STATUTORY INSTRUMENTS

2016 No. 1091

The Electromagnetic Compatibility Regulations 2016

PART 2

Obligations of economic operators

Essential requirements

7. A person must not make equipment available on the market or put equipment into service unless it complies with the essential requirements.

Manufacturers

Duty to ensure apparatus complies with the essential requirements

8. Before placing apparatus on the market, a manufacturer must ensure that it has been designed and manufactured in accordance with the essential requirements.

Technical documentation and conformity assessment

9. Before placing apparatus on the market, a manufacturer must—

(a) carry out a relevant conformity assessment procedure in respect of the apparatus or have such a procedure carried out; and

(b) draw up—

(i) the technical documentation referred to in Schedule 2 (module A: internal production control) or Schedule 3 (module B: EU-type examination and module C: conformity to type based on internal production control); and

(ii) any other technical documentation required as part of the relevant conformity assessment procedure to demonstrate the means used by the manufacturer to ensure that the apparatus complies with the essential requirements.

EU declaration of conformity and CE marking

10.—(1) Where the conformity of apparatus with the essential requirements has been demonstrated by a relevant conformity assessment procedure, the manufacturer must, before placing the apparatus on the market—

(a) draw up an EU declaration of conformity in accordance with regulation 41 (EU declaration of conformity); and

(b) affix the CE marking in accordance with regulation 42 (CE marking).

(2) The manufacturer must keep the EU declaration of conformity up-to-date.

(3) Where apparatus is subject to more than one EU instrument requiring a declaration of conformity to be drawn up, the manufacturer must draw up a single declaration of conformity, which—

(a) identifies the EU instruments; and

(b) includes references to the publication of those EU instruments in the Official Journal.

Retention of technical documentation and EU declaration of conformity

11. A manufacturer must keep the technical documentation and the EU declaration of conformity (as referred to in regulation 41) drawn up in respect of the apparatus for a period of 10 years beginning on the day on which the apparatus is placed on the market.

Compliance procedures for series production

12.—(1) A manufacturer of apparatus which is manufactured by series production must ensure that, before placing apparatus on the market, procedures are in place to ensure that any apparatus will be in conformity with Part 2.

(2) In doing so, the manufacturer must take adequate account of—

(a) any change in the design or characteristics; and

(b) any change in a harmonised standard or in another technical specification by reference to which the EU declaration of conformity was drawn up.

Information identifying manufacturer

13.—(1) Before placing apparatus onto the market, a manufacturer ("M") must ensure that the following appear on the apparatus—

(a) a type, batch or serial number or an element which identifies M as the manufacturer of the apparatus;

(b) the name, registered trade name or registered trade mark of the manufacturer; and

(c) a postal address at which the manufacturer can be contacted.

(2) The manufacturer must include the relevant information specified in paragraph (1) on the packaging of the apparatus or in a document accompanying the apparatus where—

(a) due to the size or nature of the apparatus, it is not possible for the information in paragraph (1)(a) to appear on the apparatus; or

(b) it is not possible for the information in paragraphs (1)(b) or (1)(c) to appear on the apparatus.

(3) The postal address in paragraph (1)(c) must indicate a single point at which the manufacturer can be contacted.

(4) The information specified in paragraphs (1)(b) and (1)(c) must be in a language which can be easily understood by end-users and the competent national authority in the member State in which it is to be made available to such end-users.

Instructions and information

14.—(1) When placing apparatus on the market, a manufacturer must ensure that the apparatus is accompanied by instructions and the information referred to in regulation 36 (information concerning the use of apparatus) which—

(a) is in a language that can be easily understood by consumers and other end-users in the member State in which the apparatus is to be made available; and

(b) is clear and understandable.

(2) When the apparatus is being made available to consumers and other end-users in the United Kingdom, the language referred to in paragraph (1)(a) is English.

Manufacturer's duty to take action in respect of apparatus placed on the market which is considered not to be in conformity

15.—(1) A manufacturer who considers, or has reason to believe, that apparatus which the manufacturer has placed on the market is not in conformity with Part 2 must immediately take the corrective measures necessary to—

(a) bring the apparatus into conformity;

(b) withdraw the apparatus; or

(c) recall the apparatus.

