



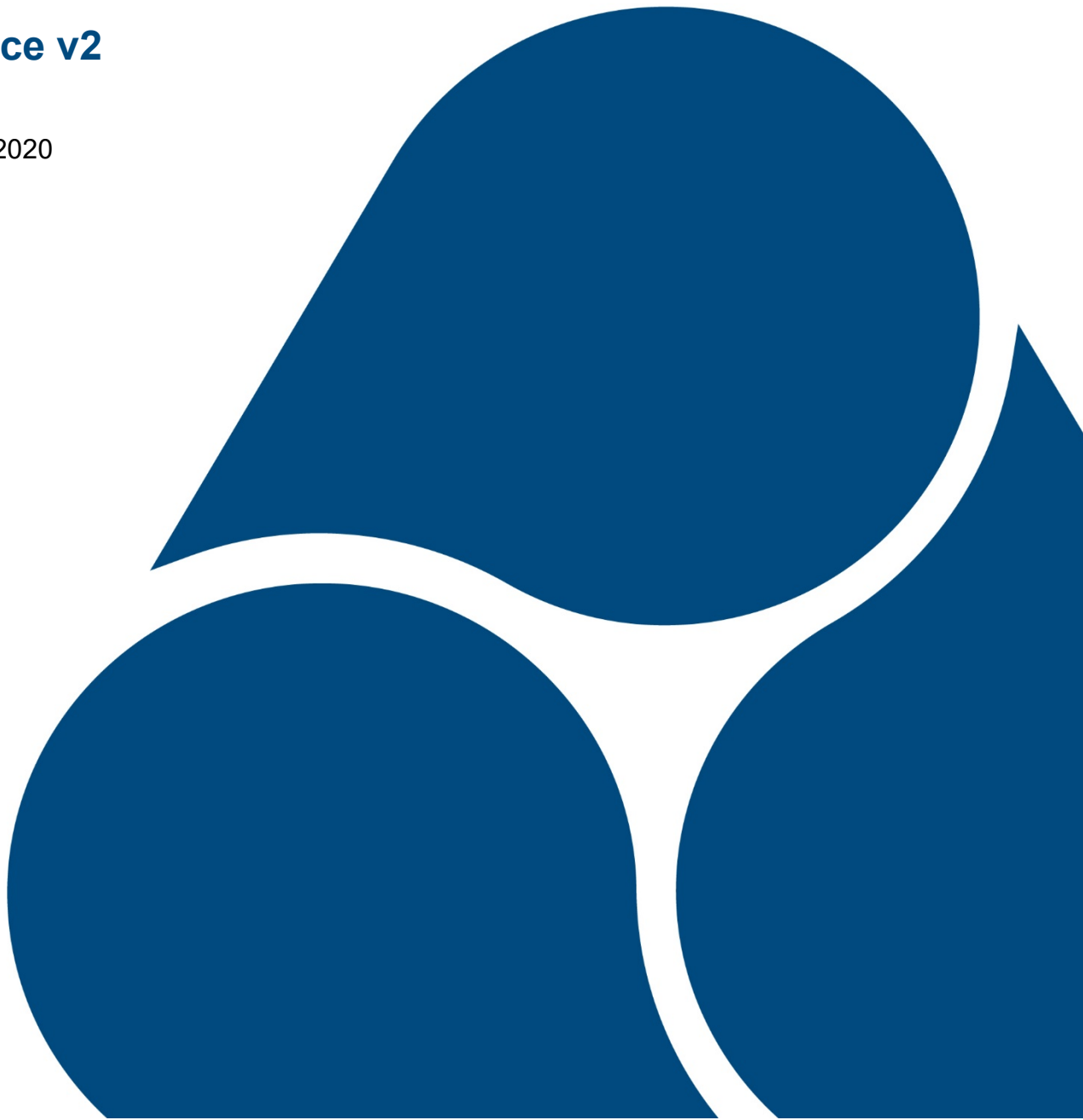
Office for Product
Safety & Standards

Regulation 2016/425 and the Personal Protective Equipment (Enforcement) Regulations 2018

As they apply to equipment being supplied in or into Great
Britain from 1 January 2021

Guidance v2

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Guidance

1. Introduction

This Guide is for businesses placing personal protective equipment (PPE) on the market in Great Britain from 1 January 2021¹. If you are placing PPE on the market in Northern Ireland, you should read separate guidance:

<https://www.gov.uk/guidance/product-safety-and-metrology-from-1-january-2021-northern-ireland>

Regulation (EU) 2016/425 (as incorporated into UK law) sets out the essential health and safety requirements that must be met before PPE products can be placed on the GB market. The purpose of the legislation is to ensure safe and effective products are placed on the GB market by requiring manufacturers to show how their products meet the ‘essential health and safety requirements’. The Personal Protective Equipment (Enforcement) Regulations 2018 provide a system for the enforcement of the 2016 Regulation.

