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Business in Focus

Personal Protective Equipment (PPE) and COVID-19

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Department for Business, Energy & Industrial Strategy

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This booklet was produced on contract
by Fourth Estate Creative Ltd.
www.fourthestatecreative.com

Published by:
Chartered Trading Standards Institute, 1
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Southfields Business Park,
Basildon SS15 6TH
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www.tradingstandards.uk

www.businesscompanion.info

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Published:
28. 07. 2020

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Personal Protective Equipment (PPE) and COVID-19

Guidance for all manufacturers, importers and distributors on bringing PPE to the market during COVID-19 and beyond

Is this guide for you?

This guide is about PPE, not 'medical devices' or face coverings. PPE is an umbrella term which means things like gloves, aprons, high viz clothing and devices for the face (e.g. visors and respirators). The laws governing PPE apply from the points of its manufacture right through to its ultimate use – more on this later.

PPE is designed to protect the wearer in a workplace setting. It must therefore provide adequate protection for the wearer against the risks it is intended to protect from. It follows that PPE equipment which doesn't meet the required standards must not be used in the workplace because:

- It may not be safe
- It may not be able to protect as claimed
- It may not meet the essential health and safety requirements of the regulations.

The regulations prescribe three categories of PPE. That which is provided for protection against the risk of COVID-19 (including respiratory face masks), is category 3 PPE. Retailers may sell PPE directly to consumers too, for use in the home, commonly for DIY projects (e.g. during building work that might generate dust) and of course for protection in COVID-19 circumstances. Requirements are described later in this guide.

What are medical devices?

Unlike PPE, medical devices protect others from the user. These types of products might look similar to PPE but they are governed by a completely separate legal regime. An example of a medical device is a surgical face mask worn by a doctor during a consultation. Medical devices are not included in this guide.

What is a 'face covering'?

Face coverings are not PPE and they are not medical devices either! A different standard applies for those making and selling face coverings; they must be safe in order to be 'placed on the market.' There's guidance from the government on what this means: *https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/899806/Guidance-for-businesses-and-individuals-face-coverings-version-3.pdf*

Face coverings are required on public transport (from 15th June in England) and in some shops (from 24th July). Face coverings are not included in this guide.

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COVID-19 and regulatory easements

During COVID-19 there has been unprecedented global demand for PPE from the health and social care sector as well as from other sectors where workers are in close proximity to each other or with customers. The level of demand on PPE supplies, particularly those for the face, has resulted in a worldwide shortage.

The legal framework for PPE is complex and involves stringent product safety controls. This often means extensive responsibilities for those involved in bringing PPE to the market.

To help sustain supplies of PPE during COVID-19, measures across Europe have been put in place to prioritise and speed up the process of getting PPE to those in need. **These measures or 'easements' of the legal requirements have been implemented throughout Europe and the UK and they apply only for the duration of COVID-19.**

Supplies introduced under the applicable easements must still be able to protect those wearing the PPE and also meet the essential health and safety requirements (EHSRs) of the EU PPE Regulation.

Three categories of PPE

There are three categories of PPE; 1, 2 and 3. The categories are assigned according to the severity of the hazard it is intended to protect the wearer from, rather than the complexity of the PPE itself.

CATEGORY 1	CATEGORY 2	CATEGORY 3
Lowest level of risk PPE, rules allow manufacturers to self-declare conformity. Examples include sunglasses and washing up gloves	Is any other PPE that does not sit within Categories 1 or 3. This PPE requires 'type approval' but manufacturers can self-declare on the production control aspects. Product examples include high viz jackets and protective gloves	Highest level of risk, where the hazard may cause serious harm to the wearer. Products must be 'type approved' and the production control system reviewed by a notified body (NB) through either audit or sample testing. **All PPE specifically provided to protect against the risk of COVID-19 is category 3. The respirator face mask is an example.**

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The PPE regulations

EU Regulation 2016/425 Personal Protective Equipment

This is an EU Regulation that has direct effect in every EU Member State at the same time. It is applicable from 21st April 2018 with a two year transition period and it repeals the EU PPE Directive 89/686/EEC.