(2) Where the apparatus presents a risk, the manufacturer must immediately inform the market surveillance authority, and the competent national authorities of any other member State in which the manufacturer has made the apparatus available on the market, giving details of, in particular—

(a) the respect in which the apparatus is considered not to be in conformity with Part 2; and

(b) any corrective measures taken.

Provision of information and co-operation

16.—(1) A manufacturer must, when requested by an enforcing authority and within such period as the authority may specify, provide the authority with all of the information and documentation necessary to demonstrate the conformity of the apparatus with Part 2.

(2) A request made under paragraph (1) must be accompanied by the reasons for making the request.

(3) The information and documentation referred to in paragraph (1)—

(a) may be provided in paper or electronic form; and

(b) must be in a language that can be easily understood by the enforcing authority.

(4) The manufacturer must, at the request of the enforcing authority, co-operate with the authority on any action taken to—

(a) evaluate the apparatus in accordance with regulation 56 (evaluation of apparatus presenting a risk);

(b) eliminate the risks posed by apparatus that the manufacturer has placed on the market.

Importers

Prohibition on placing apparatus on the market which is not in conformity

17. An importer must not place apparatus on the market unless it is in conformity with the essential requirements.

Requirements that must be satisfied before an importer places apparatus on the market

18.—(1) Before placing apparatus on the market an importer must ensure that—

(a) a relevant conformity assessment has been carried out by the manufacturer;

(b) the manufacturer has drawn up the technical documentation;

(c) the apparatus—

(i) bears the CE marking; and

(ii) is accompanied by the required documents; and

(d) the manufacturer has complied with the requirements of regulation 13 (information identifying manufacturer).

(2) In paragraph (1)(c)(ii) "required documents" means any documents that are required to be provided pursuant to regulation 13(2).

Duty not to place non-conforming apparatus on the market

19.—(1) Where an importer considers or has reason to believe that apparatus is not in conformity with the essential requirements, the importer must not place the apparatus on the market.

(2) Where apparatus presents a risk, the importer must inform the manufacturer and the market surveillance authority of that risk.

Information identifying importer

20.—(1) An importer must, before placing apparatus on the market, ensure that the following appear on the apparatus or, where that is not possible, on the packaging of the apparatus or in a document accompanying the apparatus—

(a) the name, registered trade name or registered trade mark of the importer; and

(b) a postal address at which the importer can be contacted.

(2) The information specified in paragraph (1) must be in a language which can be easily understood by end-users and the competent national authority in the member State in which it is to be made available.

Instructions and information

21.—(1) When placing apparatus on the market, an importer must ensure that the apparatus is accompanied by instructions and the information referred to in regulation 36 (information concerning the use of apparatus) which is in a language which can be easily understood by consumers and other end-users in the member State in which the apparatus is to be made available.

(2) When the apparatus is being made available to consumers and other end-users in the United Kingdom, the language referred to in paragraph (1) is English.

Storage and transport

22. Where an importer has responsibility for apparatus, the importer must ensure that the conditions under which the apparatus is stored or transported do not jeopardise its conformity with the essential requirements.

Importer's duty to take action in respect of apparatus placed on the market which is considered not to be in conformity

23.—(1) An importer who considers or has reason to believe that apparatus that the importer has placed on the market is not in conformity with Part 2 must immediately take the corrective measures necessary to—

(a) bring the apparatus into conformity;

(b) withdraw the apparatus; or

(c) recall the apparatus.

(2) Where the apparatus presents a risk, the importer must immediately inform the market surveillance authority and the competent authorities of any member State in which the importer has made the apparatus available on the market of the risk, giving details of—

(a) the respect in which the apparatus is considered not to be in conformity with Part 2; and

(b) any corrective measures taken.

Retention of technical documentation and EU declaration of conformity

24. An importer must keep the technical documentation and the EU declaration of conformity (as referred to in regulation 41) drawn up in respect of the apparatus for a period of 10 years beginning on the day on which the apparatus is placed on the market.

Provision of information and co-operation

25.—(1) An importer must, when requested by an enforcing authority and within such period as the authority may specify, provide the authority with all of the information and documentation necessary to demonstrate the conformity of the apparatus with Part 2.

(2) A request made under paragraph (1) must be accompanied by the reasons for making the request.

(3) The information and documentation referred to in paragraph (1) —

(a) may be provided in paper or electronic form; and

(b) must be in a language that can be easily understood by the enforcing authority.

