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## STATUTORY INSTRUMENTS

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# 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: <sup>[F1</sup>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.

##### Textual Amendments

**F1** Word in [reg. 9\(b\)\(i\)](#) omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), [reg. 1](#), [Sch. 20 para. 6](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

##### <sup>[F2]</sup>Declaration of conformity and <sup>[F3]</sup>UK marking **E+W+S**

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 <sup>[F4]</sup>a declaration of conformity in accordance with regulation 41 <sup>F5</sup>...; and

(b) affix the [F<sup>6</sup>UK] marking in accordance with regulation 42 ([F<sup>6</sup>UK] marking).

(2) The manufacturer must keep the F<sup>7</sup>... declaration of conformity up-to-date.

[F<sup>8</sup>(3) Where apparatus is subject to more than one enactment requiring the drawing up of a declaration of conformity, the manufacturer must draw up a single declaration of conformity which identifies each enactment concerned by its title.]

#### Extent Information

**E1** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

- F2** Word in reg. 10 heading substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 20 para. 7(a)(i)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F3** Word in reg. 10 heading substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 20 para. 7(a)(ii)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F4** Word in reg. 10(1)(a) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 20 para. 7(b)(i)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in reg. 10(1)(a) omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 20 para. 7(b)(ii)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F6** Word in reg. 10(1)(b) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 20 para. 7(c)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F7** Word in reg. 10(2) omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 20 para. 7(d)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F8** Reg. 10(3) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 20 para. 7(e)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### EU declaration of conformity and CE marking **N.I.**

**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 [F<sup>39</sup>NI Protocol obligation] requiring a declaration of conformity to be drawn up, the manufacturer must draw up a single declaration of conformity, which—

(a) identifies the [F<sup>40</sup>relevant] EU instruments; and

(b) includes references to the publication of [F<sup>41</sup>the relevant EU] instruments in the Official Journal.

### Textual Amendments

- F39** Words in [reg. 10\(3\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1112), reg. 1(b), **Sch. 8 para. 3(1)(a)**
- F40** Word in [reg. 10\(3\)\(a\)](#) inserted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1112), reg. 1(b), **Sch. 8 para. 3(1)(b)**
- F41** Words in [reg. 10\(3\)\(b\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1112), reg. 1(b), **Sch. 8 para. 3(1)(c)**

### Retention of technical documentation and [F9]EU declaration of conformity

**11.** A manufacturer must keep the technical documentation and the [F10]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.

### Textual Amendments

- F9** Word in [reg. 11](#) heading omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 20 para. 8** (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F10** Word in [reg. 11](#) omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 20 para. 8** (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### Compliance procedures for series production **E+W+S**

**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 [F11]designated standard or in another technical specification by reference to which the [F12]... declaration of conformity was drawn up.

### Extent Information

- E2** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

### Textual Amendments

- F11** Word in [reg. 12\(2\)\(b\)](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 20 para. 9(a)** (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F12** Word in [reg. 12\(2\)\(b\)](#) omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 20 para. 9(b)** (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

## Compliance procedures for series production **N.I.**

**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 **E+W+S**

**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 <sup>F13</sup>clear, legible and in easily understandable English].

### Extent Information

**E3** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

### Textual Amendments

**F13** Words in [reg. 13\(4\)](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 20 para. 10](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#))

## Information identifying manufacturer **N.I.**

**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 [<sup>F42</sup>relevant state] in which it is to be made available to such end-users.

#### Textual Amendments

**F42** Words in [reg. 13\(4\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), [reg. 1\(b\)](#), [Sch. 8 para. 3\(2\)](#)

#### Instructions and information **E+W+S**

[<sup>F14</sup>**14.** 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 are clear, legible and in clearly understandable English.]

#### Extent Information

**E4** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F14** [Reg. 14](#) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 20 para. 11](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#))

#### Instructions and information **N.I.**

**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 [<sup>F43</sup>relevant 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 [<sup>F44</sup>Northern Ireland], the language referred to in paragraph (1)(a) is English.

#### Textual Amendments

- F43** Words in [reg. 14\(1\)\(a\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), [Sch. 8 para. 3\(2\)](#)
- F44** Words in [reg. 14\(2\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), [Sch. 8 para. 3\(3\)](#)

### Manufacturer's duty to take action in respect of apparatus placed on the market which is considered not to be in conformity **E+W+S**

**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, <sup>F15</sup>... 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.

#### Extent Information

- E5** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

- F15** Words in [reg. 15\(2\)](#) omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 20 para. 12](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

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

**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 [<sup>F45</sup>relevant 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.

