



Office for Product
Safety & Standards

For use only if the UK has left the EU without a deal

EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES REGULATIONS 2016 as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

Guidance

September 2019

This will only apply if the UK leaves the EU without a deal.



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1. Introduction

The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 set out the essential health and safety requirements which must be met before products can be placed on the UK market. The purpose of the legislation is to ensure safe products are placed on the market by requiring manufacturers to show how their products meet the 'essential health and safety requirements'.

This guidance is designed to help you understand the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 now the UK has left the EU, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 ("2016 Regulations as amended").

2. Legislative Background

The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 implemented Directive 2014/34/EU on equipment and protective systems intended for use in potentially explosive atmospheres.

The EU Withdrawal Act 2018 preserves the 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 2019 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.

3. Scope

The 2016 Regulations as amended apply to equipment and protective systems intended for use in potentially explosive atmospheres as defined in regulation 3.

Specifically, the Regulations relate to:

- equipment intended for use in potentially explosive atmospheres, defined as machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy or the processing of material and which are capable of causing an explosion through their own potential sources of ignition;
- protective systems intended for use in potentially explosive atmospheres, defined as devices which are intended to halt incipient explosions immediately and/or to limit the effective range of explosion flames and explosion pressures. Protective systems may be integrated into equipment or separately placed on the market for use as autonomous systems;
- safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres but which are required for or contribute to the safe functioning of equipment and protective systems, with respect to the risks of explosion; and
- components defined as any item essential to the safe functioning of equipment and protective systems but with no autonomous function.

These 2016 Regulations as amended do not apply to products listed in regulation 3(3).

4. Obligations of manufacturers

A manufacturer is a person who manufactures products, or has products designed or manufactured, and markets those products under their name or trade mark.

Obligations of manufacturers of products:

1. Before placing a product on the market, a manufacturer must ensure that the product has been designed and manufactured in accordance with the essential health and safety requirements and that they have had the relevant conformity assessment procedure carried out and technical documentation drawn up.
2. Once this has been done, a manufacturer must draw up a declaration of conformity, or a written attestation of conformity (for components of products), ensure that declaration or attestation accompanies the product; where applicable affix the UK marking and the specific marking of explosion protection followed by the symbol of the equipment group and category to the product.
3. Manufacturers must keep the declaration of conformity up to date and keep it, along with the technical documentation, for 10 years after the equipment has been placed on the market.
4. Manufacturers must also label their products with their name, registered trade name or registered trademark and address; the type batch or serial number (or other identification); and ensure that they are accompanied by relevant instructions and safety information in easily understandable English.
5. Manufacturers must, when appropriate with regard to any risk posed to end-users, carry out sample testing of products and investigate any complaints that the products are not in conformity and keep records of these complaints.
6. Manufacturers must take action where they have reason to believe that the products they have placed on the market are not in conformity with the 2016 Regulations as amended.
7. Manufacturers must also cooperate with and provide information to enforcing authorities following any requests.

5. Obligations of authorised representatives

Manufacturers are able to appoint authorised representatives to perform certain tasks on their behalf.

Mandated authorised representatives established in the EEA or Switzerland prior to the UK leaving the EU continue to be recognised as authorised representatives by the UK to act in the UK for the purposes of the legislation. However, any authorised representatives appointed and mandated after the UK left the EU to act in the UK must be established in the UK to be recognised under UK law.

Businesses with an existing authorised representative based in an EU Member State, can continue to use their authorised representatives in the same way in respect of the 2016 Regulations as amended.

No UK-based authorised representatives are recognised under EU law. This means they cannot carry out tasks on the manufacturer's behalf for products being placed on the EU market. Therefore, a manufacturer exporting products to the EU, who wishes to appoint an authorised representative to carry out tasks for them in respect of those products, must appoint an authorised representative based in the EU.

The obligations of authorised representatives include:

1. An authorised representative must comply with all the duties imposed on the manufacturer under the 2016 Regulations as amended that they are appointed by mandate by the manufacturer to perform, including the manufacturer's obligation under regulation 8 (retention of technical documentation and declaration of conformity), and regulation 16 (provision of information and cooperation). A manufacturer remains responsible for the proper performance of any obligations the authorised representative performs on their behalf.
2. As far as those duties are concerned as well as penalties for failure to comply with those duties any references in the 2016 Regulations as amended to the manufacturer are to be taken as a reference to the authorised representative.

6. Obligations of importers

An importer is a person or business based in the UK who places a product on the UK market from a country outside the UK. This means that UK businesses who used to act as a 'distributor' legally become an 'importer' if they place products from an EEA country or Switzerland on the UK market.

