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STATUTORY INSTRUMENTS

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**2016 No. 1091**

**ELECTROMAGNETIC COMPATIBILITY**

**The Electromagnetic Compatibility Regulations 2016**

*Made* - - - - *15th November 2016*

*Laid before Parliament* *16th November 2016*

*Coming into force* - - *8th December 2016*

<sup>M1M2</sup>The Secretary of State is a Minister designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to measures relating to apparatus which is liable to cause electromagnetic disturbance and to apparatus the performance of which could be affected by such disturbance.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for certain references to provisions of EU instruments to be construed as references to those provisions as amended from time to time.

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of, and paragraph 1A <sup>M3</sup> of Schedule 2 to, the European Communities Act 1972.

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**Modifications etc. (not altering text)**

- C1** [Regulations](#) modified (E.W.S.) (19.6.2021) by [The Conformity Assessment \(Mutual Recognition Agreements\) and Weights and Measures \(Intoxicating Liquor\) \(Amendment\) Regulations 2021](#) (S.I. 2021/730), regs. 1, 4, **Sch. 1 para. 5**

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**Marginal Citations**

- M1** [S.I. 1989/2393](#), to which there are amendments not relevant to these Regulations.
- M2** [1972 c.68](#); section 2(2) was amended by section 27(1) of the [Legislative and Regulatory Reform Act 2006](#) (c.51) and by Part 1 of the Schedule to the [European Union \(Amendment\) Act 2008](#) (c.7). The enabling powers of section 2(2) were extended by virtue of the amendment of section 1(2) by section 1 of the [European Economic Area Act 1993](#) (c.51).
- M3** Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 and amended by Part 1 of the Schedule to the European Union (Amendment) Act 2008.

## PART 1

### Citation and commencement

1. These Regulations may be cited as the Electromagnetic Compatibility Regulations 2016 and come into force on 8th December 2016.

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

2.—(1) In these Regulations—

the “1987 Act” means the Consumer Protection Act 1987 <sup>M4</sup>;

the “2006 Regulations” means the Electromagnetic Compatibility Regulations 2006 <sup>M5</sup>;

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[<sup>F3</sup>“approved body” has the meaning given in regulation 43 (approved bodies);]

“apparatus” means any finished appliance or combination thereof made available on the market as a single functional unit, intended for the end-user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance and includes—

- (a) components or sub-assemblies intended for incorporation into an apparatus by an end-user, which are liable to generate or be affected by electromagnetic disturbance;
- (b) a mobile installation defined as a combination of apparatus and, where applicable, other devices, intended to be moved and operated in a range of locations;

“authorised representative” means a person established within the [<sup>F4</sup>United Kingdom] appointed in accordance with regulation 38 (appointment of an authorised representative);

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“conformity assessment” means the process demonstrating whether the essential requirements relating to apparatus have been fulfilled;

“conformity assessment body” means a body that performs conformity assessment activities;

[<sup>F7</sup>“conformity assessment procedure” means a procedure referred to in regulation 40;]

[<sup>F7</sup>“declaration of conformity” means a declaration of conformity required to be drawn up in accordance with regulation 10(1)(a) (declaration of conformity and UK marking);]

[<sup>F7</sup>“designated standard” has the meaning given to it in regulation 2A;]

“the Directive” means Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of laws of the Member States relating to electromagnetic compatibility (recast) <sup>M6</sup>[<sup>F8</sup>(as it has effect immediately before IP completion day)];

“distributor” means any person in the supply chain, other than the manufacturer, authorised representative or importer, who makes apparatus available on the market;

“district council” means a district council within the meaning of the Local Government Act (Northern Ireland) 1972 <sup>M7</sup>;

“economic operator” means a manufacturer, authorised representative, importer or distributor;

“electromagnetic compatibility” means the ability of equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to other equipment in that environment;

“electromagnetic disturbance” means any electromagnetic phenomenon which may degrade the performance of equipment; an electromagnetic disturbance may be electromagnetic noise, an unwanted signal or a change in the propagation medium itself;

“electromagnetic environment” means all electromagnetic phenomena observable in a given location;

“enforcing authority” is to be interpreted in accordance with regulation 52 (designation of enforcing authorities);

“equipment” means any apparatus or fixed installation;

“essential requirements” means the requirements set out in Schedule 1;

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“European Commission” means the Commission of the European Union;

“fixed installation” means a particular combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently, at a predefined location;

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“immunity” means the ability of equipment to perform as intended without degradation in the presence of electromagnetic disturbance;

[<sup>F12</sup>“importer” means a person who—

- (a) is established in the United Kingdom and places apparatus from a country outside of the United Kingdom on the market; or
- (b) is established in Northern Ireland and places apparatus on the market that has been supplied to them for distribution, consumption or use in the course of a commercial activity, whether in return for payment or free of charge, from an EEA state;]

“make available on the market” means any supply of apparatus for distribution or use on the [<sup>F13</sup>market of Great Britain] in the course of a commercial activity, whether in return for payment or free of charge, and related expressions must be construed accordingly;

“manufacturer” means a person who—

- (a) manufactures apparatus or has apparatus designed or manufactured; and
- (b) markets that apparatus under that person's name or trademark;

“market surveillance authority” has the meaning given in regulation 53 (designation of market surveillance authorities);

“mobile installation” means a combination of apparatus and, where applicable, other devices, which are intended to be moved and operated in a range of locations;

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“OFCOM” means the Office of Communications established under the Office of Communications Act 2002 <sup>M8</sup>;

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“place on the market” means the first making available of apparatus on the [<sup>F18</sup>market of Great Britain], and related expressions must be construed accordingly;

“put into service” means the first use of equipment in the [<sup>F19</sup>United Kingdom market] by its end-user for the purposes for which it was intended, and related expressions must be construed accordingly;

“RAMS” means Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93<sup>M9</sup>;

“recall” means any measure aimed at achieving the return of apparatus that has already been made available to the end-user, and related expressions must be construed accordingly;

“relevant conformity assessment procedure” means a conformity assessment procedure referred to in regulation 40 (conformity assessment procedures);

“relevant economic operator” means, in relation to apparatus, an economic operator with obligations in respect of that apparatus under Part 2;

“technical specification” means a document that prescribes technical requirements to be fulfilled by the equipment;

[<sup>F20</sup>“UK marking” means the marking in the form set out in Annex 2 of RAMS;]

[<sup>F20</sup>“UK national accreditation body” means the body appointed by the Secretary of State in accordance with Article 4 of RAMS;]

“weights and measures authority” means a local weights and measures authority within the meaning set out in section 69 of the Weights and Measures Act 1985<sup>M10</sup>;

“withdrawal” means any measure aimed at preventing apparatus in the supply chain from being made available on the market, and related expressions must be construed accordingly.

(2) In these Regulations, a reference to apparatus or equipment being “in conformity with Part 2” means that—

- (a) the apparatus or equipment is in conformity with the essential requirements; and
- (b) each relevant economic operator has complied with the obligations imposed on them under Part 2 which must be satisfied at or before the time at which they make the apparatus or equipment available on the market.

(3) In these Regulations, “risk” means a risk to [<sup>F21</sup>the protections against electromagnetic disturbance referred to in these Regulations].

<sup>F22</sup>(4) .....

<sup>F22</sup>(5) .....

