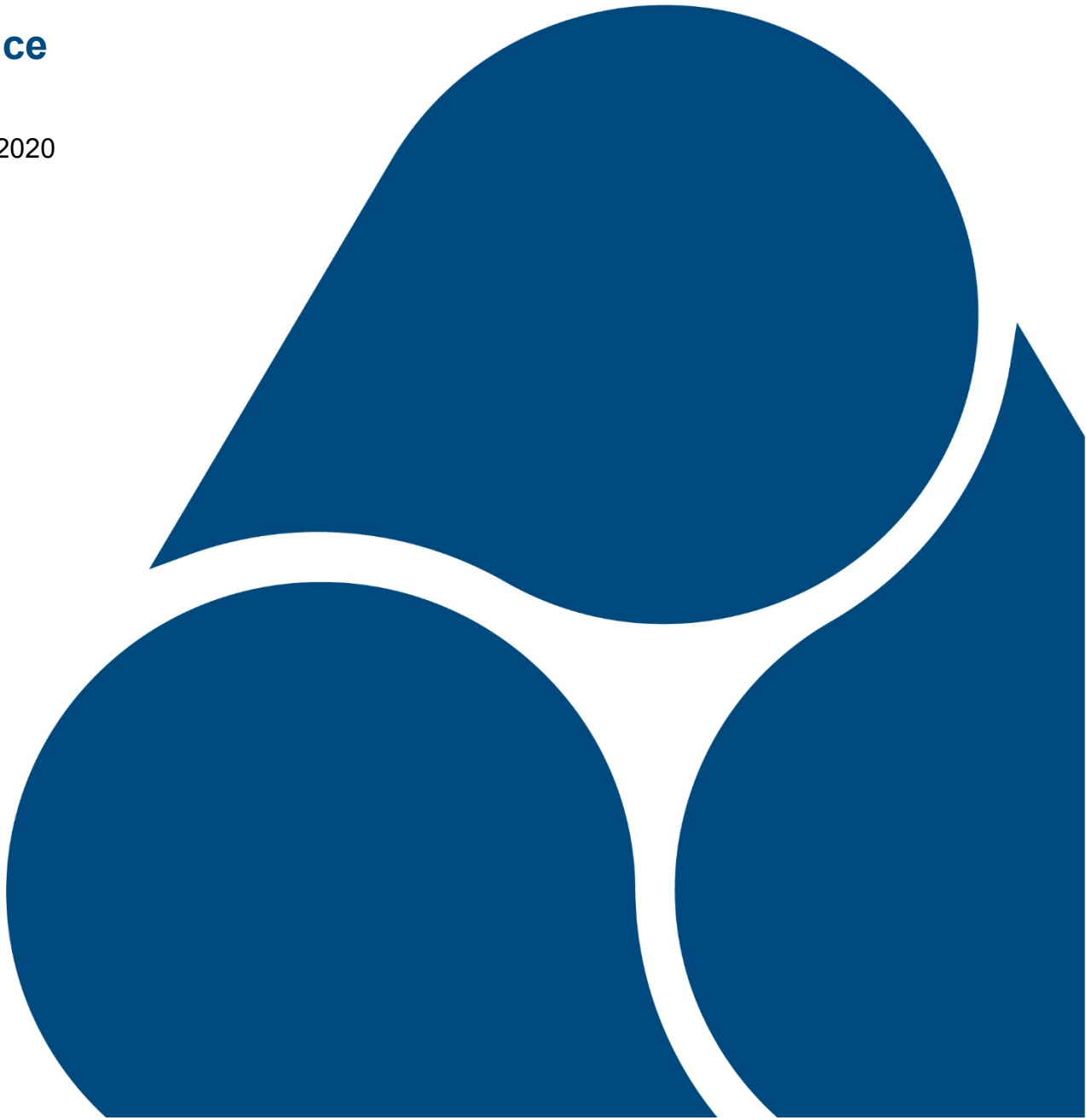
Office for Product Safety & Standards

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

As they apply to equipment being sold in or into Northern Ireland

Guidance

November 2020



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Guidance

1. Introduction

This Guide is for businesses placing personal protective equipment (PPE) on the market in Northern Ireland from 1 January 2021[1].

