

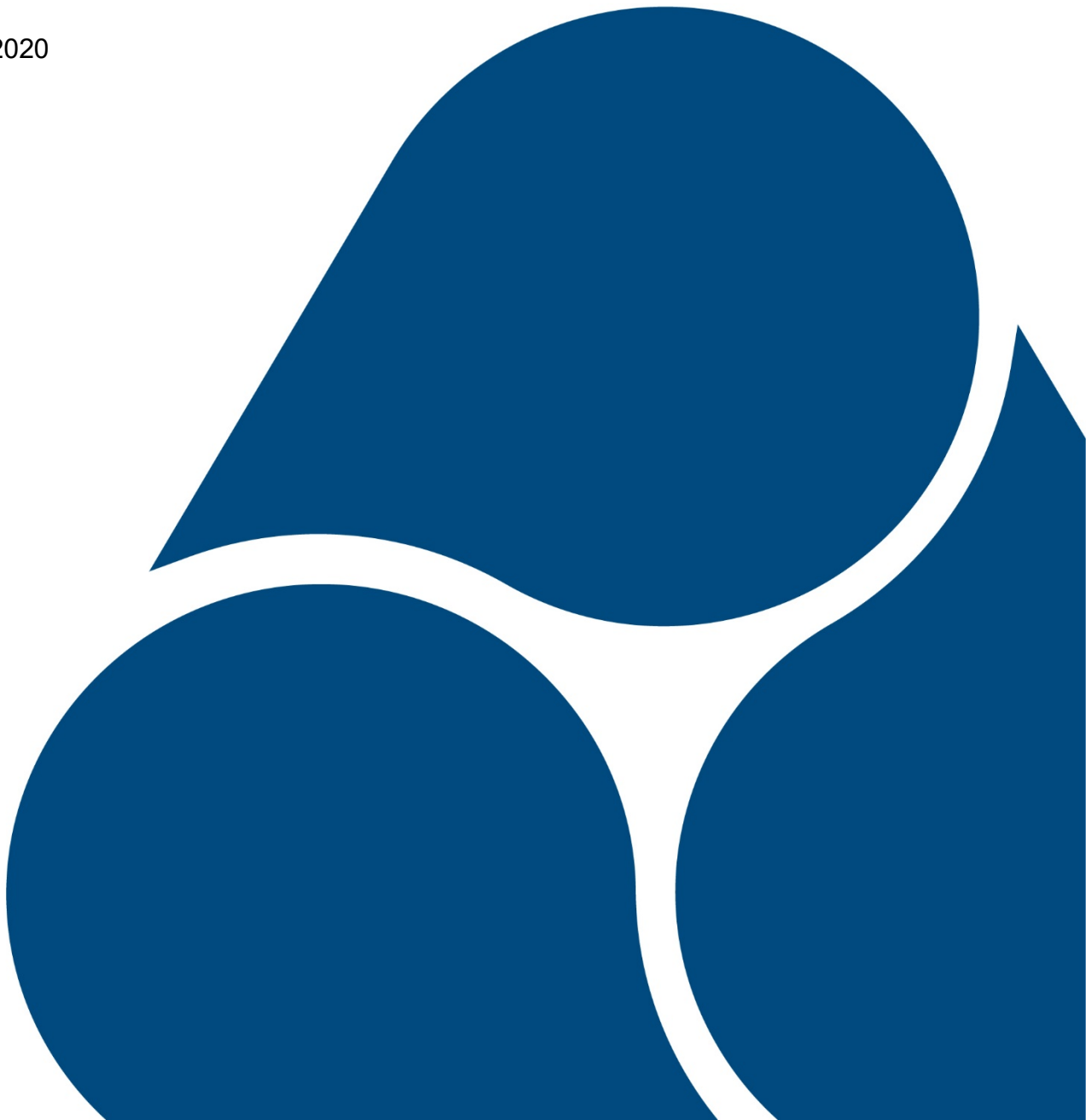


Office for Product
Safety & Standards

Personal Protective Equipment (PPE) Regulations

OPSS PPE Legislation Guidance for Businesses, Version 4

September 2020



Contents

1.	Introduction	3
2.	Legislative background	3
3.	Scope	3
4.	Requirements	4
5.	Obligations of manufacturers	5
6.	Obligations of authorised representatives	6
7.	Obligations of importers	6
8.	Obligations of distributors	8
9.	Notified Bodies	9
10.	Enforcement	11
11.	Where to find EU guidance about The EU Regulation on Personal Protective Equipment 2016/425	12
12.	Glossary	12

Personal Protective Equipment (PPE) Regulations

1. Introduction

EU Regulation 2016/425 ('the EU PPE Regulation') sets out the essential requirements which must be met before personal protective equipment ('PPE') products can be placed on the UK market. The purpose of the legislation is to ensure safe products are placed on the market by requiring manufacturers to show how their products meet the 'essential requirements'. The Personal Protective Equipment (Enforcement) Regulations 2018 ('the 2018 Regulations') provide a regime for the enforcement of the EU PPE Regulation. Although the UK left the European Union on 31 January 2020, these two pieces of legislation continue to apply to the UK during the Transition Period.

In light of the COVID-19 outbreak, the Government has taken steps to ease regulatory requirements for a limited time to speed up the supply of essential COVID-19 related PPE on to the UK market. These steps are in line with European Commission Recommendation 2020/403 dated 13 March 2020.

This guidance is designed to help you understand EU Regulation 2016/425, the Personal Protective Equipment (Enforcement) Regulations 2018 (collectively 'the PPE Regulations'), and the easements set out in Recommendation 2020/403.

If you are new to manufacturing or importing COVID-19 related PPE during the Spring 2020 COVID-19 outbreak, and you are able to sell or donate high volumes of PPE to the Government/ NHS, please read the [guidance for New high volume manufacturers of COVID-19 PPE](#).

2. Legislative background