This covers new PPE being placed on the market for the first time during COVID-19 and beyond. PPE must comply with this regulation unless one of the easement routes are available (during COVID-19 only).

It requires PPE to be safe by meeting the prescribed EHSRs and specifies the processes that manufacturers must follow to evidence this. The Regulation also provides the detail of definitions, categories of PPE, exemptions, legal obligations as well as the EHSRs.

More on the easements later in this guide.

The Personal Protective Equipment (Enforcement) Regulations 2018

These UK Regulations implement the EU Regulation and provide for their enforcement. These UK regulations designate the Market Surveillance Authority (MSA) responsibilities (HSE/HSENI for PPE in the workplace).

The Government's Office for Product Safety and Standards (OPSS) is an 'enforcing authority.' Local Authority Trading Standards (Great Britain) and District Councils in Northern Ireland have the market surveillance responsibilities for the enforcement of PPE for private use, in other words where consumers are the end users.

Enforcement action may be taken against 'economic operators' (manufacturers, importers and distributors) by MSAs in relation to non-compliant and unsafe PPE, or other breaches of consumer protection legislation.

What about EU Exit?

The EU Regulation applies to the UK during the transition period (up to and including 31st December 2020) and beyond, by virtue of the European Union (Withdrawal) Act 2018, which retains already-existing EU law into UK law until parliament decides otherwise.

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Interested in diversifying to produce PPE?

You may be able to adapt your business to manufacture PPE for sale or donation to assist with the PPE shortage.

There's quite a bit to think about and some legal requirements that must be followed.

The UK easements exist to support those keen to diversify in the short term (during COVID-19, not forever) and they implement the European Commission's EU Recommendation (EU) 2020/403 which provides for it.

The easements speed up the process for bringing PPE to those in need, Further information on the Recommendation and its application can be found here: *https://ec.europa.eu/newsroom/growth/item-detail.cfm?item_id=672953*

Remember - PPE must still be manufactured to meet the EHSRs of the Regulation

Supply chain considerations

COVID-19 has inevitably led to an increase in new businesses (manufacturers, importers, distributers and retailers) entering the PPE supply chain for the first time.

If you're interested in being a part of the supply chain, you will need to know what is expected of you in terms of the legal obligations; whether the PPE you can manufacture or supply is safe; that it will protect as claimed; that it meets the EHSRs and that you can meet the requirements of the regulations.

? Where do your activities sit within the PPE supply chain?

