
STATUTORY INSTRUMENTS

2016 No. 1091

The Electromagnetic Compatibility Regulations 2016

PART 2

Obligations of economic operators

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.