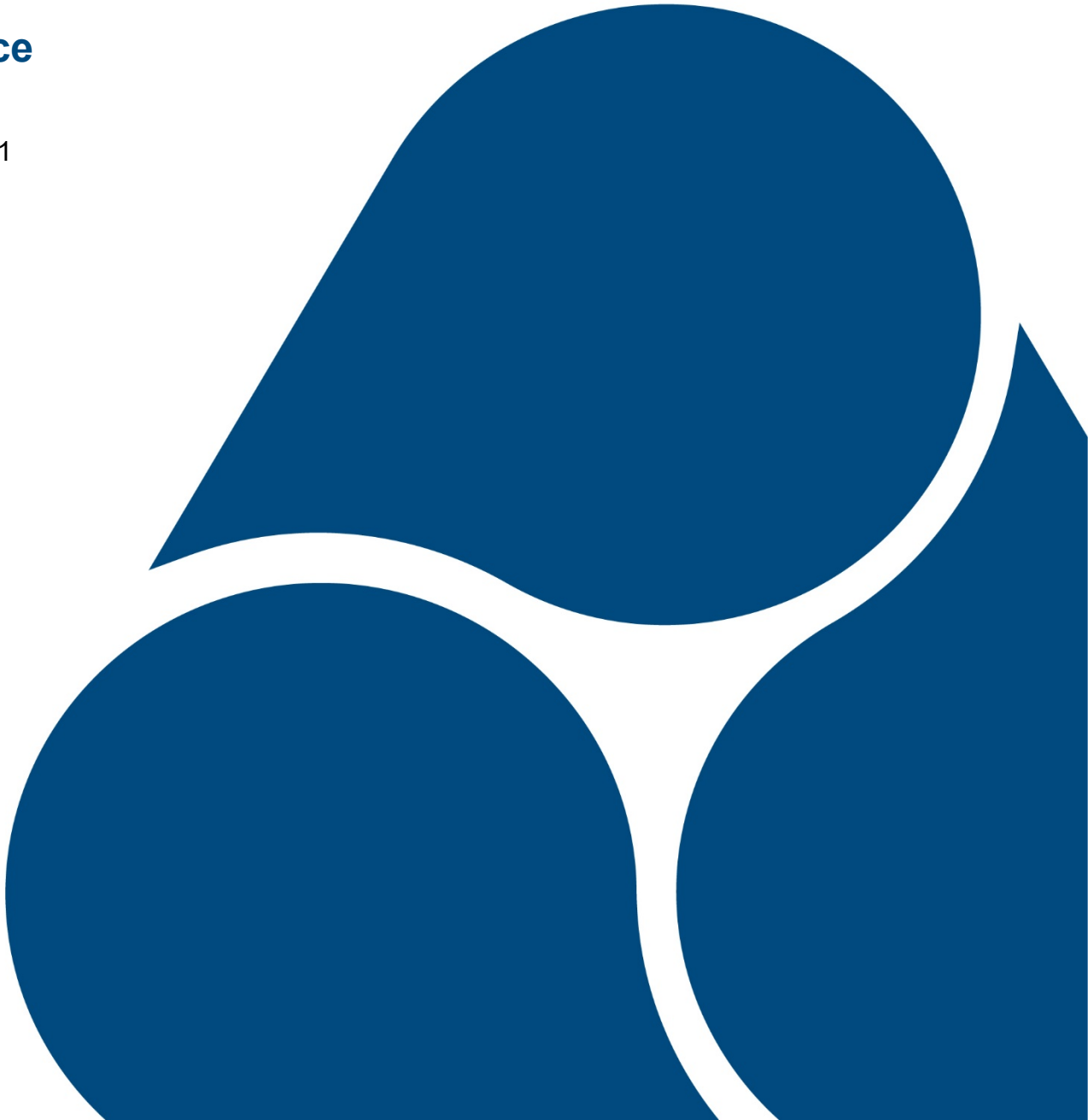
Office for Product Safety & Standards

Electromagnetic Compatibility Regulations 2016

As they apply to products being supplied in or into Northern Ireland from 1 January 2021

Guidance

January 2021



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1. Introduction

This Guide is for businesses placing electrical and electronic equipment 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. Electrical and electronic equipment placed on the NI market must therefore follow UK law as it applies to NI. The relevant law is the Electromagnetic Compatibility Regulations 2016, which apply across the UK but some of their provisions apply differently in NI so that they continue to implement in NI the Directive 2014/30/EU relating to electromagnetic compatibility.

This Guide is designed to help you comply with The Electromagnetic Compatibility Regulations 2016, as they apply in NI. References to "The 2016 Regulations" in this document are therefore references to The Electromagnetic Compatibility Regulations 2016, as they apply in NI.