EU Regulation 2016/425 applies to all PPE first placed on the market from 21 April 2018. The enforcement and sanctions regime was implemented into UK law by the Personal Protective Equipment (Enforcement) Regulations 2018 (SI 2018 No. 390).

Recommendation 2020/403 was published by the European Commission on 13 March 2020. While not a binding piece of legislation, the steps set out in it have been adopted by the UK Government for a limited time in the interests of ensuring the safety of UK healthcare workers by speeding up supply of essential COVID-19 PPE.

3. Scope

The PPE Regulations apply to PPE which is:

- a) equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety;
- b) interchangeable components for equipment referred to in point (a) which are essential for its protective function;
- c) connexion systems for equipment referred to in point (a) that are not held or worn by a person, 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.

The PPE Regulations do not apply to PPE:

- a) specifically designed for use by the armed forces or in the maintenance of law and order;
- b) designed to be used for self-defence, except for PPE intended for sporting activities;
- c) designed for private use to protect against:
 - atmospheric conditions that are not of an extreme nature,
 - damp and water during dishwashing;
- d) for exclusive use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable to the UK;
- e) for head, face or eye protection of users, that is covered by Regulation No 22 of the United Nations Economic Commission for Europe on uniform provisions concerning the approval of protective helmets and their visors for drivers and passengers of motorcycles and mopeds.

Some types of products that appear to be similar to PPE may actually be regulated as medical equipment if their main purpose is to protect others from the user (like a surgical face mask). A medical 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.

4. Requirements

The essential health and safety requirements (listed in Annex II of EU Regulation 2016/425) apply to all PPE within the scope of that Regulation.

Under article 19, all PPE within scope must undergo a conformity assessment procedure in accordance with its risk categorisation (specified in Annex I) to demonstrate compliance with the essential requirements.