This guidance is designed to help you understand Regulation 2016/425 and the Personal Protective Equipment (Enforcement) Regulations 2018, (collectively the “Amended PPE Regulations”, and individually the “2016 Regulation” and the “2018 Regulations” respectively), as applicable in Great Britain from 1 January 2021 and as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019.

Temporary disapplication in England, Wales and Northern Ireland of the obligations of economic operators to ensure full conformity assessment

As part of its response to the COVID-19 outbreak, the Government took steps in March 2020 to temporarily ease regulatory requirements to speed up the supply of essential COVID-19 related PPE on to the UK market, in line with European Commission Recommendation 2020/403 dated 13 March 2020. This Recommendation does not form part of our domestic law in GB at the end of the Transition Period and steps have been taken to extend the availability of these regulatory arrangements for a limited period after the end of the Transition Period.

England

From 1 January 2021, temporary arrangements apply in England, governed by the Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (England) Regulations 2020 (“the 2020 PPE Regulations”).

The 2020 PPE Regulations disapply the requirement for economic operators based in England to complete full conformity assessment and conformity marking of COVID-19 related PPE, before placing it on the GB market, provided the Health and Safety Executive (HSE) has assessed the PPE as meeting the essential safety requirements. The HSE assessment is only available for a limited time period.

The 2020 PPE Regulations also disapply the requirement for economic operators based in England to undergo conformity assessment and conformity marking of COVID-19 related PPE intended for use by **healthcare and other frontline workers**. Healthcare

¹ The Implementation or Transition Period officially ends at 11pm on 31 December 2020; therefore references to 1 January 2021 should be read as meaning 11pm on 31st December 2020.

workers are individuals working in the health service continued under section 1(1) of the National Health Service Act 2006 including hospital and clinical services, GPs, pharmacists, dentists, orthodontists and optometrists. Other frontline services means social care and community or residential drug and alcohol services. Such PPE can be offered for sale or donation via NHS competitive tendering processes and put into use by the NHS, provided HSE has assessed and certified it as meeting the essential safety requirements. The HSE assessment is only available for a limited time period.

On **31 March 2021** HSE will cease assessment of COVID-19 related PPE intended for the general GB market. After this date, all PPE (including COVID-19 related PPE) intended for the general GB market for use in the workplace, must undergo full conformity assessment.

On **30 June 2021**, HSE will cease assessing COVID-19 related PPE, procured by the Government or NHS bodies. While existing stocks purchased by the NHS can continue to be used, all PPE procured after that date for use by healthcare workers must be fully conformity assessed and conformity marked.

Wales

The same arrangements will apply in Wales from 1 January 2021, under the provisions of the Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Wales) Regulations 2020. This means economic operators based in Wales can place COVID-19 related PPE on the GB market before full conformity assessment is complete where the HSE has completed its assessment on or before 31 March 2020, and supply COVID-19 related PPE to NHS Wales where the HSE has completed its assessment on or before 30 June 2020.

Northern Ireland

In Northern Ireland, the Northern Ireland Protocol means that Recommendation 2020/403 will continue to apply there directly, until the Recommendation is withdrawn or either the UK Government, or the people of Northern Ireland (by voting to end the Protocol arrangements), decide to end its application in NI. This means economic operators based in Northern Ireland can continue to place PPE on the NI market, provided it meets essential safety requirements and has been approved by HSE/HSENI, before full conformity assessment is complete, and may be procured by NHS NI with HSE/HSENI approval.

Scotland

The powers used to make the 2020 PPE Regulations are devolved. Accordingly, the government has legislated for England, and the Welsh Government for Wales. The Scotland Government is considering if it wishes to mirror these provisions. Until it does so, this means that economic operators based in Scotland must comply fully with their obligations under Regulation 2016/425 in order to place PPE on the GB or EEA markets, or supplying NHS Scotland, once full conformity assessment and conformity marking is complete.

This is in response to a specific set of circumstances and the end dates will be kept under review.