Importers have additional legal obligations which go beyond those of distributors, such as checking that manufacturers have carried out the right conformity assessment procedures and included their name, registered trade name or mark and a postal address on the product 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 of 18 months to allow those UK operators who import goods from the EEA or Switzerland (who post exit are importers) to provide their details on the accompanying documentation as an alternative to placing them on the product itself.

The EU does not have any such transitional provision – in the absence of this, products being exported from the UK to the EU must be labelled with the EU-based importer's address.

The obligations of importers in the UK include:

1. Before placing a product on the market an importer must ensure that it is in conformity with the essential health and safety requirements.
2. The importer must ensure that the relevant conformity assessment has been carried out by the manufacturer; the manufacturer has drawn up technical documentation; the product is UK marked (or for a time limited period CE marked) and is accompanied by the declaration of conformity or attestation of conformity (as applicable) as well as required labelling including the specific marking of explosion protection followed by the symbol of the equipment group and category to the product and manufacturer's identification.
3. The importer must keep a copy of the declaration of conformity or attestation of conformity (as applicable) and technical documentation for a period of 10 years after the product has been placed on the market.

4. The importer must not place products on the market unless they conform with the essential health and safety requirements.
5. The importer must provide their name, registered trade name and a postal address at which they can be contacted on the product (or – see above for transitional provisions – on its packaging or in accompanying documentation).
6. The importer must ensure that when placing a product on the market, it is accompanied by instructions which can be easily understood by the end user.
7. The importer must, when appropriate, with regard to any risk posed to end-users, carry out sample testing of products and investigate complaints about products that are not in conformity with the 2016 Regulations as amended and keep a register of those complaints.
8. The importer must take action where they have reason to believe that the products that they have placed on the market are not in conformity with the 2016 Regulations as amended.
9. The importer must ensure that while products are under their responsibility, their storage and transport conditions do not jeopardise their conformity with the essential health and safety requirements.
10. The importer must also cooperate with and provide information to enforcing authorities following any requests.

7. Obligations of distributors

UK businesses which were distributors of goods within the EU single market should now consider whether they are importers from the EU single market and therefore what additional requirements they might face – see section 6 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 products available on the market.

The obligations of distributors include:

1. When making a product available on the market a distributor must act with due care to ensure that it is in conformity with Part 2 of the 2016 Regulations as amended, which means the product must be in conformity with the essential health and safety requirements.
2. Where a distributor considers that a product is not in conformity with the health and safety requirements, the distributor must not make that product available on the market.
3. Before placing a product on the market, the distributor must verify that the product bears a UKCA marking (or for a time limited period the CE marking), is accompanied by the declaration of conformity or the attestation of conformity; that it is accompanied by instructions and safety information and that the importer and manufacturer have complied with their obligations as to required labelling including the specific marking of explosion protection followed by the symbol of the equipment-group and category to the product and their identification.
4. The distributor must take action where they have reason to believe that the products that they have made available on the market are not in conformity with the 2016 Regulations as amended.

5. The distributor must ensure that while products are under their responsibility, their storage and transport conditions do not jeopardise their conformity with the essential health and safety requirements.
6. The distributor must also cooperate with and provide information to enforcing authorities following any requests.

8. Transitional arrangements

'Deeming' provision

Equipment and protective systems intended for use in potentially explosive atmospheres, which have undergone full conformity assessment under the equivalent EU requirements, and which bear the CE conformity mark, are deemed compliant with the UK legislation and can be placed on the UK market as if they have been UK conformity marked.

The UK continues to recognise the competency of EU recognised conformity assessment bodies (notified bodies) to assess products for the UK market. Products assessed by an EU recognised notified body prior to the UK leaving the EU do not need reassessment before being placed on the UK market. This means that for a time-limited period, products assessed by an EU recognised notified body can be placed on the UK market. (For the status of UK notified bodies, please see section 10 below).

This 'deeming provision' is available for a time-limited period. This will be the subject of amending legislation in the future at a time yet to be decided. The Government will consult with industry and provide notice before ending this time-limited period.

9. UK Conformity Mark

Assessment through third-party organisations:

The UKCA conformity mark will replace the CE marking for products placed on the UK market which have been assessed by a UK approved body. In all other cases, manufacturers will be able to continue using the CE marking for products being placed on the UK market instead of the new UKCA marking for a time-limited period. The Government will engage with industry before making any decision on when this period will end.

Rules around physically affixing the new UKCA conformity marking mirror those which currently apply for the application of the CE marking.

Self-assessment

CE marking based on self-declaration of conformity by the manufacturer is still possible, including when exporting to the EU.

Manufacturers selling goods on the UK market can alternatively affix the new UKCA conformity marking before placing a product on the UK 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. When exporting to the EU, the CE marking remains mandatory.