The 2016 Regulations regulate the electromagnetic compatibility of equipment. They require equipment to comply with an adequate level of electromagnetic compatibility. They set out the requirements that must be met before electrical and electronic equipment can be placed on the NI market. The purpose of the legislation is to ensure safe equipment is placed on the market by requiring manufacturers to show how their equipment 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.

Electrical and electronic equipment 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 electrical and electronic equipment on the GB market, you should read the relevant separate guidance:

https://www.gov.uk/government/publications/electromagnetic-compatibility-regulations-2016

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

The government has committed to providing unfettered access for qualifying NI goods to the rest of the UK market after 1 January 2021. Electrical and electronic equipment that can be placed on the market in NI in accordance with the 2016 Regulations, as they apply to NI, can be sold in the rest of the UK without any additional approvals. The arrangements here are explained in detail in the separate guidance for placing electrical and electronic equipment on the market in GB.

2. Legislative Background

Directive 2014/30/EU of 26 February 2014 on the harmonisation of the laws of Member States (the "EMC Directive") relating to electromagnetic compatibility entered into force on 20 April 2016 and was implemented into UK law with effect from 8 December 2016 by way of the Electromagnetic Compatibility Regulations 2016. As such the Regulations apply to the whole of the UK.

The Directive will continue to be implemented in Northern Ireland, for as long as the Protocol is in force. However, the 2016 Regulations also implement parts of the Protocol which have particular provisions in them, recognising that the UK has left the EU.

There is therefore one set of UK 2016 Regulations, but some of the provisions apply differently in NI and GB. References to the 2016 Regulations in this guidance are references to those Regulations as they apply in NI.

The 2016 Regulations were amended by 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 to give effect to the Protocol as it relates to the placing on the NI market of electrical and electronic equipment[3].

3. Scope

The 2016 Regulations apply to all electrical and electronic equipment that is liable to generate electromagnetic disturbance with some exceptions, including:

- equipment covered by other specific EU 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 exclusions please refer to the 2016 Regulations.

The 2016 Regulations do not apply to apparatus placed on the market before 8 December 2016.

[3] In 2019, the 2016 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.

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 NI market, a manufacturer must ensure that it has been designed and manufactured in accordance with the essential requirements and that they have had have a relevant conformity assessment procedure carried out and technical documentation drawn up.
2. Once this has been done, a manufacturer must draw up an EU Declaration of Conformity, and affix the CE marking visibly, legibly and indelibly to the apparatus. Where it is not possible or warranted, on account of the nature of the apparatus, to affix the CE marking to the apparatus, it must be affixed to the packaging and the accompanying documents.
3. 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. A product assessed by a UK notified body cannot then be placed on the market in the European Economic Area (EEA). There is separate guidance on when and how to use the UKNI marking online:

   https://www.gov.uk/guidance/using-the-ukni-marking
4. Manufacturers must keep technical documentation and the EU Declaration of Conformity for 10 years after the apparatus has been placed on the NI market.
5. Manufacturers must also label apparatus with their name, registered trade name or registered trade mark and address; the type batch or serial number (or other identification) and ensure that they are accompanied by relevant instructions in a language easily understood by the end user. If the end user is in NI, the language must be English. When placing apparatus on the NI market, the manufacturer must ensure that it is accompanied by information concerning the use of apparatus (see regulation 36).
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 EU 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 NI market is not in conformity with the 2016 Regulations.
8. Manufacturers must also cooperate with and provide information to enforcing authorities following any requests.

5. 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 them 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 2016 Regulations as they apply in NI, carry out tasks on the manufacturer's behalf for products placed on the NI or EEA markets.

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 written 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

For the purposes of the 2016 Regulations as they apply in NI, an importer is a business or person established in NI or the EEA who places apparatus 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 2016 Regulations if they then sell that product on the NI (or EEA) markets.

The obligations of importers include:

1. Before apparatus is placed on the NI market, an importer must ensure that it is in conformity with the essential requirements and that a relevant conformity assessment has been carried out.
2. The importer must ensure the manufacturer has drawn up technical documentation and an EU Declaration of Conformity; the apparatus is CE marked[4] and is accompanied by the required documents and information regarding the manufacturer.
3. 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. A product with the CE UKNI marking cannot then be placed on the market in the EEA. There is separate guidance on when and how to use the UKNI marking online:

   https://www.gov.uk/guidance/using-the-ukni-marking
4. The importer must keep a copy of the EU Declaration of Conformity and technical documentation for a period of 10 years after the apparatus has been placed on the NI market.

[4] The CE marking must be visibly, legibly and indelibly affixed to the equipment. Where it is not possible or warranted, on account of the nature of the equipment, to affix the CE marking to the equipment, it must be affixed to the packaging and the accompanying documents.

