Electromagnetic Compatibility Regulations 2016

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

Guidance

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Guidance

1. Introduction

This Guide is for businesses placing electrical and electronic equipment on the market in Great Britain from 1 January 2021\(^1\). If you are placing electrical and electronic equipment on the market in Northern Ireland, you should read separate guidance:


This Guide is designed to help you comply with The Electromagnetic Compatibility Regulations 2016, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (referred to in this document at “The 2016 Regulations”). The 2016 Regulations set out the requirements that must be met before products can be placed on the GB market. The purpose of the legislation is to ensure safe products are placed on the GB market by requiring manufacturers to show how their products meet the ‘essential requirements’.

The essential requirements are that:

a) equipment must be designed and manufactured to ensure that the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended; and

b) the equipment has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

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\(^2\) fix any deficiencies that arose from the UK leaving the EU (such as references to EU institutions) and make specific provision for the GB market.

There is therefore one set of UK 2016 Regulations, but some of the provisions apply differently in NI for as long as the Northern Ireland Protocol is in force. References to the 2016 Regulations in this guidance are references to those Regulations as they apply in Great Britain. For guidance on placing on the Northern Ireland market, please see:

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\(^1\) 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 31 December 2020.

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

The Regulations apply to all electrical and electronic equipment which is liable to generate electromagnetic disturbance, 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. Nothing in the Regulations affects the application of legislation regulating the safety of equipment.

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 GB market, the manufacturer must ensure that it has been designed and manufactured in accordance with the essential requirements as set out in Schedule 1 to the 2016 Regulations and that they have had 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 conformity³, and affix the UKCA marking⁴ to the apparatus, except where it is not possible or warranted to affix the UKCA marking to the apparatus, in which case it must be affixed to the packaging and the accompanying documents. Until 31 December 2022, the UKCA marking may be affixed to a label affixed to, or a document accompanying, the apparatus, even where it can otherwise be affixed to the apparatus.

3. Qualifying Northern Ireland goods can be placed on the GB market with the CE and CE UKNI conformity markings, see further detail in Section 10 on Qualifying Northern Ireland Goods.

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

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³ **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.

⁴ Until 31 December 2021, apparatus conforming to EU rules, including the CE marking, may be placed on the market of Great Britain.
5. 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.

6. Manufacturers must ensure that procedures are in place for series production to remain in conformity with Part 2 of the 2016 Regulations. In doing so, they must take account of any changes in electrical equipment design or characteristics, and any change in a harmonised standard or in another technical specification by reference to which the Declaration of Conformity was drawn up.

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

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

Manufacturers based in Northern Ireland can follow the legislation as it applies to Northern Ireland and place qualifying Northern Ireland goods on the GB market without any additional approvals. See further detail in Section 10 on Qualifying Northern Ireland Goods.

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 for the GB market can be based in GB or Northern Ireland but after 1 January 2021 cannot be based outside the UK. A manufacturer can only mandate an authorised representative established in the UK under the 2016 Regulations as they apply in GB.

No GB-based authorised representatives are recognised under EU law. This means GB-based authorised representatives cannot carry out tasks on the manufacturer’s behalf for apparatus being placed on the Northern Ireland or EEA markets. Therefore, a GB manufacturer selling products to the EEA or into Northern Ireland, 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 Northern Ireland or in the EEA.

An authorised representative must comply with all the duties imposed on the manufacturer under the 2016 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 2016 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.
6. Obligations of importers

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

This includes apparatus that is supplied to NI businesses from the EEA and then placed on the GB market. In this instance the NI business will take on importer obligations for EEA-supplied goods that are placed on the GB market (see also Section 10 on Qualifying Northern Ireland Goods).

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

To assist with the transition, the UK has applied a transitional period ending 31 December 2022 to allow UK suppliers of apparatus from the EEA or Switzerland who became importers into the GB market to provide their details on the accompanying documentation as an alternative to placing them on the apparatus itself (even in cases where it would have otherwise been possible to include them on the apparatus itself). This applies to goods that are not qualifying Northern Ireland goods. For further detail on qualifying Northern Ireland goods, please see Section 10 on Qualifying Northern Ireland Goods.