### Textual Amendments

- F45** Words in [reg. 15\(2\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), [reg. 1\(b\)](#), [Sch. 8 para. 3\(2\)](#)

### 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 **E** **+W+S**

**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 <sup>F16</sup>UK 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).

### Extent Information

- E6** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only



### Textual Amendments

- F16** Word in reg. 18(1)(c)(i) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 20 para. 13 (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### Requirements that must be satisfied before an importer places apparatus on the market **N.I.**

**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 **E+W+S**

**20.—**(1) An importer must, before placing apparatus on the market, ensure that the following appear on the apparatus <sup>F17</sup>...—

- (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.

[<sup>F18</sup>(1A) Paragraph (1) does not apply where—

- (a) either—
  - (i) it is not possible to set out the information referred to in paragraph (1) on the packaging of the apparatus or on the apparatus, or
  - (ii) the importer has imported the apparatus from an EEA state or Switzerland and places it on the market within the period of [<sup>F19</sup>seven years] beginning with IP completion day, and
- (b) before placing the apparatus on the market, the importer sets out the information referred to in paragraph (1) in a document accompanying the apparatus.]

(2) The information specified in paragraph (1) must be in a language which can be easily understood by end-users and the [<sup>F20</sup>enforcing authority].



### Extent Information

- E7** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

### Textual Amendments

- F17** Words in [reg. 20\(1\)](#) omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, [Sch. 20 para. 14\(a\)](#) (with [Sch. 20 para. 33](#)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F18** [Reg. 20\(1A\)](#) inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, [Sch. 20 para. 14\(b\)](#) (with [Sch. 20 para. 33](#)) (as amended by: S.I. 2019/1246, regs. 1(3), [5](#), [6](#); S.I. 2020/676, regs. 1(1), [2](#); S.I. 2020/852, regs. 2(2), 4(2), [Sch. 1 para. 1\(i\)\(iii\)](#); and S.I. 2020/1460, reg. 1(4), [Sch. 3 para. 2\(1\)\(e\)](#)); 2020 c. 1, Sch. 5 para. 1(1)
- F19** Words in [reg. 20\(1A\)\(a\)\(ii\)](#) substituted (E.W.S.) (31.12.2022) by [The Product Safety and Metrology \(Amendment and Transitional Provisions\) Regulations 2022](#) (S.I. 2022/1393), regs. 1(1), 4, [Sch. 3 para. \(g\)](#)
- F20** Words in [reg. 20\(2\)](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, [Sch. 20 para. 14\(c\)](#) (with [Sch. 20 para. 33](#)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### Modifications etc. (not altering text)

- C1** [Reg. 20](#) modified (temp.) by S.I. 2019/392, reg. 6 (as inserted (10.9.2019) by [The Product Safety, Metrology and Mutual Recognition Agreement \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/1246), regs. 1(2)(4), [2\(3\)](#) (with [reg. 18](#)))

### Information identifying importer **N.I.**

**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 [<sup>F46</sup>relevant state] in which it is to be made available.

### Textual Amendments

- F46** Words in [reg. 20\(2\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1112), reg. 1(b), [Sch. 8 para. 3\(2\)](#)

### Instructions and information **E+W+S**

**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 [<sup>F21</sup>are clear, legible and in easily understandable English].

<sup>F22</sup>(2) .....

### Extent Information

- E8** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

### Textual Amendments

- F21** Words in [reg. 21\(1\)](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 20 para. 15(a)** (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F22** [Reg. 21\(2\)](#) omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 20 para. 15(b)** (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

### Instructions and information **N.I.**

**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 [<sup>F47</sup>relevant 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 [<sup>F48</sup>Northern Ireland], the language referred to in paragraph (1) is English.

### Textual Amendments

- F47** Words in [reg. 21\(1\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 8 para. 3(2)**
- F48** Words in [reg. 21\(2\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 8 para. 3(3)**

### 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 **E+W+S**

**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 <sup>F23</sup>... 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.

#### Extent Information

- E9** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

- F23** Words in [reg. 23\(2\)](#) omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 20 para. 16](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))

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

**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 [<sup>F49</sup>relevant 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.

#### Textual Amendments

- F49** Words in [reg. 23\(2\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), [reg. 1\(b\)](#), [Sch. 8 para. 3\(2\)](#)

### Retention of technical documentation and [<sup>F24</sup>EU] declaration of conformity

**24.** An importer must keep the technical documentation and the [<sup>F25</sup>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.