If you are new to manufacturing or importing COVID-19 related PPE during the 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 which can be found here:

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

2. Legislative Background

EU Regulation 2016/425 was directly applicable in the UK from 21 April 2018. The enforcement and sanctions system was implemented into UK law by the Personal Protective Equipment (Enforcement) Regulations 2018 (SI 2018 No. 390). The EU Withdrawal Act 2018 preserves these regulations and enables them to be amended so as to continue to function effectively now that the UK has left the EU. Accordingly, the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019² fix any deficiencies that arose from the UK leaving the EU (such as references to EU institutions) and make specific provision for the GB market.

There is therefore one set of Amended PPE Regulations, but some of the provisions apply differently in GB and in NI (for as long as the Northern Ireland Protocol is in force). References to the Amended PPE Regulations in this guidance are references to those Regulations as they apply in Great Britain. For guidance on placing on the Northern Ireland market, please see:

<https://www.gov.uk/guidance/product-safety-and-metrology-from-1-january-2021-northern-ireland>.

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 were adopted by the UK Government as a temporary measure in the interests of ensuring the safety of UK healthcare workers by speeding up supply of essential COVID-19 PPE. The arrangements in the Recommendation have been replaced from 1 January 2021 in England by similar arrangements set out in the 2020 PPE Regulations, and in Wales in The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Wales) Regulations 2020. The Recommendation continues to apply in NI, and falls away in Scotland unless mirrored in Scottish Government legislation from the 1 January 2021.

3. Scope

The Amended PPE Regulations apply to PPE which is:

- 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;

² The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 were amended by the Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 to apply to Great Britain only, and not to Northern Ireland, in support of implementing The Protocol of Ireland and Northern Ireland ("The Northern Ireland Protocol"). The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 were further amended by the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (subject to Parliamentary approval) to provide for a 24 month transition period for importer labelling (for goods from the EEA), and transitional arrangements for the UKCA marking, to amend the definition of "authorised representative" as well as introducing an end (in 12 months from the end of the Transition Period) to the recognition of goods meeting EU requirements, as well as introducing provisions for qualifying Northern Ireland goods.

- interchangeable components for equipment referred to in point (a) which are essential for its protective function;
- 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 Amended PPE Regulations do not apply to PPE:

- specifically designed for use by the armed forces or in the maintenance of law and order;
- designed to be used for self-defence, except for PPE intended for sporting activities;
- designed for private use to protect against:
 - a. atmospheric conditions that are not of an extreme nature,
 - b. damp and water during dishwashing;
- for exclusive use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable to the UK;
- 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.

4. Requirements

The essential health and safety requirements (listed in Annex II) apply to PPE within the scope of the 2016 Regulation as amended as appropriate. 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.

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

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:

1. Before placing PPE on the GB 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 2016 Regulation.
2. A manufacturer must also have had a relevant conformity assessment procedure carried out and technical documentation drawn up.

3. Once this has been done, a manufacturer must draw up a declaration of conformity; ensure that the declaration accompanies the product (or information as to where it can be accessed); and affix the UKCA marking³ visibly, legibly and indelibly to the PPE. Where it is not possible or warranted, on account of the nature of the PPE, to affix the UKCA marking to the PPE, it must be affixed to the packaging and the accompanying documents. In any event, until 31 December 2022, the UKCA marking may be affixed to a label affixed to, or a document accompanying, the PPE.
4. Qualifying Northern Ireland goods can be placed on the GB market with the CE and CE UKNI conformity markings, see further detail in Section 11 on Qualifying Northern Ireland Goods.

Paragraph 1 of section 5 of this guide applies to all PPE manufacturers based in the UK – all PPE must be designed and manufactured in accordance with the essential health and safety requirements.

For a limited period, in certain circumstances, new COVID-19 PPE may benefit from temporary arrangements relating to conformity assessment procedures and CE/UKCA marking:

From 1 January until 31 March 2021, the HSE may notify economic operators in England under the 2020 PPE Regulations that PPE may be placed on the market before the conformity assessment procedures have been completed. Similarly the arrangements under the Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Wales) Regulations 2020 are available to economic operators based in Wales, in relation to placing COVID-19 related PPE on the GB market.