(4) An importer must, at the request of the enforcing authority, co-operate with the authority on any action taken to—

(a) evaluate the apparatus in accordance with regulation 56 (evaluation of apparatus presenting a risk); and

(b) eliminate the risks posed by apparatus that importer has placed on the market.

Distributors

Duty to act with due care

26. When making apparatus available on the market, a distributor must act with due care to ensure that it is in conformity with Part 2.

Making available on the market

27.—(1) Before making apparatus available on the market, a distributor must verify that—

(a) the apparatus—

(i) bears the CE marking;

(ii) is accompanied by the required documents;

(iii) is accompanied by instructions and the information referred to in regulation 36 (information concerning the use of apparatus) which is in a language which can be easily understood by consumers and other end-users in the member State in which the apparatus is to be made available on the market;

(b) the manufacturer has complied with the requirements of regulation 13 (information identifying manufacturer); and

(c) the importer has complied with the requirements of regulation 20 (information identifying importer).

(2) In paragraph (1)(a)(ii) "required documents" means any documents that are required to be provided pursuant to regulation 13(2).

Duty not to make non-conforming apparatus available on the market

28.—(1) Where a distributor considers or has reason to believe that apparatus is not in conformity with the essential requirements, the distributor must not make the apparatus available on the market.

(2) Where apparatus presents a risk, the distributor must inform the manufacturer and the market surveillance authority of that risk.

Storage and transport

29. Where a distributor has responsibility for apparatus, the distributor must ensure that the conditions under which the apparatus is stored or transported do not jeopardise its conformity with the essential requirements.

Duty to take action in respect of apparatus placed on the market or made available on the market which is considered not to be in conformity

30.—(1) A distributor who considers or has reason to believe that apparatus that the distributor has made available on the market is not in conformity with Part 2 must immediately take the corrective measures necessary to—

(a) bring the apparatus into conformity;

(b) to withdraw the apparatus; or

(c) recall the apparatus.

(2) Where the apparatus presents a risk, the distributor must immediately inform the market surveillance authority and the competent authorities of any other member State in which the distributor has made the apparatus available on the market of the risk, giving details of—

(a) the respect in which the apparatus is not considered to be in conformity with Part 2; and

(b) any corrective measures taken.

Provision of information and co-operation

31.—(1) A distributor must, when requested by an enforcing authority and within such period as the authority may specify, provide the authority with all of the information and documentation necessary to demonstrate the conformity of the apparatus with Part 2.

(2) A request referred to in paragraph (1) must be accompanied by the reasons for making the request.

(3) The information and documentation referred to in paragraph (1) —

(a) may be provided in paper or electronic form; and

(b) must be in a language that can be easily understood by the enforcing authority.

(4) A distributor must, at the request of the enforcing authority, co-operate with the authority on any action taken to—

(a) evaluate the apparatus in accordance with regulation 56 (evaluation of apparatus presenting a risk); and

(b) eliminate the risks posed by apparatus that they have made available on the market.

All economic operators

Cases in which the obligations of manufacturers apply to importers and distributors

32. An economic operator ("A") who would, but for this regulation, be considered an importer or distributor, is to be considered a manufacturer for the purposes of these Regulations and is subject to the obligations of a manufacturer under Part 2, where A—

(a) places apparatus on the market under A's own name or trademark; or

(b) modifies apparatus already placed on the market in such a way that it may affect whether the apparatus is in conformity with Part 2.

Identification of economic operators

33.—(1) An economic operator ("E"), who receives a request in relation to apparatus from the market surveillance authority before the end of the relevant period, must, within such period as the authority may specify, identify to the authority—

(a) any other economic operator who has supplied E with apparatus; and

(b) any other economic operator to whom E has supplied apparatus.

(2) The relevant period is—

(a) in the case of paragraph (1)(a), the period of 10 years beginning on the day on which E was supplied with the apparatus;

(b) in the case of paragraph (1)(b), the period of 10 years beginning on the day on which E supplied the apparatus.

Translation of EU declaration of conformity

34.—(1) Before placing apparatus on the market or making apparatus available on the market, an economic operator must ensure that the EU declaration of conformity is prepared in, or translated into, the language required by the member State in which it is to be placed on the market or made available on the market.

(2) Where the apparatus is to be placed on the market or made available on the market in the United Kingdom, the language referred to in paragraph (1) is English.

