

Requirements for Personal Protective Equipment (“PPE”)

EU Requirements: Regulation (~~PPE Regulation~~)

~~Regulation~~ (EU) 2016/425 on Personal Protective Equipment (~~PPE Regulation~~) ~~contains the rules on~~ “EU PPE Regulation” regulates the import or sale of PPE in the EU. It sets out: health and safety requirements for PPE design and manufacture; labelling requirements the procedure for assessing whether products conform to these requirements; and the obligations of manufacturers, importers and distributors of PPE.

The EU PPE Regulation currently applies, and completely replaces the existing EU Personal Protection Equipment Directive 89/686/EEC (1989 Directive) on 21 April 2018. It is possible to still sell products that conform to the requirements in the 1989 Directive, so long as these are imported into or first sold in the EU before 21 April 2019. EC type-examination certificates and approval decisions issued under the 1989 Directive also remain valid until 21 April 2023, or until they expire (whichever is sooner).

EU Member States can still make laws on the use of PPE, as long as those requirements do not change the design of PPE, which conforms to the requirements under the EU PPE Regulation.

It is your responsibility to comply with the EU requirements if you are selling PPE in the EU. You must also comply with any other national requirements in the countries in which you sell these products.

Please see below for further information about EU requirements.

UK Requirements: From 1 January 2021, an amended version of the EU PPE Regulation applies to the import or sale of PPE in the UK as a result of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (the “UK Regulation on PPE”). It sets out: health and safety requirements for PPE design and manufacture; labelling requirements the procedure for assessing whether products conform to these requirements; and the obligations of manufacturers, importers and distributors of PPE. We have noted below where there will be relevant changes in the UK requirements from 1 January 2021.

Different rules apply to goods you sell in: (1) Great Britain (England, Scotland and Wales); and (2) Northern Ireland.

It is your responsibility to comply with the UK requirements if you are selling PPE in the UK. If you also sell PPE on Amazon EU website(s), then you must also comply with the EU PPE Regulation and with other national requirements in the countries in which you sell these products.

Please see below for further information about UK requirements.

This material is for ~~information only and is limited to the requirements of the new PPE Regulation. It is~~ informational purposes and you should not intended take it as a substitute for

legal advice. We encourage you to ~~seek advice from~~ consult your ~~own~~ legal counsel ~~if you have for~~ any ~~questions~~ concerns about the laws and regulations concerning your ~~products~~ product. This material only reflects the position at the date of writing and requirements across the EU and in the UK may change. You should refer to current UK Brexit guidance about your products (see below) to learn more about changes that may affect you from 1 January 2021.

~~Which~~

I. EU Requirements

What products ~~does~~ do the EU requirements for PPE ~~Regulation~~ apply to?

~~PPE~~ The EU requirements apply to PPE, which is defined generally as equipment designed to protect the wearer/user against risks to that ~~person's~~ person's health or safety. PPE includes any individual parts that are essential for the equipment's protective function; or to connect that equipment to an external device or to a reliable anchorage point. However, some products are excluded from the EU PPE Regulation (and are covered by other laws. ~~This includes~~) including those ~~products~~ that are designed: for: use by the army or police; for use in self-defence (other than for sporting activities); to protect consumers against atmospheric conditions that are not of an extreme nature (e.g. damp and water when washing dishes); or for exclusive use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable in Member States.

- ~~• Use by the army or police~~
- ~~• Use in self-defence (other than for sporting activities)~~
- ~~• Used to protect consumers against atmospheric conditions that are not of an extreme nature (for example, damp and water when washing dishes)~~

How do manufacturers assess the conformity of PPE?

Manufacturers must ensure that PPE has been designed and manufactured to conform to the applicable health and safety requirements set out in Annex II of the EU PPE Regulation. Manufacturers must draw up the Technical Documentation that specifies how they have ensured their products' conformity with Annex II, and follow the applicable conformity assessment procedure. The conformity assessment will vary depending on the categorisation of the product.

Where the manufacturer has demonstrated their product's compliance by the appropriate procedure, they must draw up the declaration of conformity and affix the CE mark to the product ~~or, where that is not possible, its packaging~~ or accompanying documentation.

The manufacturer and any other party importing the product into the EU must keep copies of the Technical Documentation and the declaration of conformity for 10 years after the last unit of the product has been sold in/imported into the EU and provide it on request to relevant national authorities.