In **England and Wales**, until 31 March 2021, under the arrangements set out in the 2020 PPE Regulations and the Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Wales) Regulations 2020 respectively, paragraphs 2 and 3 need not be completed by economic operators based in England, before PPE specifically necessary for protection in the context of the COVID-19 outbreak is placed on the GB market. However, a manufacturer must have contacted a UK Approved Body and begun conformity assessment procedures, and had the product approved by the HSE. Conformity assessment procedures, including conformity marking (see section 10) 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 provided for use by **healthcare and other frontline workers** and being purchased by the Government/NHS bodies, it can be supplied to those workers in England and in Wales so long as it has been assessed by the HSE. Such products may not be supplied to healthcare workers in Scotland. From 30 June 2021, HSE assessment of such PPE will end, and any PPE that has not yet been assessed must complete full conformity assessment (including conformity marking) before it can be purchased for use by healthcare or other frontline workers.

PPE manufacturers based in **Scotland** must comply fully with the Amended PPE Regulations before placing PPE on the GB or EEA markets. Only PPE that complies

³ Until 31 December 2021, PPE conforming to EU rules, including the CE marking, may be placed on the market of Great Britain – see below; qualifying Northern Ireland goods complying with NI rules, including the CE marking, may also be placed on the GB market – see below.

fully with the Amended PPE Regulations must be supplied to healthcare workers in Scotland.

The arrangements under Recommendation 2020/403 continue to apply to PPE being placed on the **Northern Ireland** market or being supplied to NHS NI.

5. Manufacturers must keep the declaration of conformity and the technical documentation for 10 years after the PPE has been placed on the GB market.
6. 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 designated standards or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account.
7. 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 GB 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.
8. The manufacturer must ensure that all PPE placed on the GB 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 trademark and postal address on the product. Where the size or nature of the PPE does not allow this then it may be provided on the packaging or accompanying documentation.
9. 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.

Manufacturers based in Northern Ireland can follow the legislation as it applies to Northern Ireland and place qualifying Northern Ireland goods on the GB market without any additional approvals. See further detail in Section 11 on Qualifying Northern Ireland Goods.

6. Obligations of authorised representatives

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

Mandated authorised representatives for the GB market can be based in GB or Northern Ireland, but after 1 January 2021 cannot be based outside the UK. A manufacturer can only mandate an authorised representative established in the UK, under the Regulations as they apply in GB.

No GB-based authorised representatives are recognised under EU law. This means GB-based authorised representatives cannot carry out tasks on the manufacturer's behalf for PPE being placed on the Northern Ireland and EEA markets. Therefore, a GB manufacturer selling PPE to the EEA or into Northern Ireland, who wishes to appoint an authorised representative to carry out tasks for them in respect of that PPE, must appoint an authorised representative based in Northern Ireland or the EEA.

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 GB 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 2016 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 and an authorised representative is under a duty to perform those tasks, and any failure to do so may make the authorised representatives liable to penalties.

7. Obligations of importers

An importer is a person or business based in the UK who places PPE on the GB market from a country outside the UK. This means that UK businesses which used to act as a 'distributor' before the end of the transition period legally become an 'importer' if they place products from an EEA country on the GB market.

This includes PPE that are supplied to NI businesses from the EEA and then placed on the GB market. In this instance the NI business will take on importer obligations for EEA-supplied goods that are placed on the GB market (see also Section 11 on Qualifying Northern Ireland Goods).

Importers have additional legal obligations which go beyond those of distributors, such as checking that manufacturers have carried out the required conformity assessment procedures and including their (the importer's) name, registered trade name or mark and a postal address on the equipment or, where this is not possible, on its packaging or in accompanying documentation.

To assist with the transition, the UK is applying a transitional period ending on 31 December 2022 to allow UK suppliers of PPE into the GB market from the EEA or Switzerland (who from 1 January 2021 are importers for the purposes of the law in GB) to provide their details on the accompanying documentation as an alternative to placing them on the equipment itself. This applies to goods that are not qualifying Northern Ireland goods. For further detail on qualifying Northern Ireland goods, please see Section 11 on Qualifying Northern Ireland Goods.

Can you be contacted easily if there is a problem?

A key principle underpinning product safety, for the benefit of consumers and regulators, is traceability of a product back to its source.

In recognition that under the new regulatory regime you may have the new status of an importer when placing goods from an EEA state on the GB market for the first time, you

may provide your contact details in a document that accompanies the product. This will be allowed until 31 December 2022.

We understand that there may be a period of adjustment to the new arrangements for importer documentation for the GB market, and it may be difficult to provide your details on documentation accompanying each and every individual product.

You may therefore use an alternative method where, for example, your contact information is on a document accompanying a batch of products. This document would then follow each batch of products through the distribution chain. Your contact details must follow each product through the distribution chain, but not necessarily by one document per product. Ultimately, the end user, each distributor (and a regulator) must be able to access the information.