- Manufacturer →
- Importer →
- Distributor-retailer →

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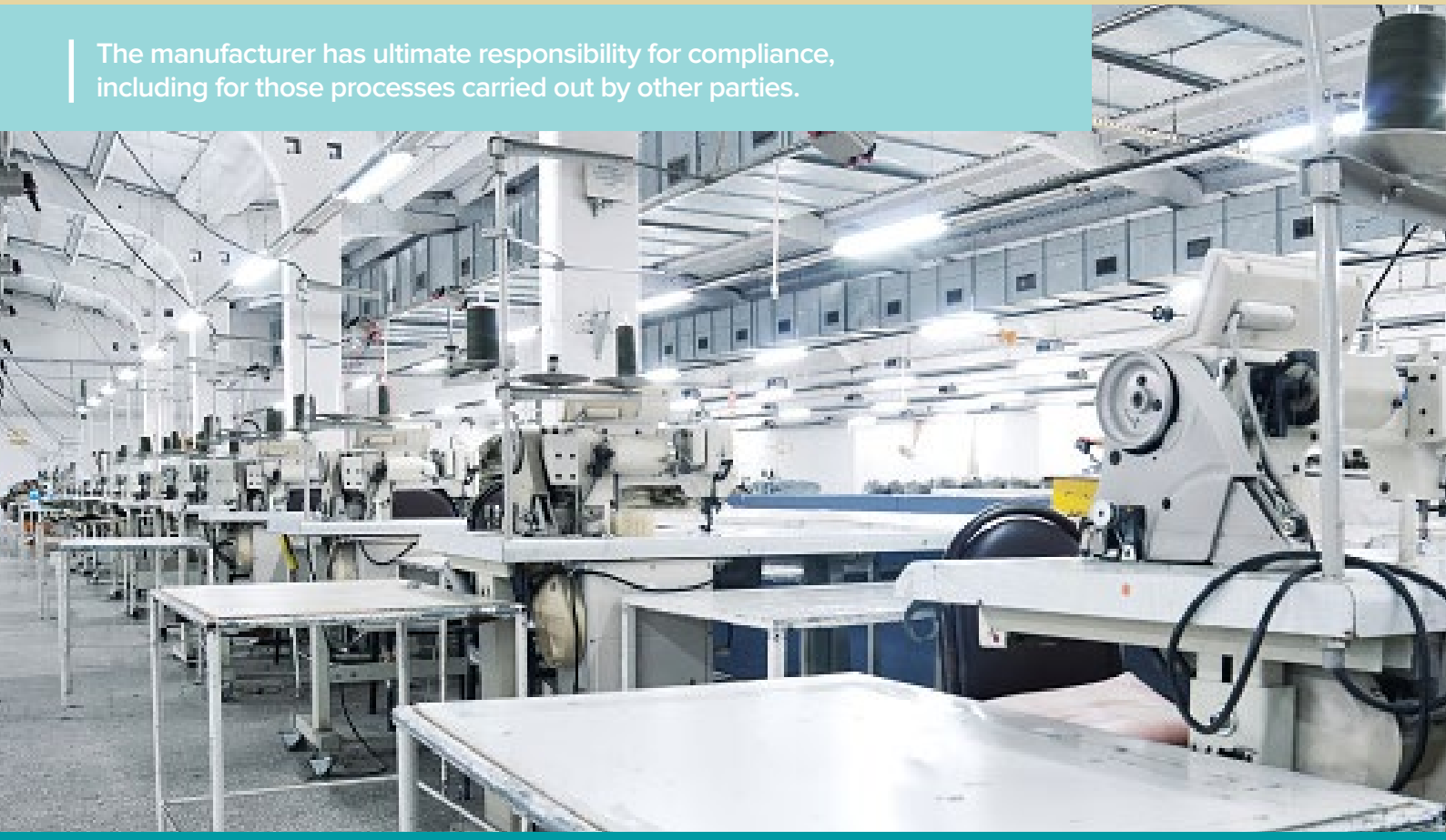
Advice for manufacturers

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



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Routes to supply

There are three routes to placing PPE onto the UK market:

1

NHS

Supply to the Government for purchase by the NHS/frontline healthcare workers (during COVID-19)

2

EHSR

Manufacture of (high and low volume) non-CE marked PPE for all other supply avenues (during COVID-19)

3

CE

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).

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1 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. This means manufactured in accordance with either;
- A relevant harmonised European standard (ESHRs); 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 of supply 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

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2 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.

Further guidance on easements applicable to the manufacturing circumstances described on pages 9 and 10 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.

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3 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 to 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 ESHRs... 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.

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4 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 EHSR's?

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 the BSI website:

https://www.bsigroup.com/en-GB/topics/novel-coronavirus-covid-19/medical-devices-ppe/

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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).

The table below details what is required for each category of PPE – further detail is in the Regulation.

- 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).