Under the easements in Recommendation 2020/403, PPE specifically necessary for protection in the context of the COVID-19 outbreak must continue to meet the essential safety requirements. However, for a limited time, provided it meets the essential safety requirements and has been approved by the relevant UK Market Surveillance Authority, and provided conformity assessment procedures have been started via a Notified Body, PPE can be placed on the UK market, even if the conformity assessment, including affixing of CE marking procedures, has not been completed. PPE approved in this way cannot be placed on the EU market more generally.

For a limited time, where COVID-19 related PPE is being purchased by the Government/ NHS bodies for use by healthcare workers it does not need to be conformity assessed providing it has been manufactured either in line with a relevant European Standard, in accordance with a standard referenced in the WHO guidelines or to an alternative technical solution that delivers adequate safety. Products procured in this way must be approved by the Market Surveillance Authority

[Standards relevant to PPE for COVID-19](#) are available free from the British Standards Institution and there are also [WHO guidelines](#) on COVID-19.

Please note that any COVID-19 PPE approved without undertaking any conformity assessment can only be supplied as part of a Government procurement for use by healthcare workers during the current health crisis and may not be supplied to other parties or for any other uses.

5. Obligations of manufacturers

A manufacturer is a person who manufactures PPE, or has PPE designed or manufactured, and markets that PPE under their name or trademark.

The obligations of manufacturers of PPE include:

- a) Before placing PPE on the market, a manufacturer must ensure that it has been designed and manufactured in accordance with the applicable essential health and safety requirements. These are set out in Annex II to the Regulation.
- b) A manufacturer must also have had a relevant conformity assessment procedure carried out and technical documentation drawn up.
- c) Once this has been done a manufacturer must draw up a declaration of conformity, ensure that the declaration accompanies the product, and affix the CE marking to the PPE.

Under the easements in Recommendation 2020/403, paragraph 1 still applies – all PPE must be designed and manufactured in accordance with the essential health and safety requirements.

Paragraphs 2 and 3 need no longer be completed before PPE specifically necessary for protection in the context of the COVID-19 outbreak is placed on the UK market. However, a manufacturer must have contacted a Notified Body and begun conformity assessment procedures, and had the product approved by the relevant UK Market Surveillance Authority, before PPE specifically necessary for protection in context of COVID-19 outbreak can be placed on the market. Conformity assessment procedures must be completed as soon as possible unless the following paragraph applies.

Where PPE necessary for protection in the context of the COVID-19 outbreak is being manufactured for healthcare workers and being purchased by the Government/ NHS bodies, it can be purchased without conformity assessment. Such products may not be placed on the wider market.

- d) Manufacturers must keep the declaration of conformity¹ and the technical documentation for 10 years after the PPE has been placed on the market.
- e) Manufacturers must ensure that procedures are in place for series production to remain in conformity. Changes in the design or characteristics of the PPE and changes in the harmonised standards or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account.

¹ Manufacturers of PPE necessary for protection in the context of the COVID-19 outbreak, manufactured for healthcare workers and being purchased by the Government/ NHS will not have a Declaration of Conformity if the PPE has not been subject to conformity assessment procedures.

- f) When deemed appropriate with regard to the risks presented by PPE, manufacturers shall, to protect the health and safety of consumers and other end-users, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.
- g) The manufacturer must ensure that all PPE placed on the market bears a type and serial or batch number, or other element allowing its identification. The manufacturer should also include its name, registered trade name or registered trade mark 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.
- h) The manufacturer must ensure that PPE is accompanied by instructions and safety information as set out in point 1.4 of Annex II to the Regulation, which is clear, legible and in easily understandable English.

6. Obligations of authorised representatives

Manufacturers are able to appoint authorised representatives to perform certain tasks on their behalf under a written mandate.

The mandate shall at least allow the authorised representative to perform the following tasks:

- Keeping the declaration of conformity and the technical documentation at the disposal of the market surveillance authority in the UK for 10 years after the PPE has been placed on the EU market.
- Further to a reasoned request from the enforcement authority in the UK, providing that authority with all the information and documentation necessary to demonstrate the conformity of the PPE.
- Cooperating with the enforcement authority in the UK, at its request, on any action taken to eliminate the risks posed by PPE covered by the authorised representative's mandate.