#### 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
- F1** Words in [reg. 2\(1\)](#) 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. 2\(2\)\(a\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F2** Words in [reg. 2\(1\)](#) 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. 2\(2\)\(b\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

- F3** Words in reg. 2(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. 2(2)(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)
- F4** Words in reg. 2(1) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(2), **Sch. 5 para. 1(1)(a)**
- F5** Words in reg. 2(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. 2(2)(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)
- F6** Words in reg. 2(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. 2(2)(f)** (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** Words in reg. 2(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. 2(2)(g)** (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** Words in reg. 2(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. 2(2)(h)** (as amended by The Product Safety and Metrology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/852), regs. 2(2), 4(2), Sch. 1 para. 1(i), (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)
- F9** Words in reg. 2(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. 2(2)(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)
- F10** Words in reg. 2(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. 2(2)(j)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F11** Words in reg. 2(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. 2(2)(k)** (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** Words in reg. 2(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. 2(2)(l)** (as substituted by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 12(2)**) (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F13** Words in reg. 2(1) substituted (31.12.2020) by S.I. 2019/696, **Sch. 20 para. 2(2)(m)** (as substituted by The Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 (S.I. 2020/676), regs. 1(1), **4(8)(a)**)
- F14** Words in reg. 2(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. 2(2)(n)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F15** Words in reg. 2(1) omitted (26.12.2017) by virtue of The Radio Equipment Regulations 2017 (S.I. 2017/1206), regs. 1, **81(2)(a)** (with regs. 3-5, 77)
- F16** Words in reg. 2(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. 2(2)(o)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F17** Words in reg. 2(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. 2(2)(p)** (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** Words in reg. 2(1) substituted (31.12.2020) by S.I. 2019/696, Sch. 20 para. 2(2)(q) (as substituted by The Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 (S.I. 2020/676), regs. 1(1), **4(8)(b)**)

- F19** Words in [reg. 2\(1\)](#) 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. 2(2)(r)** (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F20** Words in [reg. 2\(1\)](#) 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. 2(2)(s)** (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F21** Words in [reg. 2\(3\)](#) 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. 2(3)** (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. 2\(4\)\(5\)](#) 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. 2(4)** (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Marginal Citations

- M4** [1987 c.43.](#)
- M5** [S.I. 2006/3418.](#)
- M6** [OJ L 96](#), 29.3.2014, p. 79.
- M7** [1972 c.9.](#)
- M8** [2002 c.11.](#)
- M9** [OJ L 218](#), 13.8.2008, p. 30.
- M10** [1985 c.72](#); section 69 was amended by Schedule 1 to the [Statute Law \(Repeals\) Act 1989](#) (c.43); paragraph 75 of Schedule 16 to the [Local Government \(Wales\) Act 1994](#) (c.19); and paragraph 144 of Schedule 13 to the Local Government etc. (Scotland) Act 1994 (c.39).

#### Interpretation **N.I.**

##### 2.—(1) In these Regulations—

the “1987 Act” means the Consumer Protection Act 1987 ;

the “2006 Regulations” means the Electromagnetic Compatibility Regulations 2006 ;

“accreditation” means accreditation as defined in paragraph 10 of Article 2 of RAMS (as amended from time to time);

“accreditation certificate” means a certificate, issued by the United Kingdom Accreditation Service (a company limited by guarantee incorporated in England and Wales under number 03076190) or a national accreditation body in another [<sup>F188</sup>relevant state], attesting that a conformity assessment body meets the notified body requirements;

“apparatus” means any finished appliance or combination thereof made available on the market as a single functional unit, intended for the end-user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance and includes—

- components or sub-assemblies intended for incorporation into an apparatus by an end-user, which are liable to generate or be affected by electromagnetic disturbance;
- a mobile installation defined as a combination of apparatus and, where applicable, other devices, intended to be moved and operated in a range of locations;

“authorised representative” means a person established within the [<sup>F189</sup>relevant market] appointed in accordance with regulation 38 (appointment of an authorised representative);

“CE marking” means a marking which takes the form set out in Annex II of RAMS (as amended from time to time);

“competent national authority” means an authority having responsibility for enforcing the law of a [F190relevant state] which implements the Directive;

“conformity assessment” means the process demonstrating whether the essential requirements relating to apparatus have been fulfilled;

“conformity assessment body” means a body that performs conformity assessment activities;

“the Directive” means Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of laws of the Member States relating to electromagnetic compatibility (recast) ;

“distributor” means any person in the supply chain, other than the manufacturer, authorised representative or importer, who makes apparatus available on the market;

“district council” means a district council within the meaning of the Local Government Act (Northern Ireland) 1972 ;

“economic operator” means a manufacturer, authorised representative, importer or distributor;

“electromagnetic compatibility” means the ability of equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to other equipment in that environment;

“electromagnetic disturbance” means any electromagnetic phenomenon which may degrade the performance of equipment; an electromagnetic disturbance may be electromagnetic noise, an unwanted signal or a change in the propagation medium itself;

“electromagnetic environment” means all electromagnetic phenomena observable in a given location;

“enforcing authority” is to be interpreted in accordance with regulation 52 (designation of enforcing authorities);

“equipment” means any apparatus or fixed installation;

“essential requirements” means the requirements set out in Schedule 1;

“EU declaration of conformity” means a declaration of conformity required to be drawn up in accordance with regulation 10(1)(a) (EU declaration of conformity and CE marking);

“EU harmonisation legislation” means any EU legislation harmonising the conditions for the marketing of apparatus;

“European Commission” means the Commission of the European Union;

“fixed installation” means a particular combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently, at a predefined location;

“harmonised standard” has the meaning given by Article 2(1)(c) of Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation (as amended from time to time);

“immunity” means the ability of equipment to perform as intended without degradation in the presence of electromagnetic disturbance;

“importer” means any person established within the [F191relevant market] who places apparatus from a [F192market outside of the relevant market on the relevant] market;

“make available on the market” means any supply of apparatus for distribution or use on the [F193relevant] market in the course of a commercial activity, whether in return for payment or free of charge, and related expressions must be construed accordingly;

“manufacturer” means a person who—

(a) manufactures apparatus or has apparatus designed or manufactured; and



(b) markets that apparatus under that person's name or trademark;

“market surveillance authority” has the meaning given in regulation 53 (designation of market surveillance authorities);

“mobile installation” means a combination of apparatus and, where applicable, other devices, which are intended to be moved and operated in a range of locations;

“national accreditation body” has the meaning set out in point 11 of Article 2 of RAMS (as amended from time to time);

[<sup>F194</sup>“NI Protocol obligation” means any obligation created or arising by or under the Protocol on Ireland/ Northern Ireland in the EU withdrawal agreement, whether or not an obligation to which section 7A(2) of the European Union (Withdrawal) Act 2018 applies;]

...

“notified body requirements” means the requirements set out in Schedule 5 (requirements for notified bodies);

“OFCOM” means the Office of Communications established under the Office of Communications Act 2002 ;

“Official Journal” means the Official Journal of the European Union;

“place on the market” means the first making available of apparatus on the [<sup>F195</sup>relevant] market, and related expressions must be construed accordingly;

“put into service” means the first use of equipment in the [<sup>F196</sup>relevant market] by its end-user for the purposes for which it was intended, and related expressions must be construed accordingly;

“RAMS” means Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 ;

“recall” means any measure aimed at achieving the return of apparatus that has already been made available to the end-user, and related expressions must be construed accordingly;

“relevant conformity assessment procedure” means a conformity assessment procedure referred to in regulation 40 (conformity assessment procedures);

“relevant economic operator” means, in relation to apparatus, an economic operator with obligations in respect of that apparatus under Part 2;

[<sup>F197</sup>“relevant market” means—

- (a) the market in Northern Ireland; and
- (b) the market of the EEA states;]

[<sup>F197</sup>“relevant state” means—

- (a) Northern Ireland; or
- (b) any EEA state;]

“technical specification” means a document that prescribes technical requirements to be fulfilled by the equipment;

[<sup>F198</sup>“UK(NI) indication” means the marking in the form set out in Schedule 1 to the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020;]

“weights and measures authority” means a local weights and measures authority within the meaning set out in section 69 of the Weights and Measures Act 1985 ;



“withdrawal” means any measure aimed at preventing apparatus in the supply chain from being made available on the market, and related expressions must be construed accordingly.

(2) In these Regulations, a reference to apparatus or equipment being “in conformity with Part 2” means that—

- (a) the apparatus or equipment is in conformity with the essential requirements; and
- (b) each relevant economic operator has complied with the obligations imposed on them under Part 2 which must be satisfied at or before the time at which they make the apparatus or equipment available on the market.

(3) In these Regulations, “risk” means a risk to aspects of public interest protection referred to in the Directive.

(4) .....

[<sup>F199</sup>(5) In these Regulations (except Part 4 (notification of conformity assessment bodies) and Schedules 5 (requirements for notified bodies) and 6 (operational obligations of notified bodies)), “notified body” means—

- (a) a notified body within the meaning set out in regulation 43 (notified bodies), or
- (b) a notified body under the laws of any other [<sup>F200</sup>relevant state] which implements the Directive.]