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

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? 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 manufacturer's written declaration that the PPE meets the applicable EHSRs. 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:

- 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 ESHRs
- A copy of the instructions for use
- Technical drawings, details of production methods and controls in place to ensure conformity

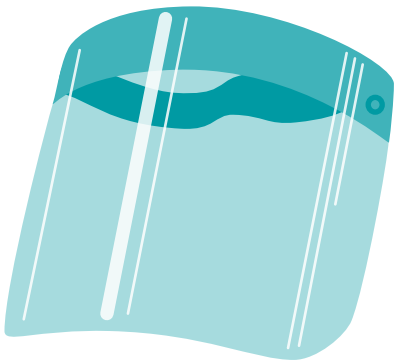
An example of PPE

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



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Advice for importers

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What is an importer?

Importers are not solely a re-seller of products but have a significant and vital role in ensuring only compliant PPE is imported and placed on the UK market. Importers have legal accountability for PPE compliance and product liability when PPE has been manufactured outside of the EU.

An Importer is defined in the regulations (Regulation (EU) 2016/425) as 'a person established within the Union who places PPE from a third country on the Union market.'

COVID-19 has meant that many import businesses, whether new start-ups or those that have adapted and increased their import base, now have the chance to assist in meeting the global demand for PPE.

Importers have legal accountability for PPE compliance and product liability when PPE has been manufactured outside of the EU.

What are my legal obligations as an importer (during COVID-19 only)?

If you are an importer, you will have a number of obligations that you need to meet to ensure the PPE you place on the market is in conformity with the regulations, prior to placing it on the market.

There are COVID-19 easements in place and the following takes these into account:

Importer obligations build upon those of manufacturers and the key is to ensure the manufacturer has fulfilled his/her obligations. It is therefore essential to read this Importer chapter alongside the Manufacturer chapter.

Importers must:

- **Assure themselves that the PPE is compliant before it is placed on the market – gain assurance from the NB that the product is likely to pass and that the process for approval is in progress**
- For use by the Government/NHS – COVID-19 PPE does not have to undergo conformity assessment procedures but can be imported without the CE marking or Declaration of Conformity and purchased, provided it meets the EHSRs
- In relation to supplying the NHS, importers should have documentary proof that the manufacturer has met all their responsibilities. Remember that PPE for the NHS cannot be made available on the general market
- PPE for the NHS market should be assessed and approved by the Market Surveillance Authority (HSE), under the easements
- For use in other sectors (non NHS) – COVID-19 PPE can be imported and sold, providing conformity assessment procedures have begun, but not necessarily completed. These products will not be CE marked or have a completed Declaration of Conformity
- Importers supplying the non NHS market should also have documentary proof from their manufacturers that they have met all their responsibilities
- Carry out sample testing and keep distributors informed of the results and actions taken regarding complaints or non-conforming PPE/recalls
- Include your name, trade name or trademark and postal address (unless already on the packaging)
- Ensure that the PPE is accompanied by instructions and safety information, in English
- Keep a copy of the (incomplete) Declaration of Conformity for 10 years (not applicable to NHS supply)
- Store and transport the goods so that they are not damaged which could jeopardise the EHSR of the PPE
- Immediately notify the UK enforcement authority* of non-compliant PPE that you have placed on the market and immediately take corrective measures to bring it into conformity (or withdraw it or recall it, as appropriate). Where it presents a risk, inform the enforcement authority to that effect and give details as well as of any corrective measures taken. Respond to requests from the enforcement authority that might be necessary to demonstrate conformity and otherwise co-operate on any action required to eliminate risks which arise.
- Ensure that a chain of traceability exists, so that all those that have been supplied the PPE can be notified of any issues that arise

**The UK enforcement authority is the Secretary of State who exercises these powers via the Office for Product Safety and Standards (OPSS, within the Department for Business, Energy and Industrial Strategy)*

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How do I meet my importer obligations?

Know what you are importing, so that you can meet your responsibilities as an importer. Check your products and their documentation.

Examine the products (where possible) to ensure the legally required markings have been applied.