An authorised representative must comply with all the duties imposed on the manufacturer under the EU PPE Regulation that they are appointed for and mandated by the manufacturer to perform. A manufacturer remains responsible for the proper performance of any obligations the authorised representative performs on their behalf.

As far as those duties are concerned as well as penalties for failure to comply with those duties any references in the PPE Regulations to the manufacturer are to be taken as a reference to the authorised representative.

7. Obligations of importers

An importer is a person or business based in the UK who places a product on the UK market from a country outside the EEA.

The obligations of importers include the following:

- a) Before placing PPE on the market, an importer must ensure that the appropriate conformity assessment procedures referred to in article 19 have been carried out by the manufacturer. They must ensure that the manufacturer has drawn up technical documentation; the PPE bears the CE marking; and is accompanied by the declaration of conformity and required documents and identification marks.

For a limited period, in certain circumstances, new COVID-19 PPE need not have a CE marking, in line with EU Recommendation 2020/403:

COVID-19 related PPE being purchased by the Government/ NHS for use by health workers 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 essential health and safety requirements, and has been approved by the relevant UK Market Surveillance Authority

Other COVID-19 related PPE can be imported and sold on the UK Market, provided conformity assessment procedures have begun, and the product has been approved by the relevant Market Surveillance Authority. In these circumstances, they will not be CE marked and will only have a partially completed Declaration of Conformity. Full conformity assessment should be completed as soon as possible.

While the easements are in place, importers will need to have documentary proof either that:

1. A manufacturer wishing to supply COVID-19 PPE to the general UK market has applied to a Notified Body for conformity assessment, has had their application accepted, has had their PPE assessed as meeting the essential health and safety requirements, and has had their product approved by the relevant UK Market Surveillance Authority, even though the formal conformity assessment procedures have not been completed. Such PPE can only be placed on the UK Market, not on the EU market.

or

2. Where a manufacturer has contracted to supply the Government with COVID-19 PPE for purchase by the NHS, 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 as meeting the essential health and safety requirements. PPE supplied through this process cannot be made available to the general UK or EU markets.

- b) When deemed appropriate, regarding risk presented by an item of PPE, the importer must carry out sample testing, investigate and, if necessary, keep a register of complaints, of non-conforming PPE and recalls of such PPE, and keep distributors informed of any such monitoring.
- c) Importers must indicate on the PPE their name, registered trade name or registered trademark and postal address. This obligation does not apply where the importer has set out such information on the packaging of the PPE.
- d) The importer must ensure that PPE is accompanied by instructions and safety information as set out in point 1.4 of Annex II to the EU PPE Regulation ensure that they are clear, legible and in easily understandable English.
- e) The importer must keep a copy of the declaration of conformity² for a period of 10 years after the PPE has been placed on the market at the disposal of the market surveillance authority and ensure that the technical documentation can be made available to that authority, upon request.

² See footnote 1.

- f) The importer must ensure that PPE under their responsibility are safely stored and transported in such a way that does not jeopardise conformity with the essential health and safety requirements.
- g) Importers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with the EU PPE Regulation must immediately take the corrective measures necessary to bring the PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, importers shall immediately inform the enforcement authority in the UK to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.
- h) Importers must, further to a reasoned request from the enforcement authority in the UK, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of PPE in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

8. Obligations of distributors

A distributor is any person, other than the manufacturer or importer, who makes PPE available on the market.

The obligations of distributors include the following:

- a) Before making PPE available on the market, a distributor must act with due care to ensure that it is in conformity with the EU PPE Regulation, which means the PPE must be in conformity with the essential health and safety requirements.
- b) Before making PPE available on the market, a distributor must ensure that it bears the CE marking; is accompanied by instructions and information as set out in point 1.4 of Annex II to the Regulation and ensure and that they are clear, legible and in easily understandable English; and that the manufacturer and importer have complied with the marking requirements as to required labelling.