**F188** Words in [reg. 2\(1\)](#) 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. 2\(1\)\(a\)\(i\)](#)

**F189** Words in [reg. 2\(1\)](#) 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. 2\(1\)\(b\)](#)

**F190** Words in [reg. 2\(1\)](#) 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. 2\(1\)\(a\)\(ii\)](#)

**F191** Words in [reg. 2\(1\)](#) 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. 2\(1\)\(c\)\(i\)](#)

**F192** Words in [reg. 2\(1\)](#) 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. 2\(1\)\(c\)\(ii\)](#)

**F193** Word in [reg. 2\(1\)](#) 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. 2\(1\)\(e\)\(i\)](#)

**F194** Words in [reg. 2\(1\)](#) 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. 2\(1\)\(d\)](#)

**F195** Word in [reg. 2\(1\)](#) 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. 2\(1\)\(e\)\(ii\)](#)

**F196** Words in [reg. 2\(1\)](#) 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. 2\(1\)\(f\)](#)

**F197** Words in [reg. 2\(1\)](#) 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. 2\(1\)\(g\)](#)

**F198** Words in [reg. 2\(1\)](#) inserted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(UK\(NI\) Indication\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1460), [reg. 1\(2\)](#), [Sch. 2 para. 7\(2\)](#)

- F199** Reg. 2(5) inserted (26.12.2017) by The Radio Equipment Regulations 2017 (S.I. 2017/1206), regs. 1, 81(2)(b) (with regs. 3-5, 77)
- F200** Words in reg. 2(5) 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. 2(3)

### [<sup>F23</sup>Designated standard

**2A.**—(1) Subject to paragraphs (6) and (7), in these Regulations a “designated standard” means a technical specification which is—

- (a) adopted by a recognised standardisation body [<sup>F24</sup>or an international standardising body], for repeated or continuous application, with which compliance is not compulsory; and
- (b) designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

(2) For the purposes of paragraph (1), a “technical specification” means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one or more of the following—

- (a) the characteristics required of a product, including—
  - (i) levels of quality, performance, interoperability, environmental protection, health, safety or dimensions, and
  - (ii) the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; and
- (b) production methods and processes relating to the product, where these have an effect on the characteristics of the product.

(3) For the purposes of this regulation a “recognised standardisation body” means any one of the following organisations—

- (a) the European Committee for Standardisation (CEN);
- (b) the European Committee for Electrotechnical Standardisation (Cenelec);
- (c) the European Telecommunications Standards Institute (ETSI);
- (d) the British Standards Institution (BSI).

[<sup>F25</sup>(3A) In this regulation “international standardising body” has the same meaning as it has for the purposes of the Agreement on Technical Barriers to Trade, part of Annex 1A to the agreement establishing the World Trade Organisation signed at Marrakesh on 15 April 1994 (as modified from time to time).]

(4) When considering whether the manner of publication of a reference is appropriate in accordance with paragraph (1)(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.

(5) Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with [<sup>F26</sup>such] technical specifications adopted by the other recognised standardisation bodies [<sup>F27</sup>or by international standardising bodies as the Secretary of State considers to be relevant].

(6) The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph (1)(b).

(7) Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.

(8) In this regulation, a reference to a “product” is a reference to apparatus to which these Regulations apply.

(9) The Secretary of State may by regulation amend paragraph (3) to reflect any changes in the name or structure of the recognised standardisation bodies.

(10) Regulations made under paragraph (9) are to be made by statutory instrument.

(11) A statutory instrument containing regulations made under paragraph (9) is subject to annulment in pursuance of a resolution of either House of Parliament.]

- F23** Reg. 2A 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. 3** (with Sch. 20 para. 33) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F24** Words in [reg. 2A\(1\)\(a\)](#) inserted (31.12.2020) by [European Union \(Future Relationship\) Act 2020](#) (c. 29), s. 40(7), **Sch. 4 para. 9(a)**; [S.I. 2020/1662](#), reg. 2(ee)
- F25** [Reg. 2A\(3A\)](#) inserted (31.12.2020) by [European Union \(Future Relationship\) Act 2020](#) (c. 29), s. 40(7), **Sch. 4 para. 9(b)**; [S.I. 2020/1662](#), reg. 2(ee)
- F26** Word in [reg. 2A\(5\)](#) inserted (31.12.2020) by [European Union \(Future Relationship\) Act 2020](#) (c. 29), s. 40(7), **Sch. 4 para. 9(c)(i)**; [S.I. 2020/1662](#), reg. 2(ee)
- F27** Words in [reg. 2A\(5\)](#) inserted (31.12.2020) by [European Union \(Future Relationship\) Act 2020](#) (c. 29), s. 40(7), **Sch. 4 para. 9(c)(ii)**; [S.I. 2020/1662](#), reg. 2(ee)

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

3.—(1) Subject to paragraphs (2) to (4) and regulations 4 to 6, these Regulations apply to all equipment.

(2) These Regulations do not apply to—

- (a) equipment to which [<sup>F28</sup>the Radio Equipment Regulations 2017 apply];
- (b) aeronautical apparatus, parts and appliances as referred to in Regulation [\(EC\) 216/2008](#) of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency and repealing Council Directive [91/670/EEC](#), Regulation [\(EC\) No 1592/2002](#) and Directive [2004/36/EC](#)<sup>M11</sup>;
- (c) radio equipment used by radio amateurs within the meaning of the Radio Regulations adopted in the framework of the Constitution of the International Telecommunication Union and the Convention of the International Telecommunication Union<sup>M12</sup>;
- (d) equipment the inherent nature and physical characteristics of which is such that—
  - (i) it is incapable of generating or contributing to electromagnetic emissions which exceed a level allowing radio and telecommunication equipment and other equipment to operate as intended; and
  - (ii) it operates without an unacceptable degradation in the presence of the electromagnetic disturbance normally consequent upon its intended use;
- (e) custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

(3) These Regulations do not apply to kits of components to be assembled by radio amateurs and equipment made available on the market and modified by and for the use of radio amateurs.

(4) These Regulations do not apply to equipment covered by [<sup>F29</sup>the Measuring Instruments Regulations 2016].

(5) Each provision of these Regulations applies to equipment in so far as there are no specific provisions in <sup>F30</sup>... [<sup>F31</sup>any enactment] governing the conformity of the equipment with the essential requirements, other than [<sup>F32</sup>these Regulations]. Where equipment is subject to essential requirements imposed by <sup>F30</sup>... [<sup>F31</sup>any enactment] other than [<sup>F32</sup>these Regulations], these Regulations only apply insofar as the equipment is not covered by the other provisions of [<sup>F33</sup>that enactment].

#### 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
- F28** Words in [reg. 3\(2\)\(a\)](#) 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. 4\(a\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F29** Words in [reg. 3\(4\)](#) 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. 4\(b\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F30** Words in [reg. 3\(5\)](#) 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. 4\(c\)\(i\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F31** Words in [reg. 3\(5\)](#) 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. 4\(c\)\(ii\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F32** Words in [reg. 3\(5\)](#) 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. 4\(c\)\(iv\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F33** Words in [reg. 3\(5\)](#) 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. 4\(c\)\(iii\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

#### Marginal Citations

- M11** OJ L 79, 19.3.2008, p. 1, as last amended by Regulation (EU) 2016/4 (OJ L 3, 6.1.2016, p.1).
- M12** Constitution and Convention of the International Telecommunications Union adopted by the Additional Plenipotentiary Conference (Geneva, 1992) as amended by the Plenipotentiary Conference (Kyoto, 1994).

#### Application **N.I.**

3.—(1) Subject to paragraphs (2) to (4) and regulations 4 to 6, these Regulations apply to all equipment.

(2) These Regulations do not apply to—

- (a) equipment to which Directive [1999/5/EC](#) of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity applies;
- (b) aeronautical apparatus, parts and appliances as referred to in Regulation [\(EC\) 216/2008](#) of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency and repealing

Council Directive [91/670/EEC](#), Regulation (EC) No [1592/2002](#) and Directive [2004/36/EC](#) ;

- (c) radio equipment used by radio amateurs within the meaning of the Radio Regulations adopted in the framework of the Constitution of the International Telecommunication Union and the Convention of the International Telecommunication Union ;
- (d) equipment the inherent nature and physical characteristics of which is such that—
  - (i) it is incapable of generating or contributing to electromagnetic emissions which exceed a level allowing radio and telecommunication equipment and other equipment to operate as intended; and
  - (ii) it operates without an unacceptable degradation in the presence of the electromagnetic disturbance normally consequent upon its intended use;
- (e) custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

(3) These Regulations do not apply to kits of components to be assembled by radio amateurs and equipment made available on the market and modified by and for the use of radio amateurs.

(4) These Regulations do not apply to equipment covered by Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast) as regards the immunity of such equipment.

(5) .....

#### [<sup>F34</sup>Disapplication where more specific obligations apply

**3A.**—(1) Each provision of these Regulations does not apply to equipment if, or to the extent that, paragraph (2) applies.

(2) This paragraph applies where any NI Protocol obligation, other than any obligation in relation to the Directive, applies to the equipment and makes more specific provision than the Directive in relation to the conformity of the equipment with the essential requirements.]

