE

In this section



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The manufacturer has ultimate responsibility for compliance, including for those processes carried out by other parties.

## Routes to supply

There are three routes to placing PPE onto the UK market

1. Supply to the Government for purchase by the NHS/frontline healthcare workers (during COVID-19)
2. Manufacture of (high and low volume) non-CE marked PPE for all other supply avenues (during COVID-19)
3. Business as usual - CE marked PPE compliant with regulations (beyond COVID-19)

Depending upon who you wish to produce PPE for, whether for sale or donation, there are different legal responsibilities and conformity assessment processes that will apply to you as a manufacturer.

**This guide focuses on those which are relevant during COVID-19, i.e. when the easements apply.**

A manufacturer is anyone who 'manufacturers PPE or has it designed or manufactured, and markets it under his name or trademark' (Regulation (EU) 2016/425).

### Supply to Government/NHS only (during COVID-19 only)

**If you wish to manufacture, for sale or donation, high volumes of PPE to the Government/NHS for the frontline healthcare sector you will need to ensure that you can manufacture PPE which:**

- Ensures an adequate level of safety in respect to the essential safety requirements (EHSRs). This means manufactured in accordance with either ;
- A relevant harmonised European standard; or
- An equivalent WHO recommended standard; or
- Alternative technical solution which delivers adequate safety

If these points can be met, you will need to register with the Department of Health and Social Care (DHSC) and then apply for relevant contracts via the new competitive tendering process, in order to supply. Link:

https://www.gov.uk/government/organisations/department-of-health-and-social-care/about/procurement

**It is important to note that PPE manufactured for Government/NHS use must not be made available to general distribution channels (non healthcare) and is only valid during the current outbreak of COVID-19.**

Further guidance is available to help identify the relevant standards and minimum technical specifications, produced by the HSE and the MHRA for supplying the Government/NHS.
https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe

### For the high-volume manufacture of non-CE marked PPE for all other supply (during COVID-19 only)

If you are able to produce PPE in high volumes for COVID-19 worker protection, you can utilise the current regulatory easements to place PPE on the market for all other supply routes (this is for non- NHS supply only).

The following must be achieved to be able to make use of the current easements: -

- PPE must meet the EHSRs (under Regulation (EU) 2016/425); and be assessed in line with the easements, which means:
- Your product does not need to complete formal conformity assessment, including type approval by a notified body, however:
- You must have made a formal application to a notified body to start the conformity assessment process, obtained agreement that the PPE has been accepted into the assessment process AND gained assurance from the notified body that the PPE has met the appropriate EHSRs
- You should then be able to provide documented confirmation of this to your customers or a Market Surveillance Authority upon request
- **Manufacturers cannot start selling PPE via this route until confirmation has been received from the notified body that the PPE meets the EHSRs**
- A Declaration of Conformity must be completed with as much detail as possible, including the details of the notified body, demonstrating that the conformity assessment procedure has been started
- PPE must also be marked with: -
    - a type and serial or batch number for identification and traceability
    - the manufacturers name, registered trade name or trademark and postal address - this can be

    - on packaging or accompanying documentation if the size or nature of the PPE doesn't allow it
    - instructions for use and safety information as set out in point 1.4 of Annex II of the Regulation (EU) 2016/425 that is clear, legible and in easily understandable English.
- Keep your technical documentation for 10 years
- Carry out sample testing of PPE and keep the purchaser and distributor informed of your findings
- Continue down the conformity assessment process with the notified body, securing all applicable documentation and meeting all the marking and labelling requirements that will be applicable in the future.

**For small businesses and individuals manufacturing PPE (during COVID-19 and for non-NHS use)**

Guidance from OPSS in July 2020 has been produced to help small businesses that want to produce PPE during COVID-19. It can be accessed here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/899856/Guidance-for-businesses-and-individuals-small-scale-manufacture-of-ppe-version-2.pdf

Remember that general purpose face coverings (the type which must be worn on public transport and in shops) are not PPE. Face coverings should be made according to this guidance: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/899806/Guidance-for-businesses-and-individuals-face-coverings-version-3.pdf

The key aspects of small-scale manufacture of PPE are listed here:

- The legal responsibilities for ensuring that your PPE is effective in protecting against the risks it is designed for, are yours as the manufacturer
- Follow a relevant BS/EU Standard or another equivalent technical solution (the latter is probably better suited for more experienced manufacturers). By following the BS/EU standard exactly, it will be presumed that your PPE will comply with the essential health and safety requirements
- Read the BS/EU Standards (here: https://www.bsigroup.com/en-GB/topics/novel-coronavirus-covid-19/medical-devices-ppe/ ) and read the HSE's simplified technical specifications too https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe
- If you are happy that your PPE is suitable, then arrange for a third-party assessor (a Notified Body, or NB) to assess it. The NB must have been appointed by the Government for this purpose - the OPSS guidance contains a list of NBs and it also shows the type of PPE that they can each assess.

## When can you start selling?

The COVID-19 easements mean that you can sell a little earlier than in non-COVID-19 times.