For a limited period, in certain circumstances, new COVID-19 PPE need not have a CE marking or a Declaration of Conformity, as in line with EU Recommendation 2020/403:

COVID-19 related PPE being purchased by the Government/ NHS for use by health workers 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 essential health and safety requirements, and has been approved by the relevant UK Market Surveillance Authority. It cannot be distributed, however, outside the NHS on to the general UK market.

Other COVID-19 related PPE can be imported and sold on the UK Market, provided conformity assessment procedures have begun, and the product has been approved by the relevant Market Surveillance Authority. In these circumstances, they will not be CE marked and will only have a partially completed Declaration of Conformity. It cannot be distributed outside the UK on to the EU market.

- c) The distributor must ensure that PPE under their responsibility is safely stored and transported in such a way that does not jeopardise its conformity with the essential health and safety requirements.
- d) Distributors who consider or have reason to believe that PPE which they have placed on the market is not in conformity with the EU PPE Regulation must immediately take the corrective measures necessary to bring the PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, importers shall immediately inform the enforcement authority in the UK to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.
- e) Distributors must, further to a reasoned request from the enforcement authority in the UK, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of PPE in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

9. Notified Bodies

Notified Bodies are independent organisations appointed by EU Member State governments and notified to the European Commission to carry out the procedures for conformity assessment and certification set out in the Regulations.

The contact details of the UK Notified Bodies appointed under the Regulations are set out in the table below:

<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>	Notified Body number: 0086
<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>	Notified Body number: 1105
<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>	Notified Body number: 0194

<p>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: marc.gaten@intertek.com / tina.ball@intertek.com Website: www.intertek.com</p>	Notified Body number: 0362
<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>	Notified Body number: 0321
<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>	Notified Body number: 0120
<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>	Notified Body number: 0338
<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>	Notified Body number: 0518
<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>	Notified Body number: 0843

A [full list of EU Notified Bodies](#) can be found on the NANDO website. Economic operators are free to select any suitable Notified Body from any Member State including the UK during the Transition Period.

10. Enforcement

As set out in the Enforcement Regulations (Personal Protective Equipment (Enforcement) Regulations 2018 (SI 2018 No. 390)), for PPE intended for workplace use, or for use otherwise than at work in non-domestic premises made available to persons at a place where they may use the PPE provided for their own use there, the [Health and Safety Executive \(HSE\)](#) acts as the Market Surveillance Authority and has a duty to enforce the Regulations in Great Britain. In Northern Ireland enforcement is the responsibility of the [Health and Safety Executive for Northern Ireland \(HSENI\)](#).

In Great Britain Local Authority trading standards, and in Northern Ireland District Councils, are responsible for enforcing the PPE Regulations in relation to PPE retained for private use or consumption (other than in circumstances subject to the remit of HSE/HSENI).

Where PPE is intended to be used exclusively or primarily on relevant nuclear sites as defined in Regulation 3(4) of the 2018 Regulations, the [Office for Nuclear Regulation](#) is responsible for enforcing the PPE Regulations.

The Enforcement Regulations give powers to enforcement authorities to take action against economic operators for PPE that are not in conformity with the EU PPE Regulation. There are requirements on manufacturers, distributors and importers to co-operate with the enforcement authority as appropriate on request.

The 2018 Regulations also give the Secretary of State powers to enforce the EU PPE Regulation and RAMS (Regulation (EC) 765/2008), in so far as they set out requirements for market surveillance of products.

UK market surveillance authorities will take all appropriate measures to withdraw from the market or to prohibit and restrict the supply of products which may endanger the health and safety of persons, property or the environment.