Can you be contacted easily if there is a problem?

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

In recognition that under the new regulatory regime you may have the new status of an importer when placing goods from an EEA state on the GB market for the first time, you may provide your contact details in a document that accompanies the product. This will be allowed until 31 December 2022.

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

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

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

- The importer address is present in shipping documents.
- The importer address is present on the invoice to the GB customer.
- The importer address is present on the label that is on the outer packaging (“shipper”) in which a number of finished goods is packed (normally customers will
receive shippers unless the order is very small so that the shipper has to be opened and split).

- The importer address is included on the EU Declaration of Conformity and/or UK Declaration of Conformity (whichever is relevant for the product in question).

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

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

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

The EU does not have any such transitional provision. In the absence of this, apparatus being sold from GB to NI or the EEA must be labelled with the NI or EU-based importer’s address. For further detail about placing on the NI market please see: https://www.gov.uk/government/publications/electromagnetic-compatibility-regulations-2016

The obligations of importers in the UK include:

1. Before placing apparatus on the GB 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 UKCA marked and is accompanied by the required documents and information regarding the manufacturer. Until 31 December 2022, the UKCA marking may be affixed to a label affixed to, or a document accompanying, the apparatus. There is also a non-time-limited provision for the UKCA marking to be affixed on the packaging and accompanying documents where it is not possible or warranted on account of the nature of the apparatus to affix the UK marking on the apparatus or its data plate.

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 GB 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 in an accompanying document.

5. The importer must ensure that when placing apparatus on the GB market, it is accompanied by instructions which can be easily understood by the end user in English in the circumstances that this is allowed (see above).

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5 Until 31 December 2021, apparatus conforming to EU rules, including the CE marking, may be placed on the market of Great Britain.
6. The importer must ensure that while apparatus is under their responsibility, their storage and transport conditions do not jeopardise their conformity with the legal requirements of the 2016 Regulations.

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

8. The importer must also cooperate with and provide information to enforcing authorities following any requests.

Qualifying Northern Ireland goods complying with the legislation as it applies in Northern Ireland, including affixing the CE marking, may also be placed on the GB market. See further detail in Section 10 on Qualifying Northern Ireland Goods.

7. Obligations of distributors

UK businesses that 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 responsibilities they may have – 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 GB market.

The obligations of distributors include:

1. When making apparatus available on the GB 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 established by Part 2 of the regulations.

2. Before placing the apparatus on the GB market, the distributor must verify that the apparatus bears the UKCA marking (or until 31 December 2021 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. Until 31 December 2022, the UKCA marking may be affixed to a label or a document accompanying the apparatus.

3. The distributor must not make apparatus available on the GB market if they consider or have reason to believe 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 GB market is not in conformity with the legal requirements of the 2016 Regulations.

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

Products placed on the market before 1 January 2021

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

A fully manufactured good is ‘placed on the market’ when 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; and
- documents concerning the shipping of goods for distribution.

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

Existing CE marked stock

The UK continues to recognise the competency of EU recognised conformity assessment bodies (notified bodies) to assess apparatus for the GB market. Products assessed by an EU recognised notified body and placed on the GB market before 31 December 2021 do not need reassessment.

Apparatus which has undergone full conformity assessment under the equivalent EU requirements and bears the CE marking will be deemed compliant with the GB legislation and can be placed on the GB market as if it had been UKCA marked until 31 December 2021.

9. UKCA Marking

Assessment through third-party organisations

From 1 January 2021, electrical and electronic equipment that are conformity assessed by a UK approved body should be UKCA marked, not CE marked. If the conformity assessment was carried out by a UK notified body and the CE marking was affixed to the fully made product before 1 January 2021, the CE marking can still be used. But it can only be placed on the GB market and must be placed on the GB market before 31 December 2021.