Methods which enable traceability of the product after the initial batch has been broken up could include:

- The importer address is present in shipping documents.
- The importer address is present on the invoice to the GB customer.
- The importer address is present on the label that is on the outer packaging (“shipper”) in which a number of finished goods is packed (normally customers will receive shippers unless the order is very small so that the shipper has to be opened and split).
- The importer address is included on the EU Declaration of Conformity and/or UK Declaration of Conformity (whichever is relevant for the product in question).

You should work with your distributors to ensure physical documentation does accompany batches of product as far as possible, and in all cases that there are measures in place to ensure end users are able to identify the UK importer.

Alongside that, but not as an alternative, you can use your company website to provide more information, access to product details and contact points for retailers, consumers and enforcement bodies.

These options are for a time limited period only and may not be used after 31 December 2022. You are encouraged to put in place measures to ensure that individual items do carry the importer’s address where required ahead of this date.

The EU does not have any such transitional provision. In the absence of this, PPE being sold from GB to NI or the EU must be labelled with the NI or EU-based importer’s address. For further detail about placing on the NI market please see:

<https://www.gov.uk/guidance/product-safety-and-metrology-from-1-january-2021-northern-ireland>

The obligations of importers include the following:

1. Before placing PPE on the GB market, an importer must ensure that the appropriate conformity assessment procedures referred to in Article 19 have been carried out by the manufacturer. This means that the PPE must comply with the essential health and safety requirements set out in Annex II of the 2016 Regulation. They must ensure that the manufacturer has drawn up technical documentation; the PPE bears

the UKCA marking⁴ and is accompanied by the declaration of conformity and required documents and identification marks. Until 31 December 2022, the UKCA marking may be affixed to a label affixed to, or a document accompanying, the PPE.

For a limited period, in certain circumstances, new COVID-19 PPE may benefit from temporary arrangements relating to conformity assessment procedures and CE/UKCA marking:

COVID-19 related PPE being purchased by the Government/ NHS bodies for use by healthcare workers in England and in Wales does not have to undergo conformity assessment procedures and can be imported or otherwise supplied without the CE or UKCA marking or Declaration of Conformity and purchased, provided it meets the essential health and safety requirements, and has been approved by HSE. This arrangement does not apply to COVID-19 related PPE being supplied under Government/NHS body purchase for healthcare workers in Scotland. The HSE approval process for this PPE will come to an end in England and in Wales on 30 June 2021.

Other COVID-19 related PPE can be imported and sold on the GB market, provided conformity assessment procedures have begun, and the product has been approved by HSE. In these circumstances, they will not be CE or UKCA or CE UKNI marked and will only have a partially completed Declaration of Conformity. Full conformity assessment should be completed as soon as possible. This arrangement does not apply to COVID-19 related PPE being placed on the market by economic operators based in Scotland. The HSE approval process for this PPE will come to an end in England and in Wales on 31 March 2021.

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

1. A manufacturer wishing to supply COVID-19 PPE to the general GB or NI markets has applied to an approved 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 HSE, even though the formal conformity assessment procedures have not been completed. Such PPE can only be placed on the GB market, but not on the EEA market, albeit that it has not yet been marked with the UKCA or both the CE and UK(NI) markings. The HSE approval process for this PPE will come to an end on 31 March 2021, after which all PPE placed on the GB market will no longer be approved for placing on the market without the conformity assessment procedure being completed and must comply fully with the Amended PPE Regulations, and be UKCA (or until 31 December 2021, CE) marked.

Or

2. Where a manufacturer has contracted to supply the Government with COVID-19 PPE for purchase by or on behalf of NHS England or NHS Wales only, 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 assessed by HSE

⁴ Until 31 December 2021, PPE conforming to EU rules, including the CE marking, may be placed on the market of Great Britain – see below; qualifying Northern Ireland goods complying with NI rules, including the CE marking, may also be placed on the GB market – see below.

as meeting the essential health and safety requirements. The HSE approval process for this PPE will come to an end on the 30th June, after which all PPE supplied to the NHS in England and in Wales will no longer be approved for procurement without the conformity assessment procedures being completed and must comply fully with the Amended PPE Regulations and be UKCA (or until 31 December 2021, CE) marked.

PPE supplied through this process is only for the use of healthcare and other frontline workers and cannot be made available to the general GB, NI or EEA markets.