In addition, ensure that the technical Standards being declared are correct, for example; PPE respirator face masks should follow the requirements of BS EN 149:2001+A1:2009 and face visors to BS EN 166:2002 and BS EN 168:2002.

Use the Technical Specification Guide which details the minimum requirements and applicable standards of PPE and medical devices for supply during COVID-19. This document has been provided for Government procurement for NHS only, however, it is a good starting point for knowing what standards and basic details are required.

https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe

Finally, ensure the PPE is as expected, do the details on the product and packaging match up to the details on the documentation?

Ensure you have all the information you need to keep all those in the supply chain informed of any issues.

Continue to check subsequent consignments or batches as you receive them to ensure ongoing compliance.

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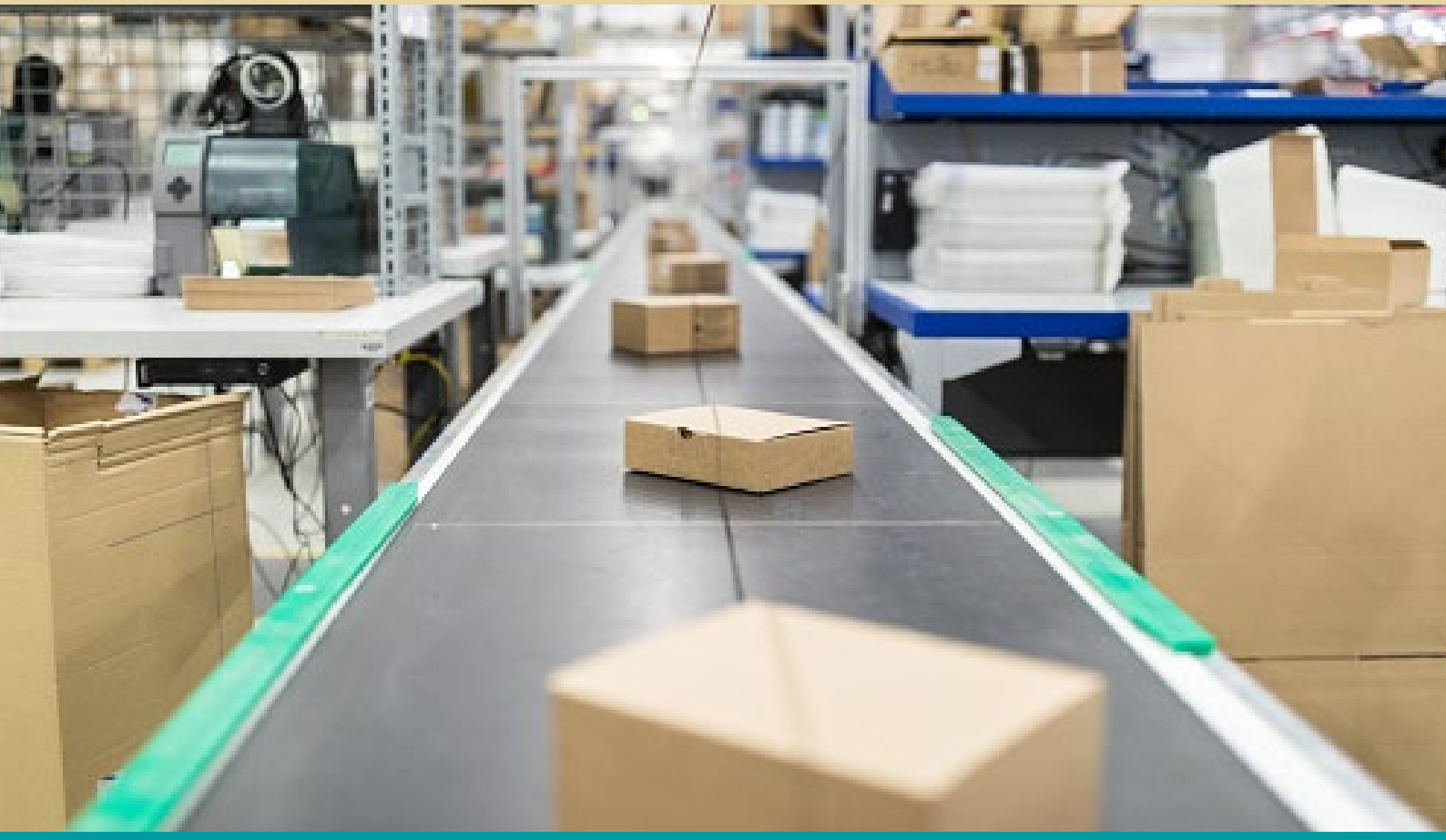
Advice for distributors (Including Retailers)



