

# businesscompanion

## trading standards law explained

### Introduction

In this section

Is this guide for you?  
What are medical devices?  
What is a 'face covering'?  
COVID-19 and regulatory easements  
Three categories of PPE  
The PPE regulations  
Interested in diversifying to produce PPE?  
Supply chain considerations

Last updated: 10 August 2020

### 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 for PPE are described later on 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.

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](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.

## 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 - Lowest level of risk PPE, rules allow manufacturers to self-declare conformity. Examples include sunglasses and washing up gloves
- Category 2 - 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
- Category 3 - 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.**

## 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.

## **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](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, distributors 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.

Q: Where do your activities sit within the PPE supply chain? (click on each one takes you to separate sections)

- Manufacturer
- Importer
- Distributer-Retailer

© 2020 Chartered Trading Standards Institute

**Source URL:** <https://www.businesscompanion.info/focus/ppe/introduction>