Regulators' Code

Market surveillance authorities (HSE, HSENI, ONR and Local Authority Trading Standards) must continue to have regard to the Regulators' Code when developing the policies and operational procedures that guide their regulatory activities in this area. They should carry out their activities in a way that supports those they regulate to comply and grow, including choosing proportionate approaches that reflect risk.

In responding to non-compliance that they identify, regulators should clearly explain what the non-compliant item or activity is, the advice being given, actions required, or decisions taken, and the reasons for these. Unless immediate action is needed to prevent a serious breach, regulators should provide an opportunity for dialogue in relation to the advice, requirements or decisions, with a view to ensuring that they are acting in a way that is proportionate and consistent. The Secretary of State takes account of the provisions of both the Regulators' Code and the Growth Duty in exercising his regulatory functions.

A link to the Regulators' Code can be found here:

<https://www.gov.uk/government/publications/regulators-code>

Penalties

A person committing an offence under the 2018 Regulations may be liable to a penalty. Penalties can include a fine or a prison sentence of up to three months for the most serious offences. It is matter for the enforcement authority to decide whether prosecution is appropriate in each case taking into account the circumstances of the case and the enforcement authority's own policies, operational procedures and practices in line with the Regulators' Code. Should a prosecution take place, it is at the discretion of the court to decide the penalties imposed on the offender.

11. Where to find EU guidance about The EU Regulation on Personal Protective Equipment 2016/425

EU Regulation 2016/425 is directly applicable in UK law. You can find further and more detailed guidance on it here:

https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment_en

The European Commission's 'Blue Guide' aims to give a better understanding of EU product safety rules and to their application across different sectors and throughout the EU single market. You can view that here:

<http://ec.europa.eu/DocsRoom/documents/18027/>

12. Glossary

- **Authorised Representative** – A person appointed in writing by a manufacturer to perform specific tasks for the manufacturer. Manufacturers remain ultimately responsible for ensuring these tasks are carried out properly.
- **CE Marking** – the conformity mark used in Member States of the European Union, and by the UK during the Transition Period.
- **Declaration of conformity** – A document prepared by the manufacturer which must detail, among other things:
 - the specific product to which the declaration is referring; and
 - the name and address of the manufacturer and, where applicable, their authorised representative.

This must be kept by the manufacturer for a period of ten years from the date on which the product was placed on the market. This declaration must be made available to the enforcing authority upon request.

- **Distributor** – Any person in the UK supply chain, other than the manufacturer or the importer, who makes PPE available on the UK market.
- **Enforcing Authority** – In Great Britain, for products in use in the workplace, this is the Health and Safety Executive. For PPE for consumer use this is local Trading Standards authorities. In Northern Ireland, for PPE in use in the workplace, this is the Health and Safety Executive Northern Ireland. For PPE for consumer use this is district councils.
- **Importer** – Until the end of the Transition Period an importer is a person established in the EEA who places PPE from a country outside of the EEA on the market.

- **Manufacturer** – A person who manufactures PPE or has PPE designed or manufactured and markets that PPE under their name or trademark.
- **Surveillance Body** – an enforcement authority designated as having a duty to enforce the regulation and to conduct surveillance of products placed on the market to ensure their compliance
- **Notified Body** – A conformity assessment body which has been approved by the Member States Authority and notified to the European Commission as competent to perform conformity assessment procedures required in the EU PPE Regulation.

© Crown copyright 2020

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated.

To view this licence, visit www.nationalarchives.gov.uk/doc/open-governmentlicence/version/3/ or write to the Information Policy Team, The National Archives, Kew, London TW9 4DU, or email: psi@nationalarchives.gsi.gov.uk. Where we have identified any third-party copyright information you will need to obtain permission from the copyright holders concerned.

This publication is available at <https://www.gov.uk/guidance/opss-coronavirus-covid-19-guidance-for-business-and-local-authorities>

Contact us if you have any enquiries about this publication, including requests for alternative formats, at: OPSS.enquiries@beis.gov.uk

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>