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What is a distributor?

In the context of PPE and many EU product safety regulations, a distributer is defined as 'any legal person in the supply chain, other than the manufacturer or the importer, who makes PPE available on the market.' Therefore this includes the activities of retailers.

Distributers make PPE available on the market, whereas manufacturers and importers place PPE on the market. 'Making available on the market' is defined as 'any supply of PPE for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.'

? What are my legal obligations as a distributor?

If you are a distributor or retailer you must check that the PPE products that you make available on the market are legally compliant by acting with due care.

There are COVID-19 easements in place and the following takes these into account:

Distributors must verify (or note where applicable) that the PPE:

- Is in conformity with the PPE Regulation (Regulation (EU) 2016/425), i.e. it still meets the EHSRs
- Need not have a CE Marking or completed Declaration of Conformity (thanks to the easements). If there is no CE mark on the product, be sure that this is because the product is subject to legitimate COVID-19 easements, rather than being omitted for any other reason.
- Do a visual inspection of the PPE, is it robust - will it fall apart with the slightest amount of effort? Does the PPE have sharp edges?
- For use in the NHS, it does not have to undergo conformity assessment procedures but can be imported without the CE Marking or Declaration of Conformity, providing it meets the EHSRs

- For use in other sectors (non NHS) it can be sold providing conformity assessment procedures have begun but not necessarily completed. In these circumstances, the products will not be CE marked or have a completed Declaration of Conformity.
- Is accompanied by instructions and safety information, in English
- That the manufacturer and importer have complied with all labelling requirements
- Must also ensure that whilst PPE is under their responsibility, storage or transport conditions do not threaten its condition
- If concerned about PPE that may not be in conformity with the Regulations then it should be withdrawn or recalled, as appropriate. Where it presents a risk, the enforcement authority* should be informed immediately and details provided, including about any corrective measures taken. The distributor/retailer should work with the enforcement authority, co-operating with its requests

**The UK enforcement authority is the Secretary of State who exercises these powers via the Office for Product Safety and Standards (OPSS, within the Department for Business, Energy and Industrial Strategy)*

How do I meet my distributor obligations?

Carrying out examinations, which are very similar to those undertaken by importers, of the products or obtaining product and packaging photos, and the applicable documentation will help you meet your obligations.

There are several straightforward checks that you can do:

- If there is no CE mark on the product, be sure that this is because the product is subject to legitimate COVID-19 easements, rather than being omitted for any other reason.

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28. 07. 2020

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Documentation checks

There are legal requirements for the creation of technical documentation under the Regulation.