If you are satisfied that your PPE meets the essential health and safety requirements you can sell or donate it as soon as you:

- Have made your application to an NB; and
- The NB confirms it has accepted your PPE product into the conformity assessment process; and
- The NB agrees that your product meets the essential health and safety requirements… and only then can you begin selling or donating it, provided you ensure that:
- If for COVID-19 PPE, it bears a type and serial or batch number, including your name, trade name or trademark and postal address (preferably on the product itself, if not, on the packaging or

documentation)
- It is accompanied by instructions that are clear and in English
- The Declaration of Conformity is completed with as much detail as possible, including the details of the NB you have applied to

Remember that this route is only valid during the current COVID-19 crisis, so you must continue working with the NB to achieve full conformity for your product in the usual way.

Further guidance for these two easement routes for newly manufactured PPE during COVID-19 can be found here:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/899855/Guidance-for-businesses-high-volume-manufacture-of-ppe-version-5.pdf

You will also find a list of UK Notified Bodies provided at the end of the document.

## Business as usual - New manufacturers (beyond COVID-19 easements)

'Business as usual' manufacture of PPE relates to PPE that is manufactured to the full regulatory requirements of the PPE Regulations, without the easements in place.

This route will also apply to those looking to source PPE from third party manufacturers which have their trade name or brand affixed to it. In which case, you will become the manufacturer and be responsible for the manufacturer obligations.

Placing on the market is defined (in Regulation (EU) 2016/425) as: 'the first making available of PPE on the Union market.'

For more information see the EU Regulation 2016/425
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0425 and guidance available from OPSS -
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/886169/Guidance-for-businesses-ppe-regulations-version-3.pdf

**Choosing this route places many obligations upon the manufacturer.**

The main obligation for a manufacturer placing PPE onto the market is to ensure PPE meets the EHSRs and that the required documentation is produced to show the actions you have taken to ensure its compliance. As a manufacturer, you have the ultimate responsibility for legal compliance.

## How do I manufacture PPE to the EHSRs?

Some product safety regulations allow for a presumption of conformity. This means that products which are designed to an applicable harmonised European standard may access a presumption of conformity when meeting the EHSRs. This can be evidenced, for example, via a test report for the applicable parts of the Standard. These Standards can be accessed for free, during COVID-19 from BSI website:-
**https://www.bsigroup.com/en-GB/topics/novel-coronavirus-covid-19/medical-devices-ppe/**

## What are the main obligations for Manufacturers?

- PPE must meet the EHSRs (Annex II - EU Regulation 2016 /425)
- Carry out a risk assessment to identify the risks which apply to the PPE, then design and manufacture it taking into account that assessment.

- PPE and instructions for use should be designed taking into account **reasonably foreseeable use**
- Undertake the prescribed conformity assessment procedures; whether by self-declaration or with a third-party conformity assessment body (notified body). This activity is dependent upon the risk category of the PPE in demonstrating compliance.

A quick guide of the Conformity Assessment Procedure set out in the table below details what is required for each Category of PPE - further detail is in the regulation

| PPE Category | PPE Regulation (EU) 2016/425 |
|---|---|
| Category I | Module A – Internal Production Control |
| Category II | Module B – EU Type Examination Plus<br>Module C – Internal Production Control |
| Category III | Module B – EU Type Examination plus either |
| | Module C2 – Sample Testing<br>or |
| | Module D – Production Quality Assurance |

- Affix the CE Mark (this may come later, thanks to the easements) and notified body number assessing production control
- Mark the product with a type/batch or serial number
- Mark the product with manufacturer name and postal address (product and/or packaging) - this provides vital traceability controls
- Draw up a Declaration of Conformity (with as much detail as possible, demonstrating that the conformity assessment procedure has been started) and provide a copy with every item of PPE or via a web link
- Provide every piece of PPE with user instructions in a language easily understood by the PPE users in that country, i.e. English
- Have procedures in place for series production control monitoring and maintaining conformity, e.g. if anything changes in the materials used or the specification, that PPE is still produced to the same quality.
- Retain technical documentation demonstrating compliance (for 10 years)

## What Documentation do I need?

### Produce a Declaration of Conformity

All PPE must be accompanied by (or supplied via a web link) a **Declaration of Conformity** (DoC) this is the manufacturers written declaration that the PPE meets the applicable EHSR's. Annex IX of the Regulation provides the format for the detail that is required.

## Hold Technical Documentation

Technical documentation is the manufacturer's evidence of the approaches taken to ensure the PPE is compliant. Annex III provides the full details of what is required.

Technical documentation should include (this is not an exhaustive list):

- A description of the PPE and of its intended use
- An assessment of the risks against which the PPE is intended to protect
- A list of the EHSRs applicable to the product

- Test Reports evidencing conformity to the ESHR's
- A copy of the Instructions for Use
- Technical drawings, details of production methods and controls in place to ensure conformity

**An example of PPE**

A face shield must be able to:

Protect the wearer by providing a barrier to liquid splashes

Relevant standards: BS EN 166:2002 and BS EN 168:2002

These standards include rules for: -

Labelling, Packaging, Manufacturer's Instructions

All face shields/visors must be: -

- Optically clear
- Resistant to fogging
- Have an adjustable head band
- Be resistant to droplets and splashes
- If re-usable, cleaning & disinfection instructions are required