**F34** [Reg. 3A](#) 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. 2\(5\)](#)

#### Application of safety legislation **E+W+S**

**4.** Nothing in these Regulations affects the application of [<sup>F35</sup>any enactment] regulating the safety of equipment.

#### 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

**F35** Words in [reg. 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. 5](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

### Application of safety legislation **N.I.**

4. Nothing in these Regulations affects the application of EU or national legislation regulating the safety of equipment.

### Exhibition at trade fairs

5. Nothing in these Regulations prevents the display or demonstration at a trade fair, exhibition or similar event of equipment which does not comply with these Regulations provided that a visible sign clearly indicates that the equipment—

- (a) is not in conformity with Part 2; and
- (b) will not be made available on the market or put into service until it has been brought into conformity with Part 2.

### Making available or putting into service **E+W+S**

6. Nothing in these Regulations prevents the making available on the market, or the putting into service in the United Kingdom, of equipment which is in conformity with Part 2 when the equipment is properly installed, maintained and used for its intended purpose.

#### 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

### Making available or putting into service **N.I.**

6. Nothing in these Regulations prevents the making available on the market, or the putting into service in [<sup>F201</sup>Northern Ireland], of equipment which is in conformity with Part 2 when the equipment is properly installed, maintained and used for its intended purpose.

- F201** Words in [reg. 6](#) 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. 2\(6\)](#)

## 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>F36</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.

**F36** 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>F37</sup>Declaration] of conformity and [<sup>F38</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>F39</sup>a] declaration of conformity in accordance with regulation 41 <sup>F40</sup>...; and
  - (b) affix the [<sup>F41</sup>UK] marking in accordance with regulation 42 ([<sup>F41</sup>UK] marking).
- (2) The manufacturer must keep the <sup>F42</sup>... declaration of conformity up-to-date.

[<sup>F43</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

- E5** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only
- F37** 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)
- F38** 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)
- F39** 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)
- F40** 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)
- F41** 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)



- F42** 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)
- F43** 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 [<sup>F202</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 [<sup>F203</sup>relevant] EU instruments; and
- (b) includes references to the publication of [<sup>F204</sup>the relevant EU] instruments in the Official Journal.

- F202** 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)**
- F203** 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)**
- F204** 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 [<sup>F44</sup>EU] declaration of conformity

**11.** A manufacturer must keep the technical documentation and the [<sup>F45</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.

- F44** 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)
- F45** 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 [<sup>F46</sup>designated] standard or in another technical specification by reference to which the <sup>F47</sup>... declaration of conformity was drawn up.

### 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
- F46** 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\(1\)](#)
- F47** 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>F48</sup>clear, legible and in easily understandable English].

#### 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
- F48** 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>F205</sup>relevant state] in which it is to be made available to such end-users.

- F205** 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>F49</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

- E8** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only
- F49** [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>F206</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>F207</sup>Northern Ireland], the language referred to in paragraph (1)(a) is English.

**F206** 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\(2\)](#)

**F207** 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>F50</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

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

**F50** 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>F208</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.

**F208** 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>F51</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

- E10** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only
- F51** 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>F52</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>F53</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>F54</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 [F55 enforcing authority].

#### 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
- F52** 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\(1\)](#)
- F53** [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\(1\)](#)
- F54** 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. \(g\)](#)
- F55** 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)

- C2** [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 [F209 relevant state] in which it is to be made available.

- F209** 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 [F56 are clear, legible and in easily understandable English].

<sup>F57</sup>(2) .....



### 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
- F56** 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)
- F57** [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>F210</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>F211</sup>Northern Ireland], the language referred to in paragraph (1) is English.

- F210** 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)**
- F211** 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>F58</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

- E13** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only
- F58** 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>F212</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.

- F212** 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>F59</sup>EU] declaration of conformity

**24.** An importer must keep the technical documentation and the [<sup>F60</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.

- F59** 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\(1\)](#)
- F60** 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>F61</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>F62</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

- E14** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only
- F61** 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\(1\)](#)
- F62** 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>F213</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).

**F213** 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>F63</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**

**E15** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

**F63** 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>F214</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.

**F214** 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>F64</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**

**E16** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

**F64** 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>[F65]</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>[F66]</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>[F67]</sup>Northern Ireland], the language referred to in paragraph (1) is English.]

- F65** 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)
- F66** 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)**
- F67** 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>F68</sup>UK] marking **E+W+S**

- 35.—**(1) An economic operator must not affix the [<sup>F69</sup>UK] marking to apparatus unless—
- that economic operator is the manufacturer of the apparatus; and
  - 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>F69</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>F69</sup>UK] marking.
- (4) An economic operator must not affix to equipment any other marking if the visibility, legibility and meaning of the [<sup>F69</sup>UK] marking would be impaired as a result.

#### Extent Information

- E17** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only
- F68** 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)
- F69** 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—
- that economic operator is the manufacturer of the apparatus; and
  - 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>F70</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>F71</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

- E18** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only
- F70** 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\(1\)](#)
- F71** 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>F72</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.

**F72** 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>F73</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.

**F72** 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)**

**F73** 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.]

**F72** 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\(1\)](#)

## PART 3

### Conformity of apparatus and equipment

#### Presumption of conformity **E+W+S**

**39.**—(1) Equipment which is in conformity with a [<sup>F74</sup>designated] standard (or part of such a standard) <sup>F75</sup>... is to be presumed to be in conformity with the essential requirements covered by that standard (or that part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

### Extent Information

- E19** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only
- F74** Word in [reg. 39\(1\)](#) 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. 25(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)
- F75** Words in [reg. 39\(1\)](#) 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. 25(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)

### Presumption of conformity **N.I.**

**39.**—(1) Equipment which is in conformity with a harmonised standard (or part of such a standard) the reference to which has been published in the Official Journal is to be presumed to be in conformity with the essential requirements covered by that standard (or that part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

### Conformity assessment procedures

**40.**—(1) Subject to paragraph (2), the manufacturer must demonstrate the conformity of the apparatus with the essential requirements by means of either—

- (a) the procedure set out in Schedule 2 (Module A: internal production control); or
- (b) the procedures set out in Schedule 3 (Module B: EU type examination followed by Module C: conformity to type based on internal production control).

(2) The manufacturer may choose to demonstrate the conformity of apparatus with some of the essential requirements by following the procedure referred to in paragraph (1)(b) provided that the procedure referred to in paragraph (1)(a) is followed for the remaining essential requirements.

### [<sup>F76</sup>Declaration] of conformity **E+W+S**

**41.** The <sup>F77</sup>... declaration of conformity for apparatus must—

- (a) state that the fulfilment of the essential requirements has been demonstrated in respect of the apparatus;
- (b) contain the elements of the relevant conformity assessment procedure or procedures followed in respect of the apparatus; and
- (c) have the model structure set out in Schedule 4.

### Extent Information

- E20** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only
- F76** Word in [reg. 41](#) 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. 26(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)
- F77** Word in [reg. 41](#) 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. 26(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)

## EU declaration of conformity **N.I.**

**41.** The EU declaration of conformity for apparatus must—

- (a) state that the fulfilment of the essential requirements has been demonstrated in respect of the apparatus;
- (b) contain the elements of the relevant conformity assessment procedure or procedures followed in respect of the apparatus; and
- (c) have the model structure set out in Schedule 4.

## <sup>F78</sup>UK] marking **E+W+S**

**42.**—<sup>F79</sup>(1) The UK marking must be affixed visibly, legibly and indelibly—

- (a) to the apparatus;
- (b) to its data plate; or
- (c) where paragraph (1A) applies, to—
  - (i) a label affixed to the apparatus or its data plate; or
  - (ii) to a document accompanying the apparatus.]

<sup>F80</sup>(1A) For a period of <sup>F81</sup>seven years] beginning with IP completion day, the UK marking may be affixed to—

- (a) a label affixed to the apparatus or its data plate; or
- (b) a document accompanying the apparatus.]

(2) Where <sup>F82</sup>paragraph (1A) does not apply and] it is not possible or warranted, on account of the nature of the apparatus, to affix the <sup>F83</sup>UK] marking in accordance with paragraph (1), the CE marking must be affixed to—

- (a) the packaging; and
- (b) the accompanying documents.