Where the apparatus has been assessed by an EU notified body, manufacturers must continue to use the CE marking and can continue to place this apparatus on the GB market until 31 December 2021. Qualifying Northern Ireland goods complying with the legislation as it applies in Northern Ireland, including affixing the CE marking, may be placed on the GB market after 31 December 2021. See further detail in Section 10 on Qualifying Northern Ireland Goods.
Rules around physically affixing the new UKCA marking mirror those which applied for the application of the CE marking, although until 31 December 2022, the UKCA marking may be affixed to a label affixed to the apparatus or a document accompanying the vessel, rather than being affixed to the apparatus itself (even where it is otherwise possible to affix it to the apparatus itself).

**Self-declaration**

Manufacturers selling apparatus on the GB market can affix the new UKCA marking before placing the apparatus on the GB market. CE marking based on self-declaration of conformity by the manufacturer is still possible where it was allowed before 1 January 2021 and can continue to be placed on the GB market until 31 December 2021. It will also be possible to affix both the UKCA marking and the CE marking to the same apparatus on the basis of self-declaration itself, as long as the EU and GB requirements remain the same. When selling to the EU, or placing on the NI market, the CE marking remains mandatory.

Further guidance on UKCA marking can be found here: https://www.gov.uk/guidance/using-the-ukca-marking

### 10. Qualifying Northern Ireland Goods

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

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

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

You can find more information about the UKNI marking here: https://www.gov.uk/guidance/using-the-ukni-marking

NI businesses that are importing products from the EEA and placing them on the GB market must ensure that the relevant conformity assessment procedure has been carried out, that the technical documentation has been drawn up and that the equipment bears the CE marking. They will also have to comply with the importer labelling duties (see Section 6 on obligations of importers).
11. Approved Bodies

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

Approved bodies can assess apparatus for the GB market against GB essential requirements (which are, as yet, the same as EU essential requirements).

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

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 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 register of UK Approved Bodies can be found on the UKMCAB system here:
https://www.gov.uk/uk-market-conformity-assessment-bodies

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

12. 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 is the local weights and measures authority (trading standards).

The 2016 Regulations also provide powers to the Secretary of State or a person appointed to act on their behalf to enforce the 2016 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 2016 Regulations provide powers to market surveillance authorities to take action to protect consumers and users when products present a risk and to take action against economic operators for products that present a risk or are not in conformity with the legal requirements of the 2016 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 trading standards authorities) will take all appropriate measures to withdraw from the GB market, to prohibit or restrict the supply of apparatus 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 their regulatory functions.

A link to the Regulator’s Code can be found here:
https://www.gov.uk/government/publications/regulators-code

Penalties
A person committing an offence under the 2016 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.

13. Glossary

- **Approved Body** – A conformity assessment body which has been approved by the Secretary of State or was previously a ‘notified body’ before 1 January 2021.

- **Authorised Representative** – A person appointed in writing by a manufacturer to perform specific tasks for the manufacturer. From 1 January 2021, authorised representatives for the GB market must be based in the UK. Manufacturers remain ultimately responsible for ensuring these tasks are carried out properly.

- **Declaration of conformity** – A document prepared by the manufacturer which must detail 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 GB market. This declaration must be made available to the enforcing authority upon request.

- **Distributor** – Any person in the GB supply chain, other than the manufacturer or the importer, who makes apparatus available on the GB market.
- **Enforcing Authority** – In Great Britain, this is OFCOM. The Secretary of State for Business, Energy and Industrial Strategy, and local trading standards authorities may also enforce these Regulations.

- **Importer** – A person established in the UK who places apparatus from a country outside of the UK on the GB market. This includes a person based in NI who has been supplied with the product from an EEA country, who would, under NI law, be a distributor. A person who before 1 January 2021 (under EU Rules) distributed apparatus within the EU (including the UK, and including Switzerland) is now an importer if they are bringing apparatus into GB 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 (including electrical and electronic equipment) being placed on the GB market, in place of the CE marking which is the conformity marking used in Northern Ireland and the European Union.

- **UKNI Marking** (also known as the UK(NI) indication) – The UKNI marking is a new marking applied in addition to the CE marking, where a good requiring mandatory third-party conformity assessment has been tested against EU requirements by a UK body. The UKNI marking applies when placing such products on the Northern Ireland market. Under the Government’s unfettered access commitments, products lawfully marked with the UKNI marking can also be placed on the GB market if they are also qualifying Northern Ireland goods.