#### Textual Amendments

- F24** Word in [reg. 24](#) heading omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 20 para. 17](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))
- F25** Word in [reg. 24](#) omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 20 para. 17](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))

### 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 **E+W+S**

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

- (a) the apparatus—
  - (i) bears the [<sup>F26</sup>UK] 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 [<sup>F27</sup>are clear, legible and in easily understandable English];
- (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).

#### Extent Information

**E10** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F26** Word in [reg. 27\(1\)\(a\)\(i\)](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 20 para. 18\(a\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**F27** Words in [reg. 27\(1\)\(a\)\(iii\)](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 20 para. 18\(b\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#))

## **Making available on the market** **N.I.**

**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 [<sup>F50</sup>relevant 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).

### **Textual Amendments**

**F50** Words in [reg. 27\(1\)\(a\)\(iii\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), [reg. 1\(b\)](#), [Sch. 8 para. 3\(2\)](#)

## **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** **E+W+S**

**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 <sup>F28</sup>... 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.

#### Extent Information

**E11** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F28** Words in [reg. 30\(2\)](#) omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 20 para. 19](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#))

### 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 **N.I.**

**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 [<sup>F51</sup>relevant 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.

#### Textual Amendments

**F51** Words in [reg. 30\(2\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), [reg. 1\(b\)](#), [Sch. 8 para. 3\(2\)](#)

### Provision of information and co-operation **E+W+S**

**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 [<sup>F29</sup>clear, legible and in easily understandable English].

(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.

#### Extent Information

**E12** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F29** Words in [reg. 31\(3\)\(b\)](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 20 para. 20](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#))

### Provision of information and co-operation **N.I.**

**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.**—<sup>[F30]</sup>(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 <sup>[F31]</sup>relevant 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 <sup>[F32]</sup>Northern Ireland], the language referred to in paragraph (1) is English.]

#### Textual Amendments

- F30** Reg. 34 omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 20 para. 21** (with Sch. 20 para. 33) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F31** Words in [reg. 34\(1\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 8 para. 3(2)**
- F32** Words in [reg. 34\(2\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 8 para. 3(3)**

### Prohibition on improper use of <sup>[F33]</sup>UK] marking **E+W+S**

- 35.**—(1) An economic operator must not affix the <sup>[F34]</sup>UK] 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 <sup>[F34]</sup>UK] 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 <sup>[F34]</sup>UK] marking.

(4) An economic operator must not affix to equipment any other marking if the visibility, legibility and meaning of the <sup>[F34]</sup>UK] marking would be impaired as a result.

#### Extent Information

- E13** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

### Textual Amendments

- F33** Word in [reg. 35](#) heading substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 20 para. 22](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#))
- F34** Word in [reg. 35](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 20 para. 22](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#))

### Prohibition on improper use of CE marking **N.I.**

**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 **E+W+S**

**38.**—(1) A manufacturer may, by written mandate, appoint a person [<sup>F35</sup>established in the United Kingdom] 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 <sup>F36</sup>... 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.

### Extent Information

- E14** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

### Textual Amendments

- F35** Words in [reg. 38\(1\)](#) inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 20 para. 23\(a\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F36** Word in [reg. 38\(2\)\(a\)](#) omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 20 para. 23\(b\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

### Appointment of an authorised representative **N.I.**

**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.

### <sup>F37</sup> Obligations which are met by complying with obligations in the Directive

**38A.—(1)** In this regulation—

- (a) any reference to an Article or an Annex is a reference to an Article or an Annex of the Directive;
- (b) “CE marking” has the meaning given to it in Article 3(25);
- (c) “harmonised standard” has the meaning given to it in Article 3(17).

(2) Paragraph (3) applies where, before placing apparatus on the market, the manufacturer—