While the Northern Ireland Protocol[2] ('the Protocol') is in force, from 1 January 2021, Northern Ireland ("NI") will align with relevant EU rules relating to the placing on the market of manufactured goods. PPE placed on the NI market must therefore follow UK law as it applies to NI. The relevant law is the Regulation EU 2016/425 ('the 2016 Regulation') and The Personal Protective Equipment (Enforcement) Regulations 2018 ('the 2018 Regulations').

The 2016 Regulation sets out the essential requirements which must be met before PPE products can be placed on the NI market. The purpose of the legislation is to ensure safe products are placed on the NI market by requiring manufacturers to show how their products meet the 'essential requirements'. The 2018 Regulations establishes a system to enforce the 2016 Regulation.

In light of the COVID-19 outbreak, the Government has taken steps to temporarily ease regulatory requirements 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. The easements continue to be temporary and are currently under Review. Therefore, manufacturers will want to familiarise themselves with the requirements relating to full conformity assessment. The Government will give industry notice of when the easements will come to an end.

This guidance is designed to help you comply with the 2016 Regulation and the 2018 Regulations (referred to in this document collectively as 'the PPE Regulations'), as they apply in NI, and the easements set out in Recommendation 2020/403.

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:

https://www.gov.uk/guidance/opss-coronavirus-covid-19-guidance-for-business-and-local-authorities [3].

PPE placed on the Great Britain ("GB") market (GB comprises England, Scotland and Wales) must follow the separate rules for the GB market. If you are placing PPE on the market in GB, you should read the relevant separate guidance:

https://www.gov.uk/guidance/product-safety-and-metrology-from-1-january-2021-great-britain

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.

2 The Protocol on Ireland/Northern Ireland (also known as 'The Northern Ireland Protocol' and referred to in this document as 'the Protocol'

3 The current version (no 7) of the guidance for new high volume manufacturers will be reviewed before 31 December 2020.

The government has committed to providing unfettered access for qualifying NI goods to the rest of the UK market after 1 January 2021. PPE that can be placed on the market in NI in accordance with the PPE Regulations, as they apply to NI, can be sold in the rest of the UK without any additional approvals. The arrangements for this are explained in detail in the separate guidance for placing PPE on the market in GB.

2. Legislative background

The 2016 Regulation applies to all PPE first placed on the market from 21 April 2018 and will continue to have direct effect in NI as a result of the Protocol. The 2018 Regulations implemented an enforcement and sanctions system in UK law.

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 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 2018 Regulations are amended by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 and The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020[4] to accommodate the UKs exit from the EU and give effect to The Protocol as it relates to the placing on the NI market of PPE[5].

There will remain one set of 2018 Regulations, but some of the provisions apply differently in NI and GB. References to the 2018 Regulations in this guidance are references to those Regulations as they apply in NI.

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;

[4] At the time of writing The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 I subject to Parliamentary approval.

[5] In 2019, the PPE Regulations were amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 to fix any deficiencies that arose from the UK leaving the EU (such as references to EU institutions) and make specific provision for the UK market. The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 were then 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 Northern Ireland Protocol.

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 the 2016 Regulation) 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 NI Market Surveillance Authority, and provided conformity assessment procedures have been started via a notified body , PPE can be placed on the NI 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 European Economic Area (EEA) 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 (HSENI).

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:

1. Before placing PPE on the NI 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 an EU Declaration of Conformity, ensure that the declaration accompanies the product, and affix the CE marking 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 CE marking to the PPE, it must be affixed to the packaging and the accompanying documents.
4. When conformity assessment has been carried out by a UK notified body, the UKNI marking (also known as the UK(NI) indication) must be affixed as well as the CE marking. PPE with the CE UKNI marking cannot be placed on the EU market. There is separate guidance on when and how to use the UKNI marking online at:

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

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

Paragraphs 2, 3 and 4 need no longer be completed before PPE specifically necessary for protection in the context of the COVID-19 outbreak can be placed on the NI or GB markets. 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 the context of the COVID-19 outbreak can be placed on the NI or GB markets. 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 in NI or GB and being purchased by the Government/ NHS bodies, it can be purchased without conformity assessment. Such products may not be placed on the wider NI, GB or EEA markets.