### Extent Information

- E21** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only
- F78** Word in [reg. 42](#) heading substituted (E.W.S.) (31.12.2020) by [S.I. 2019/696](#), [Sch. 20 para. 27\(a\)](#) (as substituted by [The Product Safety and Metrology etc. \(Amendment etc.\) \(UK\(NI\) Indication\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1460), [reg. 1\(4\)](#), [Sch. 3 para. 12\(4\)](#))
- F79** [Reg. 42\(1\)](#) substituted (E.W.S.) (31.12.2020) by [S.I. 2019/696](#), [Sch. 20 para. 27\(b\)](#) (as substituted by [The Product Safety and Metrology etc. \(Amendment etc.\) \(UK\(NI\) Indication\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1460), [reg. 1\(4\)](#), [Sch. 3 para. 12\(4\)](#))
- F80** [Reg. 42\(1A\)](#) inserted (E.W.S.) (31.12.2020) by [S.I. 2019/696](#), [Sch. 20 para. 27\(c\)](#) (as substituted by [The Product Safety and Metrology etc. \(Amendment etc.\) \(UK\(NI\) Indication\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1460), [reg. 1\(4\)](#), [Sch. 3 para. 12\(4\)](#))
- F81** Words in [reg. 42\(1A\)](#) 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\(1\), 3](#), [Sch. 2 para. \(i\)](#)
- F82** Words in [reg. 42\(2\)](#) inserted (E.W.S.) (31.12.2020) by [S.I. 2019/696](#), [Sch. 20 para. 27\(d\)](#) (as substituted by [The Product Safety and Metrology etc. \(Amendment etc.\) \(UK\(NI\) Indication\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1460), [reg. 1\(4\)](#), [Sch. 3 para. 12\(4\)](#))



**F83** Word in reg. 42(2) substituted (E.W.S.) (31.12.2020) by S.I. 2019/696, **Sch. 20 para. 27(a)** (as substituted by [The Product Safety and Metrology etc. \(Amendment etc.\) \(UK\(NI\) Indication\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 12(4)**)

## CE marking **N.I.**

**42.—**(1) The CE marking must be affixed visibly, legibly and indelibly to the apparatus or to its data plate.

(2) Where it is not possible or warranted, on account of the nature of the apparatus, to affix the CE marking in accordance with paragraph (1), the CE marking must be affixed to—

- (a) the packaging; and
- (b) the accompanying documents.

### Extent Information

**E76** This version of this provision extends to Northern Ireland only; a separate version has been created for England, Wales and Scotland only

## [<sup>F84</sup>UK(NI) indication

**42A.—**(1) Where the CE marking is affixed on the basis of an assessment or a certificate issued by a notified body established in the United Kingdom, a UK(NI) indication must be affixed in relation to the apparatus, in accordance with this regulation.

(2) The UK(NI) indication must be affixed—

- (a) visibly, legibly and indelibly; and
- (b) before apparatus is placed on the market in Northern Ireland.

(3) The UK(NI) indication must accompany the CE marking, wherever that is affixed in accordance with regulation 42.

(4) The UK(NI) indication must be affixed by—

- (a) the manufacturer; or
- (b) the manufacturer's authorised representative.

(5) When placing apparatus on the market in Northern Ireland, an importer must ensure that the manufacturer has complied with their obligations under this regulation.

**F84** [Regs. 42A, 42B](#) inserted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(UK\(NI\) Indication\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1460), reg. 1(2), **Sch. 2 para. 7(3)**

## Register of UK notified bodies

**42B.—**(1) The Secretary of State must ensure that—

- (a) each notified body established in the United Kingdom is assigned an identification number; and
- (b) there is a register of—
  - (i) notified bodies established in the United Kingdom;
  - (ii) their notified body identification number;
  - (iii) the activities for which they have been notified;

(iv) any restrictions on those activities.

(2) The Secretary of State must ensure that the register referred to in paragraph (1) is maintained and made publicly available.

(3) The Secretary of State may authorise the United Kingdom Accreditation Service to compile and maintain the register in accordance with paragraph (1)(b).]

**F84** Regs. 42A, 42B inserted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(UK\(NI\) Indication\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1460\)](#), reg. 1(2), **Sch. 2 para. 7(3)**

## PART 4

[<sup>F85</sup>Notification of conformity assessment bodies]

[<sup>F85</sup>Approval of Conformity Assessment Bodies]

**F85** Pt. 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. 28** (with Sch. 20 para. 33) (as amended by [S.I. 2020/676](#), regs. 1(1), 2, and [The Product Safety and Metrology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/852\)](#), regs. 2(2), 4(2), Sch. 1 para. 1(i), (**iv**)); 2020 c. 1, **Sch. 5 para. 1(1)**

[<sup>F85</sup>Approved bodies **E+W+S**]

**43.—**(1) An approved body is a conformity assessment body which—

- (a) has been approved by the Secretary of State pursuant to the procedure set out in regulation 44 (approval of conformity assessment bodies); or
- (b) immediately before IP completion day was a notified body in respect of which the Secretary of State had taken no action under regulation 49(1) or (2) as they had effect immediately before IP completion day to suspend or withdraw the body's status as a notified body.

(2) Paragraph (1) has effect subject to regulation 47 (restriction, suspension or withdrawal of approval).

(3) In this Part—

“notified body” means a body—

- (a) which the Secretary of State had before IP completion day notified to the European Commission and the member State of the European Union, in accordance with Article 20 of the Directive; and
- (b) in respect of which no objections had been raised, as referred to in regulation 43(1)(b), as it had effect immediately before IP completion day;

“approved body requirements” means the requirements set out in Schedule 5.]

### Extent Information

**E22** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

## Notified bodies **N.I.**

- 43.**—(1) For the purposes of this Part, a notified body is a conformity assessment body—
- (a) which has been notified by the Secretary of State to the European Commission and to the other <sup>[F215]</sup>relevant states] —
    - (i) under regulation 44 (notification); or
    - (ii) before the date these Regulations come into force, in accordance with Article 20 of the Directive; and
  - (b) in respect of which no objections <sup>[F216]</sup>, other than an immaterial objection,] were raised by the European Commission or other <sup>[F215]</sup>relevant states]—
    - (i) within 2 weeks of the date of notification, where the notification is accompanied by an accreditation certificate; or
    - (ii) within 2 months of the date of notification, where the notification is not accompanied by an accreditation <sup>[F217]</sup>certificate;]
  - <sup>[F218]</sup>(c) in sub-paragraph (b), an “immaterial objection” is an objection on the grounds that—
    - (i) the conformity assessment body is established in the United Kingdom; or
    - (ii) the accreditation certificate was issued by the United Kingdom Accreditation Service.]
- (2) Paragraph (1) has effect subject to regulation 49 (changes to notifications).

**F215** Words in [reg. 43\(1\)](#) 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. 4\(1\)\(a\)](#)

**F216** Words in [reg. 43\(1\)\(b\)](#) 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. 4\(1\)\(b\)\(i\)](#)

**F217** Word in [reg. 43\(1\)\(b\)](#) 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. 4\(1\)\(b\)\(ii\)](#)

**F218** [Reg. 43\(1\)\(c\)](#) 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. 4\(1\)\(c\)](#)

## <sup>[F85]</sup>Approval of conformity assessment bodies **E+W+S**

**44.**—(1) The Secretary of State may approve only those conformity assessment bodies that qualify for approval.

(2) A conformity assessment body qualifies for approval if the first and second conditions below are met.

(3) The first condition is that the conformity assessment body has applied to the Secretary of State to become an approved body and that application is accompanied by—

- (a) a description of—
  - (i) the conformity assessment activities that the conformity assessment body intends to carry out;
  - (ii) the conformity assessment procedure in respect of which the conformity assessment body claims to be competent;
  - (iii) the category of apparatus in respect of which the conformity assessment body claims to be competent; and

(b) either—

- (i) an accreditation certificate; or
- (ii) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the approved body requirements.

(4) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the approved body requirements.

(5) For the purposes of paragraph (4), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (3)(b), as sufficient evidence that the conformity assessment body meets the approved body requirements.

(6) When deciding whether to approve a conformity assessment body that qualifies for approval, the Secretary of State may—

- (a) have regard to any other matter which appears to the Secretary of State to be relevant; and
- (b) set conditions that the conformity assessment body must meet.

(7) For the purposes of this regulation “accreditation certificate” means a certificate, issued by the UK national accreditation body, attesting that a conformity assessment body meets the approved body requirements.]

#### Extent Information

**E23** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Notification **N.I.**

**44.**—(1) The Secretary of State may notify to the European Commission and the other [F219relevant states] only those conformity assessment bodies that qualify for notification.

