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

ELECTROMAGNETIC COMPATIBILITY REGULATIONS 2016 as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

Guidance

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1. Introduction

The Electromagnetic Compatibility Regulations 2016 set out the essential 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 requirements’.

This guidance is designed to help you understand the Electromagnetic Compatibility Regulations 2016, now the UK has left the EU, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (“the 2016 Regulations as amended”).

2. Legislative Background

The Electromagnetic Compatibility Regulations 2016 implements into UK law an EU Directive (2014/30/EU) on electromagnetic compatibility (commonly called the EMC Directive). 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 Regulations apply to all electrical and electronic equipment (whether apparatus or fixed installations) with some notable exceptions.

These exceptions include:

- equipment covered by other specific instruments governing the conformity of the equipment with the essential requirements;
- aeronautical apparatus, parts and appliances referred to in Regulation (EC) 216/2008; and
- equipment which is incapable of generating electromagnetic interference that is harmful to radio and telecommunication equipment.

For a full list of exceptions please refer to the 2016 Regulations as amended.

4. Obligations of manufacturers

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

The obligations of manufacturers of apparatus include:

1. Before placing apparatus on the UK market, the manufacturer must ensure that it has been designed and manufactured in accordance with the essential requirements as set out in the 2016 Regulations as amended and that they have had have a relevant conformity assessment procedure carried out and technical documentation drawn up.
2. Once this has been done, the manufacturer must draw up a declaration of conformity¹, and affix to the product the UKCA conformity, or for a time limited period the CE marking marking to the product.

3. Manufacturers must keep technical documentation and the declaration of conformity for 10 years after the apparatus has been placed on the market.

4. Manufacturers must also label apparatus 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 in English.

5. Manufacturers must take action where they have reason to believe that the apparatus they have placed on the market is not in conformity with the 2016 Regulations as amended.

6. Manufacturers must also cooperate with and provide information to enforcing authorities following any requests.

5. Obligations of authorised representatives

Manufacturers are able by written mandate 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 the EEA or Switzerland can continue to use their authorised representatives in the same way.

No UK-based authorised representatives are recognised under EU law. This means they cannot carry out tasks on the manufacturer’s behalf for apparatus 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 that apparatus, 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 manufacturer’s obligation under regulation 11 (retention of technical documentation and EU declaration of conformity) and regulation 16 (provision of information and co-operation). 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.

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¹ A Declaration of Conformity is a document that declares that the product is in conformity with the relevant statutory requirements applicable to the specific product.
6. Obligations of importers

An importer is a person or business based in the UK who places apparatus 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 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 equipment or, where this is not possible, on the packaging of the apparatus or in documentation accompanying the equipment.

To assist with the transition, the UK has applied a transitional period of 18 months to allow UK suppliers of apparatus from the EEA or Switzerland who became importers to provide their details on the accompanying documentation as an alternative to placing them on the apparatus itself.

The EU does not have any such transitional provision – in the absence of this, apparatus being exported from the UK to the EU must be labelled with the EU-based importer’s address, where the EU law requires it.

The obligations of importers in the UK include:

1. Before placing apparatus on the market, an importer must ensure that it is in conformity with the essential 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 apparatus is UK marked, or for a time limited period CE marked, and is accompanied by the required documents and information regarding the manufacturer.

3. The importer must keep a copy of the declaration of conformity and technical documentation for a period of 10 years after the apparatus has been placed on the market.

4. The importer must provide their name trade, registered trade name and a postal address at which they can be contacted on the apparatus (or – see above for transitional provisions – in accompanying documentation).

5. The importer must ensure that when placing apparatus on the market, it is accompanied by instructions which can be easily understood by the end user in English.

6. The importer must ensure that while apparatus is under their responsibility, their storage and transport conditions do not jeopardise their conformity with the 2016 Regulations as amended.

7. The importer must take action where they have reason to believe that the apparatus that they have placed on the market is not in conformity with the 2016 Regulations as amended.

8. 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 apparatus 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 apparatus available on the market.