These easements continue to be temporary and are currently under Review. Therefore, manufacturers will want to familiarise themselves with the regulations for full conformity assessment. The Government will give industry notice of when the easements will come to an end.

These easements do not apply to PPE being placed on the EEA market.

5. Manufacturers must keep the EU Declaration of Conformity[6] and the technical documentation for 10 years after the PPE has been placed on the NI 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 harmonised 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 NI 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 NI 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. Where the size or nature of the PPE does not allow this then it may be provided on the packaging or in an accompanying document.
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 2016 Regulation, which is in clear, legible and in easily understandable English.

6. Obligations of authorised representatives

A manufacturer can appoint an authorised representative to perform certain tasks on their behalf.

An authorised representative appointed by a manufacturer to represent him in either the NI or EEA markets cannot be based in GB. This means that GB based authorised representatives cannot carry out tasks on the manufacturer's behalf for products being placed on the NI or EEA markets.

An authorised representative based in NI can, under the PPE Regulations as they apply in NI, carry out tasks on the manufacturer's behalf for products placed on the NI or EEA markets.

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

- Keeping the EU 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 EEA 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.

[6] 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.

An authorised representative must comply with all the duties imposed on the manufacturer under the PPE Regulations that they are appointed by the manufacturer to perform. There are some duties that a manufacturer cannot mandate an authorised representative to perform (e.g. conformity assessment) and some that must form part of the authorised representatives mandate (e.g. retention of technical documentation).

A manufacturer remains responsible for the proper performance of any obligations the authorised representative performs on their behalf.

Any references in the PPE Regulations to the manufacturer are to be taken to include a reference to the authorised representative including in relation to penalties for failure to comply with those duties.

7. Obligations of importers

For the purposes of the PPE Regulations as they apply in NI (under the Protocol), an importer is a business or person established in NI or the EEA who places PPE from outside of the EEA or NI on the NI or EEA market. Therefore, a business or person based in NI who is supplied with a product from GB will be an importer under the PPE Regulations, if they then sell that product on the NI (or EEA) markets.

The obligations of importers include the following:

1. Before placing PPE on the NI 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[7]; and is accompanied by the declaration of conformity and required documents and identification marks.
2. When conformity assessment has been carried out by a UK notified body, the UKNI marking (also known as the UK(NI) indication) must be affixed as well as the CE marking. PPE with both the CE and the UKNI markings cannot be placed on the EU market. There is separate guidance on when and how to use the UKNI marking:

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

For a limited period, in certain circumstances, new COVID-19 PPE need not have a CE marking:

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 EU 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 NI or GB (but not EEA unless and until CE marked) markets, 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.

[7] When conformity assessment has been carried out by a UK approved body, the UK(NI) indication must also be affixed.

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 NI or GB (but not EEA) markets 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 NI or GB markets, but not on the EEA market unless and until CE marked.

   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 NI, GB or EEA markets.

These easements continue to be temporary and are currently under Review. Therefore, importers will want to familiarise themselves with the regulations for full conformity assessment. The Government will give industry notice of when the easements will come to an end.

3. When deemed appropriate, regarding risk presented by an item of PPE, the importer must carry out sample testing of PPE they have placed on the NI market, 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.
4. 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.
5. 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.
6. The importer must keep a copy of the declaration of conformity[8] for a period of 10 years after the PPE has been placed on the NI or EEA market at the disposal of the market surveillance authority and ensure that the technical documentation can be made available to that authority, upon request.
7. 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.

[8] See footnote 1.

8. Importers who consider or have reason to believe that PPE which they have placed on the NI 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 NI to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.
9. Importers must, further to a reasoned request from the enforcement authority in NI, 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 NI market.

8. Obligations of distributors

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

NI businesses which were distributors of PPE supplied to them from GB should now consider whether they are classified as importers under the PPE Regulations and therefore what additional requirements they need to comply with – see section 7 above. Under the PPE Regulations an NI business placing a product from GB on the NI market does so as an importer, not as a distributor under the PPE Regulations.