(2) A conformity assessment body qualifies for notification if the first and second conditions below are met.

(3) The first condition is that the conformity assessment body has applied to the Secretary of State to become a notified body and the application is accompanied by—

- (a) a description of—
  - (i) the conformity assessment activities that the conformity assessment body intends to carry out;
  - (ii) the conformity assessment module or modules in respect of which the conformity assessment body claims to be competent; and
  - (iii) the apparatus for which the conformity assessment body claims to be competent; and either
- (b) an accreditation certificate; or
- (c) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the notified body requirements.

(4) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the notified body requirements.

(5) For the purposes of paragraph (4), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (3)(b), as sufficient evidence that the conformity assessment body meets the notified body requirements.

(6) When deciding whether to notify a conformity assessment body that qualifies for notification to the European Commission and the other [<sup>F219</sup>relevant states], the Secretary of State may—

- (a) have regard to any other matter which appears to the Secretary of State to be relevant; and
- (b) set conditions that the conformity assessment body must meet.

(7) The Secretary of State must inform the European Commission of the United Kingdom's procedures for the assessment and notifications of conformity assessment bodies, and any changes to those procedures.

**F219** Words in [reg. 44](#) 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. 4\(2\)](#)

#### [<sup>F85</sup>**Presumption of conformity of approved bodies** **E+W+S**]

**45.**—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a designated standard (or part of such standard), the Secretary of State is to presume that the conformity assessment body meets the approved body requirements covered by that standard (or that part of that standard).

(2) The presumption in paragraph (1) is rebuttable.]

#### **Extent Information**

**E24** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

#### **Contents of notification** **N.I.**

**45.** A notification under regulation 44 (notification) must include—

- (a) the details of—
  - (i) the conformity assessment activities in respect of which the conformity assessment body has made its application for notification;
  - (ii) the conformity assessment module or modules in respect of which the conformity assessment body has made its application for notification;
  - (iii) the apparatus in respect of which the conformity assessment body has made its application for notification; and either
- (b) an accreditation certificate; or
- (c) documentary evidence which attests to—
  - (i) the conformity assessment body's competence; and
  - (ii) the arrangements in place to ensure that the conformity assessment body will be monitored regularly and will continue to satisfy the notified body requirements.

## <sup>F85</sup>Monitoring **E+W+S**

**46.** The Secretary of State must monitor each approved body with a view to verifying that the body—

- (a) continues to meet the approved body requirements;
- (b) meets any conditions set—
  - (i) in accordance with regulation 44(6)(b); or
  - (ii) in the case of an approved body which was a notified body immediately before IP completion day, in accordance with regulation 44(6)(b) as it applied immediately before IP completion day; and
- (c) carries out its functions in accordance with these Regulations.]

### Extent Information

**E25** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

## Presumption of conformity of notified bodies **N.I.**

**46.—**(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a harmonised standard (or part of such a standard), the reference of which has been published in the Official Journal, the Secretary of State is to presume that the conformity assessment body meets the notified body requirements covered by that standard (or part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

## <sup>F85</sup>Restriction, suspension or withdrawal of approval **E+W+S**

**47.—**(1) Where the Secretary of State determines that an approved body—

- (a) no longer meets an approved body requirement, or
- (b) is failing to fulfil its obligations under these Regulations, other than a condition referred to in regulation 46(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under regulation 43 (approved bodies).

(2) Where the Secretary of State determines that an approved body no longer meets a condition referred to in regulation 46(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body under regulation 43.

(3) In deciding what action is required under paragraph (1) or (2), the Secretary of State must have regard to the seriousness of the non-compliance.

(4) Before taking action under paragraph (1) or (2), the Secretary of State must—

- (a) give notice in writing to the approved body of the proposed action and the reasons for it;
- (b) give the approved body an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice; and
- (c) consider any such representations made by the approved body.

(5) Where the Secretary of State has taken action in respect of an approved body under paragraph (1) or (2), or where an approved body has ceased its activity, the approved body must, at the request of the Secretary of State—

- (a) transfer its files relating to the activities it has undertaken as an approved body to another approved body or to the Secretary of State; or
  - (b) keep its files relating to the activities it has undertaken as an approved body available for the Secretary of State and market surveillance authorities for a period of 10 years from the date they were created.
- (6) The activities undertaken as an approved body referred to in paragraph (5) include any activities that the body has undertaken as a notified body.]

#### Extent Information

**E26** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

### Monitoring of notified bodies **N.I.**

**47.**—(1) The Secretary of State must monitor each notified body with a view to verifying that the notified body—

- (a) continues to meet the notified body requirements;
- (b) meets any conditions set in accordance with regulation 44(6)(b); and
- (c) carries out its functions in accordance with these Regulations.

(2) The Secretary of State must inform the European Commission of the United Kingdom's procedures for the monitoring of notified bodies, and any changes to those procedures.

### [<sup>F85</sup>Operational matters in relation to approved bodies **E+W+S**

**48.**—(1) Subject to the terms of its appointment, an approved body must carry out the conformity assessment activities and procedures—

- (a) in respect of which the body's approval was given under regulation 44; or
- (b) in respect of which the body's notification as a notified body was made.

(2) Where an approved body carries out a conformity assessment procedure, it must do so in accordance with Schedule 6.

(3) An approved body must make provision for a manufacturer to be able to make an appeal against a refusal by the approved body to issue a Type-examination certificate referred to in Schedule 3.]

#### Extent Information

**E27** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

### United Kingdom Accreditation Service **N.I.**

**48.** The Secretary of State may authorise the United Kingdom Accreditation Service (a company limited by guarantee incorporated in England and Wales under number 03076190) to carry out the following activities on behalf of the Secretary of State—

- (a) assessing whether a conformity assessment body meets the notified body requirements; and



- (b) monitoring notified bodies as required by regulation 47 (monitoring of notified bodies).

**[<sup>F85</sup>Subsidiaries and contractors E+W+S]**

**49.**—(1) An approved body may subcontract specific conformity assessment activities, or use a subsidiary to carry out such activities provided—

- (a) the body is satisfied that the subcontractor or subsidiary meets the approved body requirements;
- (b) the body has informed the Secretary of State that it is satisfied that the subcontractor or subsidiary meets those requirements; and
- (c) the economic operator for whom the activities are to be carried out has consented to the activities being carried out by that person.

(2) The approved body which subcontracts specific conformity assessment activities or uses a subsidiary to carry out such activities remains responsible for the proper performance of those activities (irrespective of where the subcontractor or subsidiary is established).

(3) Where an approved body subcontracts, or uses a subsidiary to carry out, a specific conformity assessment activity, the approved body must, for a period of 10 years beginning on the day on which the activity is first carried out, keep available for inspection by the Secretary of State all relevant documentation concerning—

- (a) the assessment of the qualifications of the subcontractor or the subsidiary; and
- (b) the conformity assessment activity carried out by the subcontractor or subsidiary.

(4) In this regulation “subsidiary” has the meaning given to it in section 1159 of the Companies Act 2006.]

**Extent Information**

**E28** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

**Changes to notifications N.I.**

**49.**—(1) Where the Secretary of State determines that a notified body no longer meets a notified body requirement, or that it is failing to fulfil its obligations under these Regulations other than a condition set in accordance with regulation 44(6)(b), the Secretary of State must restrict, suspend or withdraw the body's status as a notified body under regulation 43.

(2) With the consent of a notified body, or where the Secretary of State determines that a notified body no longer meets a condition set in accordance with regulation 44(6)(b), the Secretary of State may restrict, suspend or withdraw the body's status as a notified body under regulation 43.

(3) In deciding what action is required under paragraph (1) or (2), the Secretary of State must have regard to the seriousness of the non-compliance.

(4) Before taking action under paragraph (1) or (2), the Secretary of State must—

- (a) give notice in writing to the notified body that the Secretary of State intends to take such action and the reasons for it; and
- (b) give the notified body an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice and consider any such representations.

(5) Where the Secretary of State takes action under paragraph (1) or (2), the Secretary of State must immediately inform the Commission and the other [<sup>F220</sup>relevant states].

(6) Where the Secretary of State has taken action in respect of a notified body under paragraph (1) or (2), or where a notified body has ceased its activity, the notified body must, at the request of the Secretary of State—

- (a) transfer its files relating to the activities it has undertaken as a notified body to another notified body or to the Secretary of State; or
- (b) keep its files relating to the activities it has undertaken as a notified body available for the Secretary of State and market surveillance authorities for a period of 10 years from the date on which the relevant document was created.