The obligations of distributors include:

1. When making apparatus 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, meaning that the apparatus is in conformity with the essential requirements and that each relevant economic operator has complied with their obligations imposed on them under Part 2 of the regulations.

2. Before placing the apparatus on the market, the distributor must verify that the apparatus bears the UKCA marking (or for a time limited period the CE marking); is accompanied by the required documents as well as instructions and safety information; and that the importer and manufacturer have complied with their obligations as to required labelling.

3. The distributor must not make apparatus available on the market if they think it is not in conformity with the essential requirements. The distributor must take action where they have reason to believe that the apparatus that they have made available on the market is not in conformity with the 2016 Regulations as amended.

4. The distributor must ensure that while apparatus is under their responsibility, its storage and transport conditions do not jeopardise its conformity with the essential requirements.

5. The distributor must also cooperate with and provide information to enforcing authorities following any requests.

8. Transitional arrangements

‘Deeming’ provision

Apparatus which have undergone full conformity assessment under the equivalent EU requirements and bear the CE marking are deemed compliant with the UK legislation and can be placed on the UK market as if they had 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. Apparatus 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, apparatus 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’ will be 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 apparatus placed on the UK market which have been assessed by a UK approved body. Manufacturers will be able to continue to comply with EU rules and use the CE marking for apparatus 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 where it was allowed pre-exit, including when exporting to the EU.

Manufacturers selling apparatus on the UK market can alternatively affix the new UK conformity marking before placing the apparatus on the UK market, if they use a UK approved body. 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:**

Apparatus that meets EU regulatory requirements, including those with a CE marking, which has been assessed by an EU recognised conformity assessment body or which has been self-declared can still be placed on the UK market for a time-limited period. ‘EU-recognised’ does not include UK approved bodies. Manufacturers which have had apparatus assessed by EU recognised bodies are obliged to use the CE marking and cannot use the UKCA marking.


Apparatus exported to the EU Single Market will continue to need to comply with EU Directive 2014/30/EU.

10. **Approved Bodies**

The UK has established a new framework for UK based bodies to assess apparatus 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 existing 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 apparatus for the UK market against UK essential requirements (which are the same as EU essential requirements).
Approved bodies are 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.

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 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

In Great Britain, the market surveillance authority for apparatus, in relation to protection and management of the radio spectrum is Office of Communications (OFCOM), and for other apparatus it is the local weights and measures authority (trading standards). In Northern Ireland, enforcement of Regulations for apparatus in relation to protection and management of the radio spectrum is OFCOM and for other apparatus the Department for the Economy.

In Northern Ireland, in relation to enforcement of electricity meters, this is carried out by the Northern Ireland Authority for Energy Regulation.

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

The Regulations 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 regulations 56 to 60. Economic operators are required to co-operate with the enforcement authority and on request, must provide information and take action as appropriate.

The UK market surveillance authorities (Local Authority Trading Standards) will take all appropriate measures to withdraw from the market, to prohibit or restrict the supply of apparatus which may endanger the health and safety of persons, property or the environment.

Regulators’ Code

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 Regulator’s Code can be found here:

Penalties
A person committing an offence under the Regulations is liable to a penalty. Penalties can include a fine or a prison sentence of up to three months (or both) for the most serious offences.

While it is matter for the enforcement authority to decide whether prosecution is appropriate in each case, 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 2014/30/EU
You can find further and more detailed guidance on Directive 2014/30/EU here:
https://ec.europa.eu/growth/sectors/electrical-engineering/emc-directive_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 this 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 apparatus 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 apparatus 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 apparatus available on the UK market.
- **Enforcing Authority** – In Great Britain and in Northern Ireland, this is OFCOM. The Secretary of State for Business, Energy and Industrial Strategy may also enforce these Regulations.

- **Importer** - A person established in the UK who places apparatus from a country outside of the UK on the market. A person who before the UK left the EU distributed apparatus within the EU (including the UK) or from Switzerland is now an importer if they are bringing apparatus into the UK from another country (including EU Member States, the EEA or Switzerland).

- **Manufacturer** – A person who manufactures apparatus or has apparatus designed or manufactured and markets that apparatus 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.