- Undertaking a few easy checks can be as simple as looking for obvious errors, such as spelling mistakes, details covered over or left blank, incorrect information or product type and serial/batch number details not matching up.
- Confirm that the correct legislation and relevant standards are declared. PPE new to the market should comply to Regulation (EU) 2016/425, any reference to Directive 89/686/EEC (revoked previous PPE legislation) may indicate fake or non-compliant PPE, particularly if it is dated 2020.
- A completed Declaration of Conformity should be available for checking, outside of the easements.
- When fully available, a Declaration of Conformity will give you a good idea of whether the PPE has been made in conformity and is a genuine document. Utilise the British Safety Industry Federation's (BSIF) Certificate Checklist to assist in undertaking basic checks and what to look for. *https://www.bsif.co.uk/wp-content/uploads/2020/04/CE-Certificate-Checklist-2020.pdf*
- Another handy tool is the Technical Specification guide to the minimum requirements of PPE and medical devices produced by the HSE and MHRA. Although this document has been provided for Government procurement for NHS only, it is a good starting point to know what standards and key details are required. *https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe*

General checks

There are other more general checks you can do to gain confidence in who you are buying from, these additional checks can provide another layer of diligence in meeting your obligations.

Searching the internet can provide useful information, such as what your suppliers usual sector of business is; would they be familiar with the requirements and obligations of placing compliant PPE on the market? Are they a newly incorporated Limited company for example?

Check that the PPE you receive is the same as you were expecting and ensure you have all the information you need to keep all those in the supply chain informed of any issues. Lastly, consider any claims or inferences that are being made with the PPE, either on the product and packaging or in marketing material. Claims must be accurate and not mislead, check that there is supporting evidence to meet these claims.

Published:
13. 07. 2020

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Other applicable legal aspects to all economic operators

Testing services

All economic operators within the PPE supply chain should be mindful when obtaining conformity assessment or carrying out document checks that they are not misled by certain certificates that are being provided as evidence of PPE conformity.

It is important to note that these certificates, often headed as 'Certificate of Compliance' or 'Certificate of Conformity' and carry the CE Mark, are provided by companies offering certification and consultancy services. These services are not authorised by Member States and their services are not legal conformity assessments required by the regulations.

They may also be produced by notified bodies that are sometimes not authorised for PPE.

Further detail can be accessed via the ESF website which lists some of the best-known and frequently used certificate examples. *https://www.eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe*

? What happens if I do not meet the legal obligations?

Due diligence

A defence of 'due diligence' exists in consumer protection law. A person seeking to rely on this must prove that they took all reasonable precautions and exercised all due dilience to avoid an offence being committed.

The principles of this and the steps that may be taken, can be found in the Business Companion guide, entitled Product safety: due diligence

https://www.businesscompanion.info/en/quick-guides/product-safety/product-safety-due-diligence#Duediligenceprinciples

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What are Corrective Actions and when are they required?

Corrective Actions are required when either:

- As an economic operator (i.e. a manufacturer, importer or distributor), you have reason to believe,

or

- Another organisation in the supply chain or a Market Surveillance Authority notifies you,

that PPE you have placed or made available on the market is not in conformity with relevant legislation or poses a risk, then you must take immediate appropriate corrective action necessary to remove the PPE and risk from the market.

It is an offence for an economic operator to fail to take the appropriate action required or to provide information to or comply with, any of the requirements of the Market Surveillance Authority.

Corrections actions include but are not restricted to:

Withdrawal – which is 'any measure aimed at preventing a product in the supply chain from being made available on the market'

Recall - measures 'aimed at achieving the return of a product other than a safe product, that has already been supplied or made available to consumers'

Make sure that you have all the information you need to keep all businesses in the supply chain informed of any safety issues. This will help to meet your traceability obligations. Good practice would be (as a minimum) to follow the rule of 'one step forward and one step back' – in other words, that you hold details of the supplier who supplied you with the product or production materials and that you also hold details of those that you have supplied. This means product identification (batch/serial numbers, date of manufacture and supply, etc).

PAS 7100:2018 on product recalls

BSI has published 'Code of Practice on consumer product safety related recalls and other corrective actions (PAS 7100:2018)'. This is publicly available and it helps businesses plan to deal with any potential safety issue that might arise with products they have placed on the market or distributed. The document can be obtained here: *https://www.bsigroup.com/en-GB/pas7100-supporting-better-product-recalls/*

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COVID-19 related products and standards

During this period of COVID-19, recurring questions and issues have arisen as a result of the increased demand for PPE for COVID-19 purposes, particularly around applicable standards for face masks.