2. 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.
3. 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 and either: (i) it is not possible to indicate that information on the PPE; or (ii) the importer has imported the PPE from an EEA state or Switzerland and places it on the GB market before 1 January 2022.
4. 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 2016 Regulation ensure that they are clear, legible and in easily understandable English.
5. The importer must keep a copy of the declaration of conformity and technical documentation for a period of 10 years after the PPE has been placed on the GB market at the disposal of the market surveillance authority and ensure that the technical documentation can be made available to that authority, upon request.
6. The importer must ensure that PPE under their responsibility is safely stored and transported in such a way that does not jeopardise conformity with the essential health and safety requirements.
7. Importers who consider or have reason to believe that PPE which they have placed on the GB market is not in conformity with the 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 GB to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.
8. 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 GB market.

Qualifying Northern Ireland goods complying with the legislation as it applies in Northern Ireland, including affixing the CE marking, may also be placed on the GB market. See further detail in Section 11 on Qualifying Northern Ireland Goods.

8. Obligations of distributors

UK businesses which were distributors of PPE within the EU single market should now consider whether they are importers from the EU single market and therefore what additional requirements they may face – see section 7 above. The same applies to distributors of goods from the EEA and Switzerland.

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

The obligations of distributors include the following:

1. Before making PPE available on the GB market, a distributor must act with due care to ensure that it is in conformity with the PPE Regulation, which includes ensuring that the PPE must be in conformity with the essential health and safety requirements.
2. Before making PPE available on the GB market, a distributor must ensure that it bears the UKCA marking⁵ 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. Until 31 December 2022, the UKCA marking may be affixed to a label affixed to, or a document accompanying, the PPE.

For a limited period, in certain circumstances, new COVID-19 PPE may benefit from temporary arrangements relating to conformity assessment procedures and CE/UKCA marking:

COVID-19 related PPE being purchased by the Government/NHS bodies for use by healthcare and other frontline workers in England and in Wales does not have to undergo conformity assessment procedures, and can be imported or otherwise supplied without the CE or UKCA marking or Declaration of Conformity and purchased, provided it meets the essential health and safety requirements, and has been approved by HSE. The HSE approval process for this PPE will come to an end on 30 June 2021, after which all PPE supplied under Government/NHS body purchase for healthcare and other frontline workers will no longer be approved by the HSE and the PPE must comply fully with the Amended PPE Regulations, and be UKCA (or until 31 December 2021, CE) marked. This arrangement does not apply to COVID-19 related PPE being supplied under Government/NHS body purchase for healthcare workers in Scotland.

Other COVID-19 related PPE can be imported onto the GB market and distributed within England and within Wales, provided conformity assessment procedures have begun, and the product has been approved by HSE. In these circumstances, they will not be CE or UKCA or CE UKNI marked and will only have a partially completed Declaration of Conformity. Full conformity assessment should be completed as soon as possible. The HSE approval process for this PPE will come to an end on 31 March 2021, after which PPE to be placed on the market will no longer be approved by the HSE and the PPE must comply fully with the Amended PPE Regulations, and be UKCA (or until 31 December 2021, CE) marked. This arrangement does not apply to COVID-19 related PPE being placed on the market by economic operators based in Scotland.

⁵ Until 31 December 2021, PPE conforming to EU rules, including the CE marking, may be placed on the market of Great Britain.

3. 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.
4. Distributors who consider or have reason to believe that PPE which they have placed on the GB market is not in conformity with the 2016 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 GB to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.
5. Distributors must, further to a reasoned request from the enforcement authority, 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 GB market.

9. Transitional arrangements

Products placed on the market before 1 January 2021

If you have already placed an individual fully manufactured product on the EEA or the UK market (either in Northern Ireland or Great Britain) before 1 January 2021, you do not need to do anything new. These individual goods can continue to circulate on either market until they reach their end user and do not need to comply with the changes that take effect from 1 January 2021.

A fully manufactured good is 'placed on the market' when a written or verbal agreement (or offer of an agreement) to transfer ownership or possession or other rights in the product. This does not require physical transfer of the good.

You can usually provide proof of placing on the market on the basis of any relevant document ordinarily used in business transactions, including:

- contracts of sale concerning goods which have already been manufactured and meet the legal requirements
- invoices
- documents concerning the shipping of goods for distribution

The relevant economic operator (whether manufacturer, importer or distributor) bears the burden of proof for demonstrating that the good was placed on the EEA or UK market before 1 January 2021.