**F220** Words in [reg. 49\(5\)](#) 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. 4\(3\)](#)

#### [<sup>F85</sup>Register of approved bodies **E+W+S**]

**50.**—(1) The Secretary of State must—

- (a) assign an approved body identification number to each approved body; and
- (b) compile and maintain a register of—
  - (i) approved bodies;
  - (ii) their approved body notification numbers;
  - (iii) the activities for which they have been approved; and
  - (iv) any restrictions on those activities.

(2) The register referred to in paragraph (1) must be made publicly available.]

#### Extent Information

**E29** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Operational obligations of notified bodies **N.I.**

**50.** When a notified body carries out a relevant conformity assessment procedure, Schedule 6 has effect (operational obligations of notified bodies).

#### [<sup>F85</sup>UK national accreditation body **E+W+S**]

**51.** The Secretary of State may authorise the UK national accreditation body to carry out the following activities on behalf of the Secretary of State—

- (a) assessing whether a conformity assessment body meets the approved body requirements;
- (b) monitoring approved bodies in accordance with regulation 46; and
- (c) compiling and maintaining the register of approved bodies, in accordance with regulation 50.]

### Extent Information

**E30** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

### Subsidiaries and contractors **N.I.**

**51.—**(1) A notified body may subcontract specific conformity assessment activities, or use a subsidiary to carry out such activities provided—

- (a) the body is satisfied that the subcontractor or subsidiary meets the notified body requirements;
- (b) the body has informed the Secretary of State that it is satisfied that the subcontractor or subsidiary meets those requirements; and
- (c) the economic operator for whom the activities are to be carried out has consented to the activities being carried out by that person.

(2) The notified body which subcontracts specific conformity assessment activities or uses a subsidiary to carry out such activities remains responsible for the proper performance of those activities (irrespective of where the subcontractor or subsidiary is established).

(3) Where a notified body subcontracts, or uses a subsidiary to carry out, a specific conformity assessment activity, the notified body must, for a period of at least 10 years beginning on the day on which the activity is first carried out, keep available for inspection by the Secretary of State all the relevant documentation concerning—

- (a) the assessment of the qualifications of the subcontractor or the subsidiary; and
- (b) the conformity assessment activities carried out by the subcontractor or subsidiary.

## PART 5

### Enforcement and market surveillance

#### Designation of enforcing authorities

**52.—**(1) Except in relation to the apparatus referred to in paragraph (3), it is the duty of the following authorities to enforce these Regulations and RAMS (in its application to apparatus)—

- (a) in Great Britain—
  - (i) OFCOM insofar as action taken to enforce these Regulations relates to the protection and management of the radio spectrum; and
  - (ii) within its area, the weights and measures authority.
- (b) in Northern Ireland—
  - (i) OFCOM insofar as action taken to enforce these Regulations relates to the protection and management of the radio spectrum; and
  - (ii) the Department of Enterprise, Trade and Investment.

(2) The Secretary of State, or a person appointed by the Secretary of State to act on behalf of the Secretary of State, may enforce these Regulations and RAMS (in its application to apparatus).

(3) In Northern Ireland, these Regulations may be enforced in relation to electricity meters, other than those which are wireless telegraphy apparatus, by the Northern Ireland Authority for Energy Regulation or a person appointed by the Northern Ireland Authority for Energy Regulation.

<sup>F86</sup>(4) .....

(5) In Scotland, only the Lord Advocate may commence proceedings for an offence.

**F86** Reg. 52(4) omitted (26.12.2017) by virtue of [The Radio Equipment Regulations 2017 \(S.I. 2017/1206\)](#), regs. 1, **81(3)** (with [regs. 3-5, 77](#))

### Designation of market surveillance authorities

**53.**—(1) The market surveillance authority is—

- (a) in Great Britain, within its area, the weights and measures authority; and
- (b) in Northern Ireland, within its area, the district council.

(2) The market surveillance authority must make adequate arrangements for market surveillance under these Regulations and RAMS (in its application to apparatus).

(3) When a market surveillance authority carries out market surveillance under these Regulations, Part 1 of Schedule 7 has effect.

### Enforcement powers

**54.**—(1) Part 1 of Schedule 7 (enforcement and investigatory powers conferred upon enforcing authorities and market surveillance authorities) is to have effect where the enforcing authority is—

- (a) a weights and measures authority;
- (b) OFCOM;
- (c) the Secretary of State; or
- (d) the Department of Enterprise, Trade and Investment.

(2) In addition to the powers available to an enforcing authority under paragraph (1) the authority may use the powers set out in Part 2 of Schedule 7 (compliance, withdrawal and recall notices).

### Exercise of enforcement powers

**55.** When enforcing these Regulations, the enforcing authority must exercise its powers in a manner which is consistent with—

- (a) regulation 56 (evaluation of apparatus presenting a risk);
- (b) regulation 57 (enforcement action in respect of apparatus that is not in conformity and which present a risk);
- (c) [<sup>F87</sup>regulation 58 (EU safeguard procedure);]
- (d) regulation 59 (enforcement action in respect of formal non-compliance);
- (e) regulation 60 (restrictive measures).

**F87** Reg. 55(c) 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. 29** (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### Evaluation of apparatus presenting a risk

**56.**—(1) Where the market surveillance authority has sufficient reason to believe that apparatus presents a risk, the market surveillance authority must carry out an evaluation of that apparatus covering the relevant requirements of Part 2 in respect of that apparatus.

(2) Where the enforcing authority has sufficient reason to believe that apparatus presents a risk, the enforcement authority may carry out an evaluation of that apparatus covering the relevant requirements of Part 2 in respect of that apparatus.

**Enforcement action in respect of apparatus that is not in conformity and which present a risk E+W+S**

**57.**—(1) Where in the course of the evaluation referred to in regulation 56 (evaluation of apparatus presenting a risk) the enforcing authority finds that the apparatus is not in conformity with Part 2, it must, without delay, require the relevant economic operator to—

- (a) take the appropriate corrective action to bring the apparatus into conformity with those requirements within a prescribed period;
- (b) withdraw the apparatus within a prescribed period; or
- (c) recall the apparatus within a prescribed period.

(2) The enforcing authority must inform the [<sup>F88</sup>approved] body that carried out the relevant conformity assessment procedure in relation to the apparatus of—

- (a) the respect in which the apparatus is not in conformity with Part 2; and
- (b) the actions which the enforcing authority is requiring the relevant economic operator to take.

(3) Where the enforcing authority is not the Secretary of State and it considers that the lack of conformity referred to in paragraph (1) is not restricted to the United Kingdom, it must notify the Secretary of State of—

- (a) the results of the evaluation; and
- (b) the actions which the enforcing authority has required the economic operator to take.

<sup>F89</sup>(4) .....

(5) Where the relevant economic operator does not take adequate corrective action within the prescribed period, the enforcing authority must take appropriate measures to—

- (a) prohibit or restrict the apparatus being made available on the market in the United Kingdom;
- (b) withdraw the apparatus from the United Kingdom market; or
- (c) recall the apparatus.

(6) Where the enforcing authority is not the Secretary of State and it takes measures under paragraph (5), it must notify the Secretary of State of those measures without delay.

<sup>F90</sup>(7) .....

(8) The [<sup>F91</sup>notice in paragraph (6)] must include details about the apparatus and, in particular—

- (a) the data necessary to identify the apparatus that is not in conformity with Part 2;
- (b) the origin of the apparatus;
- (c) the nature of the lack of conformity alleged and the risk involved;
- (d) the nature and duration of the measures taken;
- (e) the arguments put forward by the relevant economic operator;
- (f) whether the failure of the apparatus to conform with the requirements of Part 2 is due to—
  - (i) the failure of the apparatus to meet the requirements of that Part relating to risk; or
  - (ii) shortcomings in the [<sup>F92</sup>designated] standards referred to in regulation 39 (presumption of conformity) which confer a presumption of conformity.

- (9) In this regulation, “prescribed period” means a period which is—
- (a) prescribed by the enforcing authority; and
  - (b) reasonable and commensurate with the nature of the risk presented by the apparatus.

#### Extent Information

- E31** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only
- F88** Word in [reg. 57\(2\)](#) 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. 30\(a\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F89** [Reg. 57\(4\)](#) 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. 30\(b\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F90** [Reg. 57\(7\)](#) 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. 30\(b\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F91** Words in [reg. 57\(8\)](#) 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. 30\(c\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F92** Word in [reg. 57\(8\)\(f\)\(ii\)](#) 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. 30\(d\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Enforcement action in respect of apparatus that is not in conformity and which present a risk **N.I.**

**57.—(1)** Where in the course of the evaluation referred to in regulation 56 (evaluation of apparatus presenting a risk) the enforcing authority finds that the apparatus is not in conformity with Part 2, it must, without delay, require the relevant economic operator to—

- (a) take the appropriate corrective action to bring the apparatus into conformity with those requirements within a prescribed period;
- (b) withdraw the apparatus within a prescribed period; or
- (c) recall the apparatus within a prescribed period.