Face masks

The relevant standards to look for are:

PPE respirator face masks

- **BS EN 149:2001+A1:2009** – European harmonised standard – this standard brings in the 3 categories of masks – FFP1, FFP2 and FFP3. FFP 2 & FFP 3 have been recommended by the WHO and NHS as appropriate PPE for protection against COVID-19.

- **N95 & N99** – US standards equivalent to FFP2 & FFP3 respirator masks, respectively.

- **KN95 – GB 2626-2006** – Chinese standards and type, style of mask name. Chinese standard GB2626:2006 is different to the EU EN149 standard in that KN95 masks are not tested to a technical standard by a third party (e.g: Notified Body) whereas FFP2 and FFP3 masks are. KN95 is self-declaration by the manufacturer only. Masks quoting the KN95 standard should not be supplied as PPE in the UK.

The majority of KN95 masks are consumer use pollution masks which are not designed for protection against category 3 hazards such as COVID-19. The HSE has stated that KN95 masks must not be used as PPE at work, unless authorised by the HSE, as their effectiveness cannot be assured. *https://www.hse.gov.uk/safetybulletins/use-of-face-masks-designated-kn95.htm?utm_source=hse.gov.uk&utm_medium=refferal&utm_campaign=kn95-safety-alert&utm_content=home-page-new*

See also the face shield example included in the Manufacturer chapter of this guide.

Suggested further reading & useful tools

The Office of Product Safety & Standards (OPSS)

OPSS has a number of guidance documents on their COVID-19 web page. OPSS coronavirus (COVID-19) guidance for business and local authorities:

https://www.gov.uk/guidance/opss-coronavirus-covid-19-guidance-for-business-and-local-authorities

Including:

- Guide to the PPE Regulation
- High Volume Manufacturers Guide
- Small Scale Manufacturers Guide
- HSE/MHRA Technical Specifications guide: *https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe*

EC Recommendation 2020/403: EU Regulatory Easement

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0425

PPE Legislation - EU Regulation 2016/425

https://ec.europa.eu/newsroom/growth/item-detail.cfm?item_id=672953

Other applicable Business Companion Advice Guides

Business Protection from Misleading Marketing Regulations
https://www.businesscompanion.info/en/quick-guides/good-practice/business-to-business-marketing

Consumer Protection from Unfair Trading Regulations
https://www.businesscompanion.info/en/quick-guides/good-practice/consumer-protection-from-unfair-trading

General Product Safety Regulations - Producers (Manufacturers)
https://www.businesscompanion.info/en/quick-guides/product-safety/general-product-safety-producers

Product Safety - Due Diligence Guidance
https://www.businesscompanion.info/en/quick-guides/product-safety/product-safety-due-diligence

General Product Safety Regulations – Distributors
https://www.businesscompanion.info/en/quick-guides/product-safety/general-product-safety-distributors

Useful Tools

British Safety Industry Federation's (BSIF) Certificate Checklist
https://www.bsif.co.uk/wp-content/uploads/2020/04/CE-Certificate-Checklist-2020.pdf

European Safety Federation website page - Lists suspicious and fake certificates & DoC's
https://www.eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe

British Standards Institute - Applicable PPE for COVID-19 Standards
https://www.bsigroup.com/en-GB/topics/novel-coronavirus-covid-19/medical-devices-ppe/

Notified Bodies: The EC's list of NB's can be searched on the Nando website
https://ec.europa.eu/growth/tools-databases/nando/

HSE Bulletin on KN95 Masks
https://www.hse.gov.uk/safetybulletins/use-of-face-masks-designated-kn95.htm?utm_source=hse.gov.uk&utm_medium=refferal&utm_campaign=kn95-safety-alert&utm_content=home-page-news