Placing CE marked goods on the UK market:

Products that meet EU regulatory requirements, including those with a CE marking, which have been assessed by an EU recognised conformity assessment body or which have been self-declared can still be placed on the UK market, which is intended to be for a time-limited period. 'EU-recognised' does not include UK approved bodies. Manufacturers which have had their products assessed by EU recognised bodies against the EU requirements are obliged to use the CE marking and cannot use the UKCA marking.

Testing Certificates:

Where conformity assessment is a 2-stage process, it is possible for products to have an EU-type-examination certification (1st stage) followed by a UK declaration by the manufacturer or third party of the production process under the responsibility of a UK Approved Body (2nd stage). Such equipment and protective systems should have the UKCA conformity mark followed by the UK Approved Body Number.

Further guidance on UKCA marking can be found here:

<https://www.gov.uk/government/publications/prepare-to-use-the-ukca-mark-after-brexit/using-the-ukca-marking-if-the-uk-leaves-the-eu-without-a-deal>

Products exported to the EU Single Market must comply with EU Directive 2014/34/EU.

10. Approved Bodies

The UK has established a new framework for UK based bodies to assess products against UK rules. Existing UK notified bodies have been granted new UK 'approved body' status and are listed on a new UK database. There is no need for pre-exit UK based notified bodies to seek re-accreditation in order to benefit from UK approved body status. These approved bodies have been given a 4-digit approved body number.

Approved bodies can assess products for the UK market against UK essential health and safety requirements (which are the same as EU essential requirements).

Approved bodies are UK based conformity assessment bodies which were notified bodies before the UK left the EU 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 Regulations as amended.

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 equipment which falls within the scope of the 2016 Regulations as amended 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 list of UK approved bodies can be found [link to be added].

11. Enforcement and penalties

For products intended for workplace use, the [Health and Safety Executive \(HSE\)](#) is responsible for the enforcement of the Regulations in Great Britain.

The Office of Nuclear Regulation is responsible for enforcement in relation to products intended to be used on nuclear sites in Great Britain.

The 2016 Regulations as amended provide powers to the Secretary of State or a person appointed to act on their behalf to enforce the Regulations and RAMS (Regulation (EC 765/2008, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, which sets out requirements for market surveillance of products).

Note: ATEX has separate Regulations for Northern Ireland not covered by this guidance. The Health and Safety Executive for Northern Ireland (HSENI) are responsible for enforcement in Northern Ireland.

The 2016 Regulations as amended also provide powers to market surveillance authorities to take action against economic operators for products that present a risk or are not in conformity with the Regulations as set out in regulation 55 to 60. Economic operators are also required to co-operate with the enforcement authority and on request, must provide information and take action as appropriate.

The UK market surveillance authorities (HSE, ONR) 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/uploads/system/uploads/attachment_data/file/300126/14705-regulators-code.pdf

Penalties

A person committing an offence under the 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 a matter for the enforcement authority to decide what action is appropriate in each case taking into account the circumstances of the case and the enforcement authorities' 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.

12. Where to find guidance about Directive 2014/34/EU

You can find further and more detailed guidance on Directive 2014/34/EU here:

https://ec.europa.eu/growth/sectors/mechanical-engineering/atex_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 the Blue Guide here:

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

13. Glossary

- **Approved Bodies** – A conformity assessment body which has been approved by the Secretary of State or was a 'Notified Body' prior to the UK leaving the EU.
- **Authorised Representative** – A person appointed in writing by a manufacturer to perform specific tasks for the manufacturer. Manufacturers remain ultimately responsible for ensuring these tasks are carried out properly. This includes persons who are based in the EU, the EEA or Switzerland, if they were appointed before the UK left the EU.
- **Declaration of conformity** – A document prepared by the manufacturer which must detail 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 product was placed on the market. This declaration must be made available to the enforcing authority upon request.
- **Distributor** – Any person in the UK supply chain, other than the manufacturer or the importer, who makes a product available on the UK market.
- **Market Surveillance Authority** – This is the Health and Safety Executive or the Office for Nuclear Regulation (when the product is used on a nuclear site).
- **Importer** – A person established in the UK who places a product from a country outside of the UK on the market. A person who before the UK left the EU distributed products within the EU (including the UK) or from Switzerland will now be an importer if they are bringing products into the UK from another country (including EU Member States, the EEA or Switzerland).
- **Manufacturer** – A person who manufactures a product, or has a product designed or manufactured, and markets that product under their name or trademark.
- **UK Conformity Marking** – The UKCA (UK Conformity Assessed) marking is the new UK conformity marking used for certain goods being placed on the UK market, in place of the CE marking which is the conformity marking used in the European Union.



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