Existing CE marked stock

The UK will allow CE marked PPE that has been either self-declared as compliant (where permissible), or where compliance must and has been demonstrated through assessment by an EU-recognised conformity assessment body (notified body), to be placed on the GB market until 31 December 2021.

PPE lawfully placed on the market with a CE marking by 31 December 2021 can continue to circulate on the GB market after this date.

10. UKCA Marking

Assessment through third-party organisations:

From 1 January 2021, PPE that is conformity assessed by a UK approved body should be UKCA marked, not CE marked. If the conformity assessment was done by a UK approved body before 1 January 2021, the CE marking can still be used. But the product can only be placed on the GB market and must be placed on the GB market before 31 December 2021.

While they remain in force, the easements for COVID-19 related PPE set out in section 5 apply to conformity assessment and the UKCA marking from 1 January 2021.

Where the PPE has been assessed by an EU notified body, manufacturers must continue to use the CE marking for products being placed on the GB market instead of the new UKCA marking; these can be placed on the GB market until 31 December 2021. Qualifying Northern Ireland goods complying with the legislation as it applies in Northern Ireland, including affixing the CE marking, may be placed on the GB market after 31 December 2021. See further detail in Section 11 on Qualifying Northern Ireland Goods.

Rules around physically affixing the new UKCA marking mirror those which applied for the application of the CE marking, including where the size or nature of the PPE does not allow this the provision to provide it on the packaging or an accompanying document. Irrespective of the latter provision, until 31 December 2022, the UKCA marking may be affixed to a label affixed to the PPE or a document accompanying the PPE, rather than being affixed to the PPE itself.

Self-declaration:

Manufacturers selling PPE on the GB market can affix the new UKCA marking before placing equipment on the GB market from 1 January 2021. CE marking based on self-declaration of conformity by the manufacturer is still possible until 31 December 2021 for the GB market.

It will also be possible to affix both the UKCA marking and the CE marking to the same product on the basis of self-declaration, as long as the EU and GB requirements remain the same. When exporting to the EU, the CE marking remains mandatory.

Testing Certificates:

Where conformity assessment is a 2-stage process, it is possible for PPE to have an EU-type-examination certification (1st stage) followed by a declaration by the manufacturer or third party of the production process under the responsibility of a UK approved body (2nd stage) until 31 December 2021. Such PPE should have the UKCA mark followed by the UK Approved Body Number.

Further guidance on UKCA marking can be found here:

<https://www.gov.uk/guidance/using-the-ukca-mark-from-1-january-2021>

11. Qualifying Northern Ireland Goods

The government has committed to providing unfettered access for qualifying Northern Ireland goods to the rest of the UK market after 1 January 2021. Products that can be placed on the market in Northern Ireland in accordance with the legislation, as it applies to Northern Ireland, can be sold in the rest of the UK without any additional approvals.

This means that products that are qualifying Northern Ireland goods can be sold in the rest of the UK if any of the following apply:

- the CE marking is lawfully applied to the good on the basis of self-declaration;
- any mandatory third-party conformity assessment was carried out by an EU-recognised notified body (including a body in a country with which the EU has a relevant mutual recognition agreement) and a CE marking is affixed;
- the certificate of conformity previously held by a UK approved body has been transferred to an EU-recognised notified body and a CE marking has been affixed;
- any mandatory third-party conformity assessment was carried out by a UK-based body, and the good is therefore marked with the CE marking and with the new UKNI marking;

This will be the case even if there are changes between the EU rules that the Northern Ireland Protocol applies to NI and the GB rules.

You can find more information about the UKNI marking here:

<https://www.gov.uk/guidance/using-the-ukni-marking-from-1-january-2021>

NI businesses that are importing products from the EEA and placing them on the GB market must ensure that the relevant conformity assessment procedure has been carried out, that the technical documentation has been drawn up and that the PPE bears the CE marking. They will also have to comply with the importer labelling duties (see Section 7 on obligations of importers).

You can find out more about qualifying Northern Ireland goods here

<https://www.gov.uk/guidance/moving-qualifying-goods-from-northern-ireland-to-the-rest-of-the-uk>

12. Approved Bodies

The UK has established a new framework for UK based bodies to assess PPE against GB rules. The existing UK notified bodies have been granted new UK 'approved body' status and listed on a new UK database. They do not need to seek re-accreditation in order to benefit from UK approved body status. These approved bodies retain their 4-digit identification body number. New approved bodies will be assigned a number by the Office for Product Safety and Standards on behalf of the Secretary of State.