Importers and distributors of PPE are also responsible for checking that they only import/sell compliant PPE in the EU.

What are the labelling and information requirements for PPE?

The following information must be included on the product itself or, where that is not possible, on its packaging or in a document accompanying the product: (1) the name or registered trade mark and postal address of the manufacturer and/or EU importer; (2) the type, batch or serial number or other element allowing the identification of the PPE, and; (3) the CE mark. All information must be included in the local language of the country in which it is sold.

Also, under the EU PPE Regulation, each individual piece of PPE must be accompanied by the declaration of conformity. ~~This requirement can be met~~ Manufacturers may comply with this obligation by including in the manufacturer by means of a “simplified declaration of conformity”, which consists of a single sentence instructions and information the reference to a website internet address where the complete declaration of conformity can be found.

What should I do if PPE does not conform with the EU requirements for PPE Regulation??

Manufacturers and importers should carry out sample testing of PPE, investigate and keep a register of complaints of non-conforming PPE and PPE recalls, and keep distributors informed of any such issues.

In case of any non-conforming PPE, manufacturers, and importers ~~and distributors~~ must immediately take the corrective measures necessary to bring that PPE into conformity, and withdraw or recall it, as appropriate. Distributors shall make sure that these steps are taken. Furthermore, where the PPE presents a safety risk, manufacturers, importers and distributors are also obliged to inform immediately ~~inform~~ the competent national authorities of the Member States in which they have sold/imported the PPE of the safety risk, giving details of the non-conformity and any corrective measures taken.

Additional Information

~~For more information on PPE,~~

We strongly encourage you to visit the European Commission’s website: ~~for more information on PPE:~~

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

II. UK Requirements

Where do the UK requirements for PPE apply?

The UK requirements for PPE apply to all products sold in the UK, but the provisions apply differently to Great Britain (England, Scotland and Wales, “GB”) and Northern Ireland. You can read more about the position in Northern Ireland (“NI”) below.

What products do the UK requirements for PPE apply to?

The UK requirements apply to PPE, which is defined generally as equipment designed to protect the wearer/user against risks to that person's health or safety. PPE includes any individual parts that are essential for the equipment’s protective function or to connect that equipment to an external device or to a reliable anchorage point. However, some products are excluded from the UK’s regulatory regime (and are covered by other laws) including

those that are designed: for use by the army or police; for use in self-defence (other than for sporting activities); to protect consumers against atmospheric conditions that are not of an extreme nature (e.g. damp and water when washing dishes); or for exclusive use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable in the UK.

How do manufacturers assess the conformity of PPE?

Manufacturers must ensure that PPE has been designed and manufactured to conform to the applicable health and safety requirements set out in Annex II of the EU PPE Regulation and UK Regulation on PPE. Manufacturers must draw up the Technical Documentation that specifies how they have ensured their products' conformity with Annex II, and follow the applicable conformity assessment procedure. The conformity assessment will vary depending on the categorisation of the product. Examples of information to be included in the Technical Documentation are: a complete description of the PPE and of its intended use; an assessment of the risks against which the PPE is intended to protect; a list of the essential health and safety requirements that are applicable to the PPE. See Annex III of the EU PPE Regulation and UK Regulation on PPE for a more comprehensive list of what should be included in the Technical Documentation.

Where the manufacturer has demonstrated their product's compliance by the appropriate procedure, they must draw up the declaration of conformity and affix a conformity mark to the product (or, where that is not possible, its packaging or accompanying documentation) as follows:

- for products sold in GB, the UKCA mark;
- for products sold in NI while the Northern Ireland Protocol remains in force, the European CE mark (see "Northern Ireland" section below).

The manufacturer and any other party importing the product into the UK must keep copies of the Technical Documentation and the declaration of conformity for 10 years after the last unit of the product has been sold/imported and provide it on request to relevant national authorities.

Importers and distributors of PPE are also responsible for checking that they only import/sell compliant PPE in the UK.

What are the labelling and information requirements for PPE?

The following information must be included on the product itself or, where that is not possible, on its packaging or in a document accompanying the product: (1) the name or registered trade mark and postal address of the manufacturer and UK importer; (2) the type, batch or serial number or other element allowing the identification of the PPE, and; (3) the CE mark (and, for products sold in GB, the UKCA mark). All information must be included in clear, understandable, intelligible and legible English. The UK Government has released guidance on alternative means of providing GB importer traceability information until 31 December 2022. See the "BREXIT: UK Government Guidance" section below for links to this guidance.