The obligations of distributors include the following:

1. Before making PPE available on the NI market, a distributor must act with due care to ensure that it is in conformity with the 2016 Regulation, which means the PPE must be in conformity with the essential health and safety requirements.
2. Before making PPE available on the NI market, a distributor must ensure that it bears the CE marking[9]; is accompanied by instructions and information as set out in point 1.4 of Annex II to the 2016 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:

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 EU 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 Government/ NHS on to the general NI, GB or EEA markets.

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

[9] When conformity assessment has been carried out by a UK notified body, the UK(NI) indication must also be affixed.

marked and will only have a partially completed EU Declaration of Conformity. It cannot be distributed outside the UK on to the EEA market, unless and until CE marked.

These easements continue to be temporary and are currently under Review. Therefore, distributors will want to familiarise themselves with the regulations for full conformity assessment. The Government will give industry notice of when the easements will come to an end.

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 NI 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 the UK 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 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. 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 NI or GB) 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 there is 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 market before 1 January 2021.

10. Conformity Marking

Where PPE is being placed on the NI market, and the manufacturer chooses to have it conformity assessed by an EU recognised body, the marking for the NI and EEA markets continues to be the CE marking.

The CE marking can continue to be used for the GB market until 31 December 2021, as long as all the other rules have been met (but this only applies if there have been no changes to the EU rules between 31 December 2020 and 31 December 2021). After 31 December 2021, the UKCA marking must be used for the GB market, but there are particular rules about ensuring unfettered access that apply for qualifying NI Goods.

For qualifying Northern Ireland goods, PPE meeting NI rules (the 2016 Regulation), which are CE or both CE and UKNI marked, can be placed on the GB market from 1 January 2021 and on an ongoing basis thereafter (there is further information on the reasons for this below and this arrangement is explained further in the separate guide to placing PPE on the GB market).

PPE that does not fall within the definition of qualifying NI goods will need to meet the GB rules, including being UKCA marked, if placed on the GB market after 31 December 2021.

From 1 January 2021, where the manufacturer chooses to have the PPE conformity assessed by a UK notified body, the CE marking must be accompanied by the UKNI marking (also known as the UK(NI) indication). Products with the UKNI marking cannot be placed on the EEA market.

There is separate guidance on when and how to use the UKNI marking:

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

11. Qualifying Northern Ireland Goods

The government has committed to providing unfettered access for qualifying NI goods to the rest of the UK market after 1 January 2021. PPE that can be placed on the market in NI in accordance with the PPE Regulations, can be sold in the rest of the UK without any additional approvals. The guide to placing PPE on the GB market has further details on these arrangements.

You can find more information about qualifying NI goods at a link to be given here when available.

12. Notified Bodies

Notified Bodies are independent organisations notified to the European Commission to carry out the procedures for conformity assessment and certification set out in the PPE Regulations.

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

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
Notified Body number: 0086

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
Notified Body number: 1105

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
Notified Body number: 0194

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
Notified Body number: 0362

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
Notified Body number: 0321

SGS United Kingdom Limited
Unit 202B, Worle Parkway Weston-super-Mare, Somerset, BS22 6WA
Phone: +44 (0)1934 522917
Fax: +44 (0)1934 522137Email: globalmedical@sgs.com / sgsprodcert@sgs.com (for 89/686/EEC; 92/42/EEC)
Website: www.uk.sgs.com
Notified Body number: 0120

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 Notified Body number: 0338
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 Notified Body number: 0518
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 Notified Body number: 0843

From 1 January 2021, all UK Notified Bodies will remain Notified Bodies for the purpose of CE marking products for the NI market. When these UK bodies are used for mandatory conformity assessment activity, then the manufacturer will need to affix both the CE and the UKNI markings. A product with both the CE and the UKNI marking cannot then be placed on the EEA market. There is separate guidance on when and how to use the UKNI marking:

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

A list of EU Notified Bodies can be found on the NANDO website. If a manufacturer uses a Notified Body from this list, then they apply only the CE marking to their product (not the both the CE and the UKNI markings).

A list of UK Notified Bodies can be found at a link which will be given here when available.