Prohibition on improper use of CE marking

35.—(1) An economic operator must not affix the CE marking to apparatus unless—

(a) that economic operator is the manufacturer of the apparatus; and

(b) the conformity of apparatus with the essential requirements has been demonstrated by a relevant conformity procedure.

(2) An economic operator must not affix a marking (other than CE marking) to equipment which purports to attest to the conformity of the equipment with the essential requirements.

(3) An economic operator must not affix to equipment a marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the CE marking.

(4) An economic operator must not affix to equipment any other marking if the visibility, legibility and meaning of the CE marking would be impaired as a result.

Information concerning the use of apparatus

36.—(1) A person who places apparatus on the market must provide with the apparatus—

(a) information on any specific precautions which must be taken during assembly, installation, maintenance or use to ensure that the apparatus will be in conformity with the requirements of paragraph 1 of Schedule 1 when it is put into service;

(b) information on the restrictions on the use of the apparatus in residential areas where the conformity of the apparatus with paragraph 1 of Schedule 1 cannot be ensured; and

(c) information required to enable the apparatus to be used in accordance with its intended purpose.

(2) Where appropriate, the information referred to in paragraph (1)(b) must also be included on the packaging of the apparatus.

Fixed installations

37.—(1) Subject to paragraph (2), apparatus that has been made available on the market and which can be incorporated into a fixed installation is subject to all of the relevant provisions for apparatus in these Regulations.

(2) Where apparatus is intended for incorporation into a particular fixed installation and is not otherwise made available on the market, the requirements of Part 2 and Part 3 do not apply.

(3) A person who places apparatus of the type referred to in paragraph (2) on the market must provide information with the apparatus which—

(a) identifies the fixed installation in which it is to be incorporated and the electromagnetic compatibility characteristics of that fixed installation;

(b) sets out the precautions to be taken when the apparatus is incorporated into the fixed installation to ensure the conformity of the installation with Part 2;

(c) includes the information referred to in—

(i) regulation 13 (information identifying manufacturer); and

(ii) if relevant, regulation 20 (information identifying importer).

(4) The good engineering practices referred to in paragraph 2 of Schedule 1 must be documented and the documentation held by the person who installed the fixed installation during the period of operation of the fixed installation.

(5) The person referred to in paragraph (4) must ensure that the documentation can be made available to the relevant national authorities upon request during the period of operation of that fixed installation.

(6) Where the enforcing authority has received complaints about disturbances being generated by the fixed installation or has reason to believe that a fixed installation may not be in conformity with these Regulations, the enforcing authority may request evidence of conformity of the fixed installation and may initiate an evaluation of the fixed installation.

(7) Where the enforcing authority considers that the evaluation referred to in paragraph (6) has established that the fixed installation is not in conformity with these Regulations, the enforcing authority must ensure that appropriate measures are taken to ensure that the fixed installation is brought into conformity with the essential requirements in Schedule 1.

(8) The person referred to in paragraph (4) is responsible for ensuring that the installation is in conformity with the relevant essential requirements.

Authorised representatives

Appointment of an authorised representative

38.—(1) A manufacturer may, by written mandate, appoint a person as their authorised representative to perform specified tasks on the manufacturer's behalf.

(2) The mandate must allow the authorised representative to do at least the following in relation to apparatus covered by the mandate—

(a) perform the manufacturer's obligations under regulation 11 (retention of technical documentation and EU declaration of conformity);

(b) perform the manufacturer's obligations under regulation 16 (provision of information and co-operation).

(3) The mandate must not include the obligations contained in—

(a) regulation 8 (duty to ensure apparatus complies with the essential requirements); or

(b) regulation 9 (technical documentation and conformity assessment).

(4) A manufacturer who has appointed an authorised representative to perform, on the manufacturer's behalf, a task under these Regulations remains responsible for the proper performance of that task.

(5) An authorised representative must comply with all the duties imposed on the manufacturer in relation to each obligation under these Regulations that the representative is appointed by the mandate to perform and accordingly—

(a) as far as those duties are concerned, a reference in these Regulations to the manufacturer (except in this regulation) is to be taken as including a reference to the authorised representative; and

(b) if the authorised representative contravenes or fails to comply with any of those duties, the authorised representative may be proceeded against as though the authorised representative were the manufacturer.