Note: the UK Government has passed legislation which provides that for certain products (including products covered by the UK PPE requirements) CE marking will be accepted in GB until 1 January 2022, and that additional means of affixing the UKCA mark will be

accepted until 1 January 2023. A specific declaration of conformity will be required referencing UK (not EU) legislation and standards. See the “BREXIT: UK Government Guidance” section below for more details on the new requirements and transitional measures.

Also, under the EU PPE Regulation, each individual piece of PPE must be accompanied by the declaration of conformity. Manufacturers may comply with this obligation by including in the instructions and information the internet address where the complete declaration of conformity can be found.

Northern Ireland

Please note that different rules will apply in NI from 1 January 2021 as a result of the Northern Ireland Protocol. In particular:

- You should ensure that products meet EU requirements and that you use the CE mark.
- You are an importer if you are established in the EU or NI and you sell products from a country outside of the EU and Northern Ireland (including from GB) into NI. Products sold in NI should be marked with details of any EU / NI based importer.
- Authorised representatives can be based in NI or the EU. From 16 July 2021, new rules come into force under EU Regulation 2019/1020 and some businesses may need to appoint a responsible person in the EU or NI to carry out compliance functions (if there is no other entity in the supply chain who is able to carry out the functions). Further guidance on the new rules will be made available by the UK Government.
- If you are using a UK body to carry out mandatory third-party conformity assessment, you will need to apply a UKNI marking as well as a CE mark to products placed in NI from 1 January 2021. Goods with the CE and UKNI marking can't be sold in the EU. You do not need to use the UKNI marking if you self-certify compliance or use an EU body to carry out a mandatory third-party assessment.
- “Qualifying Northern Ireland goods” will be able to be sold in GB with the CE mark. The UK Government is issuing guidance on how this will work.

What should I do if PPE does not conform with the UK requirements for PPE?

Manufacturers and importers should carry out sample testing of PPE, investigate and keep a register of complaints of non-conforming PPE and PPE recalls, and keep distributors informed of any such issues.

In case of any non-conforming PPE, manufacturers and importers must immediately take the corrective measures necessary to bring that PPE into conformity, and withdraw or recall it, as appropriate. Distributors shall make sure that these steps are taken. Furthermore, where the PPE presents a safety risk, manufacturers, importers and distributors are also obliged to inform immediately the competent UK authorities (Health and Safety Executive or Trading

Standards) of the safety risk, giving details of the non-conformity and any corrective measures taken.

BREXIT: UK Government Guidance

The UK Government has released guidance on selling products in GB and NI from 1 January 2021. This guidance provides information for manufacturers, importers and distributors regarding compliance requirements from 1 January 2021, including on:

- whether you need to change your conformity assessment;
- when and how to use the UKCA mark;
- requirements for technical documentation and a specific declaration of conformity for products sold in GB;
- appointing an authorised representative or responsible person in the UK;
- whether your legal responsibilities will change as a result of Brexit;
- whether you need to provide GB importer information, and methods for doing this (including transitional arrangements until the end of 2022);
- how to deal with existing stock;
- what documentary evidence is required to show that products have been placed in the UK or EU before 1 January 2021; and
- specific rules for selling products in NI.

We encourage you to review this guidance (linked below), alongside any other specific UK Government Guidance that applies to your product. You should consult your legal counsel if you have questions about how the laws and regulations apply to your products from 1 January 2021.

The Brexit guidance can be found here:

GB:

- Placing manufactured goods in Great Britain from 1 January 2021
- Using the UKCA mark in GB from 1 January 2021
- Product Safety and Metrology in GB from 1 January 2021

NI:

- Placing manufactured goods in Northern Ireland from Great Britain
- Placing manufactured goods in Northern Ireland from the EU
- Using the UKNI mark
- Product Safety and Metrology – NI

Additional Information

For more information on the requirements for PPE in the UK, visit the following UK Government page:

- <https://www.hse.gov.uk/toolbox/ppe.htm>

We also encourage you to visit the Business Companion website, which contains guidance on UK product compliance rules:

- <https://www.businesscompanion.info/en/get-started>
- <https://www.businesscompanion.info/focus/ppe>