13. Enforcement

As set out in the 2018 Regulations, 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 for Northern Ireland (HSENI) acts as the Market Surveillance Authority and has a duty to enforce the PPE Regulations in NI.

In NI District Councils, have a duty to enforce 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 2018 Regulations give powers to enforcement authorities to take action against economic operators for PPE that presents a risk or is 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 give the Secretary of State powers to enforce the 2016 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.

Safeguard procedure

Enforcement authorities are required under the 2016 Regulation to take all appropriate measures to withdraw from the NI market or to prohibit, and restrict the supply of products bearing CE Marking which may endanger the health and safety of persons, property or the environment if the relevant economic operator does not do so. Under the safeguard procedure, the UK must inform the European Commission and EU Member States immediately of any enforcement action taken indicating the reasons justifying the action. This will enable Member States to act against similar products placed on the market on their territories. Similarly, if an EU Member State initiates the procedure with respect to action taken on their territories, certain actions are required of NI market surveillance authorities and the Secretary of State. The European Commission will determine whether the action taken is justified; if so, enforcement authorities must take necessary measures to ensure the PPE is withdrawn from the market.

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, or both. 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, and the economic operator is found to be in breach, 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 ("the 2016 Regulation") is directly applicable in NI. 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/

15. Glossary

- **Approved Body** – A conformity assessment body which has been approved by the Secretary of State or was a UK 'Notified Body' prior to 1 January 2021 able to carry out conformity assessment of products with a view to UKCA marking. They are not recognised by the EU (unless they have a presence in the EU) and cannot approve CE marking.
- **Authorised Representative** – A person appointed in writing by a manufacturer to perform specific tasks for the manufacturer. An authorised representative can be based anywhere in the EEA or NI, but cannot be based in GB, in respect of products being supplied on the NI market. Manufacturers remain ultimately responsible for ensuring these tasks are carried out properly.
- **CE marking** – the CE marking can be placed on products which have been conformity assessed by an EU Notified Body and are intended for the EU or NI markets. CE marked products can only be placed on the GB market until 31 December 2021, although special arrangements have been agreed to ensure NI's unfettered access to the rest of the UK.
- **Declaration of conformity** – A document prepared by the manufacturer which must detail, amongst 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 NI market. This declaration must be made available to the enforcing authority upon request.

- **Distributor** – Any person in the EEA or NI supply chains, other than the manufacturer or the importer, who makes a product available in the EEA or NI markets.
- **Enforcing Authority** – In NI, for products in the use in the workplace, the enforcing authority is the Health and Safety Executive for Northern Ireland (HSENI). For products for private use this is district councils.
- **Importer** – A person established in NI who places a product from a country outside of the EEA or NI on the NI market. A person based in NI who before 1 January 2021 distributed a product from GB on the NI (or EEA) market, will now be an importer if they are bringing products into NI from the GB.
- **Manufacturer** – A person who manufactures PPE or has it designed or manufactured and markets that product under their name or trademark.
- **Notified Body** – A conformity assessment body based in the EEA which has been approved by an EEA Member State to carry out conformity assessment for placing products on the EU and NI markets; or a conformity assessment body that is based in the UK and have been approved by the Secretary of State, including bodies which were notified bodies whilst the UK followed EU rules. If these UK based Notified Bodies are used, the CE marking must be accompanied by the UKNI marking and cannot be placed on the EEA market (just the NI market, or, where it is also a qualifying NI good, the GB market).
- **UKCA marking** – The UKCA (UK Conformity Assessed) marking is the new UK conformity marking used for certain goods being placed on the GB market, in place of the CE marking, which is the conformity marking used in the European Union. All products placed on the GB market from 1 January 2022 must be UKCA marked, but there are special arrangements in place to ensure NI's unfettered access to the rest of the UK. Products being placed on the NI market cannot be UKCA marked but must continue to be CE marked.
- **UKNI marking** (also known as the UK(NI) indication) – The UKNI marking must be used along with the CE marking if manufacturers wish to use a UK Notified Body for conformity assessment. The UKNI marking allows the product to be placed on the NI market (and, under the Government's unfettered access commitments, where the product is also a qualifying NI good, on the GB market), but not the EEA market.

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

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