5. The importer must provide their name trade, registered trade name and a postal address at which they can be contacted on the apparatus or, where that is not possible, on the packaging or in an accompanying document.
6. 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 where it is to be made available. If the end user is in NI, that language must be English.
7. The importer must ensure that apparatus under their responsibility are safely stored and transported, remaining in conformity with the legal requirements of the 2016 Regulations.
8. The importer must take action where they have reason to believe that the apparatus that they have placed on the NI market is not in conformity with the legal requirements of the 2016 Regulations.
9. The importer must also cooperate with and provide information to enforcing authorities following any requests.

7. Obligations of distributors

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

NI businesses which were distributors of apparatus supplied to them from GB should now consider whether they are classified as importers under the 2016 Regulations and therefore what additional requirements they need to comply with – see section 6 above. Under the 2016 Regulations an NI business placing a product from GB on the NI market does so as an importer, not as a distributor.

The obligations of distributors include:

1. When making apparatus available on the NI market, a distributor must act with due care to ensure that it is in conformity with Part 2 of the 2016 Regulations, 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. The distributor must verify that the apparatus bears the CE marking[5], is accompanied by the required documents as well as by instructions and information concerning the use of apparatus. The distributor must also make sure that the obligations on the manufacturer or importer regarding their identification has been complied with.
3. The distributor must not make apparatus available on the NI market if they think it is not in conformity with the essential requirements. They must take action where they have reason to believe that the apparatus that they have made available on the NI 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] When conformity assessment has been carried out by a UK notified body, the UKNI marking (also known as the UK(NI) indication) must also be affixed.

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 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; 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 market before 1 January 2021.

9. Conformity Marking

Where apparatus 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.

Tthe 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 special rules under unfettered access that apply for qualifying NI goods.

For qualifying NI goods, apparatus meeting NI rules (i.e. the 2016 Regulations) and which are CE or CE 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 apparatus on the GB market).

Apparatus 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 apparatus conformity assessed by a UK notified body, the CE marking must be accompanied by the UKNI marking. 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

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. Apparatus that can be placed on the NI market in accordance with the 2016 Regulations, can be sold in the rest of the UK without any additional approvals. The guide to placing apparatus on the GB market has further details on these arrangements.

You can find out more about qualifying Northern Ireland goods here:

https://www.gov.uk/guidance/moving-qualifying-goods-from-northern-ireland-to-the-rest-of-the-uk

11. 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 2016 Regulations.

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 apply both the CE and UKNI markings. A product with both the CE and UKNI markings cannot then be placed on the EEA 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

A list of EU Notified Bodies can be found on the NANDO website. Economic operators are free to select any suitable Notified Body from any Member State. If a manufacturer uses a Notified Body from this list, then they apply only the CE marking to their product (not the CE UKNI marking).

A list of UK Notified Bodies is available here:

https://www.gov.uk/uk-market-conformity-assessment-bodies

12. Enforcement and penalties

In NI, district councils have a duty to carry out market surveillance. Enforcement of the 2016 Regulations for apparatus in relation to protection and management of the radio spectrum is the duty of OFCOM and for other apparatus the Department for Enterprise, Trade and Investment.

In NI, enforcement of the Regulations as they apply to electricity meters (other than wireless telegraphy apparatus) is carried out by the Northern Ireland Authority for Energy Regulation.

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) which sets out requirements for market surveillance of products.

The 2016 Regulations provide powers to enforcing authorities 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 regulation 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.

Safeguard procedure

Enforcement authorities are required under the 2016 Regulations 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 take action 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 UK 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 equipment is withdrawn from the market.

Regulators' Code

Market Surveillance authorities must 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:

https://www.gov.uk/government/publications/regulators-code

Penalties

A person committing an offence under the 2016 Regulations will 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.

While it is matter for the enforcement authority to decide whether prosecution is appropriate in each case, should a prosecution take place, and the economic operator is found to be in breach, it is at discretion of the court to decide the penalties imposed on the offender.

13. European Commission Guidance

Detailed guidance on the EMC Directive can be found on the European Commission's website at:

https://ec.europa.eu/growth/sectors/electrical-engineering/emc-directive_en

The European Commission has produced guidance called the Blue Guide intended to contribute to a better understanding of EU product safety rules and to their more uniform and coherent application across different sectors and throughout the single market. A copy can be found at this link:

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

14. 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 Northern Ireland, when enforcement relates to protection and management of the radio spectrum, OFCOM is the responsible for enforcement. The Department of Enterprise, Trade and Investment is also an enforcing authority. The Secretary of State may also enforce the Regulations.
- **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 apparatus 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/government/publications/electromagnetic-compatibility-regulations-2016

Contact us if you have any enquiries about this publication, including requests for alternative formats, at: OPSS.enquiries@beis.gov.uk

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