Approved bodies can assess PPE for the GB market against GB essential health and safety requirements (which are, as yet, substantially the same as EU essential requirements).

Approved bodies are conformity assessment bodies which were registered UK notified bodies before 1 January 2021 or have been approved by the Secretary of State to carry out the procedures for conformity assessment and certification for the UK market as set out in the 2016 Regulation.

UK approved bodies must be established in the UK and be independent of the manufacturer. Approved bodies must examine the technical documentation and supporting evidence in respect of a product to assess the adequacy of the technical design.

Where an approved body finds that essential safety requirements have not been met by a manufacturer, they must not issue a certificate of conformity and they must require the manufacturer to take corrective measures.

A register of UK Approved Bodies can be found on the UKMCAB system at the link here:
[insert link]

The register also contains details of bodies in other countries such as Australia, New Zealand, Canada, Japan, and the United States of America, which the UK is designating as Approved Bodies through Mutual Recognition Agreements.

The contact details of the UK approved 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> | Approved 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> | Approved 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> | Approved 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> | Approved 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> | Approved 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> | Approved 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> | Approved 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> | Approved 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> | Approved Body number: 0843 |

13. 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) has a duty to enforce the Regulations in Great Britain.

In Great Britain local trading standards authorities have a duty to enforce the Amended PPE Regulations in relation to PPE retained for private use or consumption (other than in circumstances subject to the remit of HSE).

Where the PPE are 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 Amended PPE Regulations.

The Enforcement Regulations provides a range of powers to enforcement authorities to take action to protect workers, users and consumers and take action against economic operators for PPE that present a risk or are not in conformity with the 2016 Regulation.

There are requirements on manufacturers, distributors and importers to co-operate with the enforcement authority as appropriate on request.

The 2018 Regulations also provide powers to the Secretary of State to enforce the 2016 Regulation and RAMS (Regulation (EC) 765/2008) as retained in GB legislation, that sets out requirements and powers for effective 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 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.

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

EU Regulation 2016/425 was directly applicable in UK law before 1 January 2021 but is EU legislation. It has been retained in UK law and adapted for GB purposes in the form of the 2016 Regulation (as defined above). As a result, while the general principles may be the same, there may be differences between EU Regulation 2016/425 as applied in the EU and the 2016 Regulation as applied in the GB.

You can find further and more detailed guidance on Regulation (EU) 2016/425 here:

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

15. Glossary

- **Approved Body** – A conformity assessment body which has been approved by the Secretary of State or was previously a ‘notified body’ before 1 January 2021.
- **Authorised Representative** – A person appointed in writing by a manufacturer to perform specific tasks for the manufacturer. From 1 January 2021, authorised representatives for the GB market must be based in the UK. Manufacturers remain ultimately responsible for ensuring these tasks are carried out properly.
- **Declaration of conformity** – A document prepared by the manufacturer which must detail, among other things, the following:
 - The specific product to which the declaration is referring;
 - 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 GB market. This declaration must be made available to the enforcing authority upon request.

- **Distributor** – Any person in the GB supply chain, other than the manufacturer or the importer, who makes a PPE available on the GB market.
- **Enforcement 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. For nuclear sites in Great Britain, the Office for Nuclear Regulation is the enforcing authority.
- **Importer** – A person established in the UK who places PPE from a country outside of the UK on the GB market. This includes a person based in NI who has been supplied with the product from an EEA country, who would, under NI law, be a distributor. A person who before 1 January 2021 (under EU Rules) distributed PPE within the EU (including the UK) or from Switzerland will now be an importer if they are bringing PPE into GB from another country (including EU Member States, the EEA and Switzerland).
- **Manufacturer** – A person who manufactures PPE or has PPE designed or manufactured and markets that PPE under their name or trademark.
- **UKCA Marking** – The UKCA (UK Conformity Assessed) marking is the new UK conformity marking used for certain goods (including PPE) being placed on the GB market, in place of the CE marking which is the conformity marking used in Northern Ireland and the European Union.
- **UKNI Marking** (also known as the UK(NI) indication) – The UKNI marking is a new marking applied in addition to the CE marking, where a good requiring mandatory third-party conformity assessment has been tested against EU requirements by a UK body. The UKNI marking applies when placing such products on the Northern Ireland market. Under the Government’s unfettered access commitments, products lawfully marked with the UKNI marking can also be placed on the GB market if they are also qualifying Northern Ireland goods.

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