- (a) ensures that the apparatus has been designed and manufactured in accordance with the essential requirements set out in Annex I;
  - (b) draws up the technical documentation relating to such apparatus referred to in Annex III;
  - (c) ensures that the relevant conformity assessment procedure relating to such apparatus referred to in Article 14 has been carried out;
  - (d) ensures that the technical documentation and other records and correspondence relating to the conformity assessment procedure are prepared in or translated into English;
  - (e) affixes a CE marking, in accordance with Articles 16 and 17(1) to (2);
  - (f) draws up an EU declaration of conformity, in accordance with Article 15; and
  - (g) ensures that the EU declaration of conformity is prepared in or translated into English.
- (3) Where this paragraph applies—
- (a) the requirements of regulations 8, 9, 10(1)(a) and (b) and (3) and 42(1) are to be treated as being satisfied;
  - (b) regulations 2(2)(a), 10(2), 11, 12, 38(2) and 35 apply subject to the modifications in paragraph (8);
  - (c) Part 4 does not apply; and
  - (d) regulation 59 does not apply.
- (4) Paragraph (5) applies where, before placing a category apparatus on the market, the importer ensures that—
- (a) the relevant conformity assessment procedure referred to in Article 14 has been carried out;
  - (b) the manufacturer has drawn up the technical documentation referred to in Annex III; and
  - (c) the apparatus bears the CE marking.
- (5) Where this paragraph applies—
- (a) the requirements of regulation 18(a) to (c) are to be treated as being satisfied; and
  - (b) regulations 2(2)(a), 17, 19(1), 22 and 24 apply subject to the modifications in paragraph (8).
- (6) Paragraph (7) applies where, before making apparatus available on the market, a distributor ensures that the apparatus bears the CE marking.
- (7) Where this paragraph applies—
- (a) regulation 27(1)(a) is to be treated as being satisfied; and
  - (b) regulations 2(2)(a), 28(1) and 29 apply subject to the modifications in paragraph (10).
- (8) The modifications referred to in sub-paragraphs (3)(b), (5)(b) and (9)(b) are that—
- (a) any reference to “declaration of conformity” is to be read as a reference to the EU declaration of conformity;
  - (b) any reference to “UK marking” is to be read as a reference to the CE marking;
  - (c) any reference to “essential requirements” is to be read as a reference to the essential safety requirements referred to in Annex I;
  - (d) any reference to “designated standard” is to be read as a reference to a harmonised standard;
  - (e) any reference to “relevant conformity assessment procedure” is to be read as a reference to the relevant conformity assessment procedures referred to in Article 14;
  - (f) any reference to “technical documentation” is a reference to the technical documentation referred to in Annex III.

#### Textual Amendments

- F37** Regs. 38A-38C inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 20 para. 24** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 12(3)**); 2020 c. 1, **Sch. 5 para. 1(1)**

#### Expiry of regulation 38A

**38B.**—(1) Subject to paragraph (2), regulation 38A ceases to have effect at the end of the period of [<sup>F38</sup>four years] beginning with IP completion day.

(2) Notwithstanding the expiry of regulation 38A—

- (a) any apparatus which was placed on the market pursuant to regulation 38A may continue to be made available on the market on or after the expiry of regulation 38A;
- (b) any obligation to which a person was subject under regulation 38A in respect of apparatus placed on the market pursuant to regulation 38A continues to have effect after the expiry of regulation 38A, in respect of that apparatus.

#### Textual Amendments

- F37** Regs. 38A-38C inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 20 para. 24** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 12(3)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F38** Words in reg. 38B(1) substituted (31.12.2022) by [The Product Safety and Metrology \(Amendment and Transitional Provisions\) Regulations 2022](#) (S.I. 2022/1393), regs. 1(1), 2, **Sch. 1 para. (j)**

#### Qualifying Northern Ireland Goods

**38C.**—(1) Where paragraph (2) applies, apparatus is to be treated as being in conformity with Part 2.

(2) This paragraph applies where—

- (a) apparatus—
  - (i) is in conformity with Part 2, as that Part applies in Northern Ireland; and
  - (ii) is qualifying Northern Ireland goods; and
- (b) an importer has complied with the obligations set out in paragraph (3).

(3) The obligations referred to in paragraph (2)(b) are that, before placing the apparatus on the market, the importer—

- (a) complies with regulation 20;
- (b) ensures that—
  - (i) the relevant conformity assessment procedure has been carried out in relation to the apparatus;
  - (ii) the manufacturer has drawn up the technical documentation; and
  - (iii) the apparatus bears the CE marking.

(4) In this regulation—

“CE marking” has the meaning given to it in regulation 2(1), as it applies in Northern Ireland;

“qualifying Northern Ireland goods” has the meaning given to it in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;

“relevant conformity assessment procedure” has the meaning given to it in regulation 2(1), as it applies in Northern Ireland;

“technical documentation” means the documentation a manufacturer must draw up, in accordance with regulation 9(b), as it applies in Northern Ireland.]

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#### Textual Amendments

- F37** Regs. 38A-38C inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 20 para. 24** (with Sch. 20 para. 33) (as amended by [S.I. 2020/676](#), regs. 1(1), 2 and [S.I. 2020/1460](#), reg. 1(4), **Sch. 3 para. 12(3)**); 2020 c. 1, **Sch. 5 para. 1(1)**



**Changes to legislation:**

There are currently no known outstanding effects for the The Electromagnetic Compatibility Regulations 2016, PART 2.