**(2)** The enforcing authority must inform the notified body that carried out the relevant conformity assessment procedure in relation to the apparatus of—

- (a) the respect in which the apparatus is not in conformity with Part 2; and
- (b) the actions which the enforcing authority is requiring the relevant economic operator to take.

**(3)** Where the enforcing authority is not the Secretary of State and it considers that the lack of conformity referred to in paragraph (1) is not restricted to <sup>F221</sup>[Northern Ireland], it must notify the Secretary of State of—

- (a) the results of the evaluation; and
- (b) the actions which the enforcing authority has required the economic operator to take.

**(4)** <sup>F222</sup>[Subject to paragraph (4A),] where the Secretary of State receives notice from an enforcing authority under paragraph (3), or otherwise considers that the failure of apparatus to conform with the requirements of Part 2 referred to in paragraph (1) is not restricted to <sup>F223</sup>[Northern Ireland], the Secretary of State must inform the European Commission and the other <sup>F224</sup>[relevant states] of—

- (a) the results of the evaluation; and
- (b) the actions which the enforcing authority has required the economic operator to take.

[<sup>F225</sup>(4A) Paragraph (4) does not require the Secretary of State to inform the Commission or the other relevant states where the lack of conformity extends only to any of England or Wales or Scotland.]

(5) Where the relevant economic operator does not take adequate corrective action within the prescribed period, the enforcing authority must take appropriate measures to—

- (a) prohibit or restrict the apparatus being made available on the market in [<sup>F226</sup>Northern Ireland];
- (b) withdraw the apparatus from the [<sup>F227</sup>market in Northern Ireland]; or
- (c) recall the apparatus.

(6) Where the enforcing authority is not the Secretary of State and it takes measures under paragraph (5), it must notify the Secretary of State of those measures without delay.

(7) Where the Secretary of State receives a notice under paragraph (6), or takes measures under paragraph (5), the Secretary of State must notify the European Commission and the other [<sup>F228</sup>relevant states] of those measures without delay.

(8) The notices referred to in paragraphs (6) and (7) must include details about the apparatus and, in particular—

- (a) the data necessary to identify the apparatus that is not in conformity with Part 2;
- (b) the origin of the apparatus;
- (c) the nature of the lack of conformity alleged and the risk involved;
- (d) the nature and duration of the measures taken;
- (e) the arguments put forward by the relevant economic operator;
- (f) whether the failure of the apparatus to conform with the requirements of Part 2 is due to—
  - (i) the failure of the apparatus to meet the requirements of that Part relating to risk; or
  - (ii) shortcomings in the harmonised standards referred to in regulation 39 (presumption of conformity) which confer a presumption of conformity.

(9) In this regulation, “prescribed period” means a period which is—

- (a) prescribed by the enforcing authority; and
- (b) reasonable and commensurate with the nature of the risk presented by the apparatus.

**F221** Words in [reg. 57\(3\)](#) 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. 5\(1\)\(a\)](#)

**F222** Words in [reg. 57\(4\)](#) 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. 5\(1\)\(b\)\(i\)](#)

**F223** Words in [reg. 57\(4\)](#) 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. 5\(1\)\(b\)\(ii\)](#)

**F224** Words in [reg. 57\(4\)](#) 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. 5\(1\)\(b\)\(iii\)](#)

**F225** [Reg. 57\(4A\)](#) 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. 5\(1\)\(c\)](#)



- F226** Words in [reg. 57\(5\)\(a\)](#) 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. 5\(1\)\(d\)\(i\)](#)
- F227** Words in [reg. 57\(5\)\(b\)](#) 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. 5\(1\)\(d\)\(ii\)](#)
- F228** Words in [reg. 57\(7\)](#) 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. 5\(1\)\(e\)](#)

## EU safeguard procedure

**58.**—<sup>F93</sup>(1) Where another <sup>F94</sup>[relevant state] has initiated the procedure under Article 38 of the Directive (as amended from time to time), each enforcing authority (other than the Secretary of State) must, without delay, inform the Secretary of State of—

- (a) any measures taken by the enforcing authority in respect of the apparatus; and
- (b) any additional information which the enforcing authority has at its disposal relating to the lack of conformity of the apparatus.

(2) Where another <sup>F95</sup>[relevant state] has initiated the procedure under Article 38 of the Directive (as amended from time to time), the Secretary of State must, without delay, inform the European Commission and the other <sup>F96</sup>[relevant states] of—

- (a) any measure taken by an enforcing authority <sup>F97</sup>[in Northern Ireland] in respect of the apparatus;
- (b) any additional information which an enforcing authority has at its disposal relating to the lack of conformity of the <sup>F98</sup>[apparatus].

<sup>F99</sup>(c) .....

(3) Where a measure taken by another <sup>F100</sup>[relevant state] in respect of apparatus is considered justified under Article 38(7) of the Directive (as amended from time to time), the market surveillance authority must ensure that appropriate measures, such as the withdrawal of apparatus, are taken <sup>F101</sup>[in Northern Ireland] in respect of the apparatus without delay.

(4) Where a measure taken by another <sup>F102</sup>[relevant state] in respect of apparatus is considered justified by the European Commission under Article 39(1) of the Directive (as amended from time to time), the market surveillance authority must take the necessary measures to ensure that the apparatus is withdrawn from the <sup>F103</sup>[market in Northern Ireland].

(5) Where the market surveillance authority is not the Secretary of State and it has taken action under paragraph (3) or (4), it must inform the Secretary of State.

(6) Where the Secretary of State receives a notice under paragraph (5) or has taken action under paragraphs (3) or (4), the Secretary of State must inform the European Commission of the action taken <sup>F104</sup>[in respect of Northern Ireland].

(7) If a measure taken by an enforcing authority pursuant to regulation 57 is considered unjustified by the European Commission under Article 39(1) of the Directive (as amended from time to time), the enforcing authority must withdraw that measure <sup>F105</sup>[in respect of Northern Ireland].

- F93** [Reg. 58](#) 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. 31](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#))

- F94** Words in reg. 58(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. 5(2)(a)**
- F95** Words in reg. 58(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. 5(2)(b)(i)**
- F96** Words in reg. 58(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. 5(2)(b)(ii)**
- F97** Words in reg. 58(2)(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. 5(2)(b)(iii)**
- F98** Word in reg. 58(2)(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. 5(2)(b)(iv)**
- F99** Reg. 58(2)(c) omitted (N.I.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 8 para. 5(2)(b)(v)**
- F100** Words in reg. 58(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. 5(2)(c)(i)**
- F101** Words in reg. 58(3) 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. 5(2)(c)(ii)**
- F102** Words in reg. 58(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. 5(2)(d)(i)**
- F103** Words in reg. 58(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. 5(2)(d)(ii)**
- F104** Words in reg. 58(6) 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. 5(2)(e)**
- F105** Words in reg. 58(7) 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. 5(2)(e)**

### Enforcement action in respect of formal non-compliance **E+W+S**

**59.**—(1) Where an enforcing authority makes one of the following findings relating to apparatus, it must require a relevant economic operator to put an end to the non-compliance within a specified period—

- (a) the [<sup>F106</sup>UK] marking
  - (i) has not been affixed; or
  - (ii) has been affixed otherwise than in accordance with regulations 35 (prohibition on improper use of [<sup>F106</sup>UK] marking) and 42 ([<sup>F106</sup>UK] marking);
- (b) the <sup>F107</sup>... declaration of conformity—
  - (i) has not been drawn up; or
  - (ii) has been drawn up otherwise in accordance with regulation 10 (<sup>F107</sup>... declaration of conformity and [<sup>F108</sup>UK] marking) and 41 (<sup>F107</sup>... declaration of conformity);

- (c) the technical documentation is either not available or not complete;
  - (d) the information set out in regulation 13 (information identifying manufacturer) is absent, false or incomplete;
  - (e) any other administrative requirement imposed on the manufacturer or importer under Part 2 has not been fulfilled.
- (2) Until the specified period has elapsed, the enforcing authority must not commence proceedings under these Regulations, or take any other enforcement action under these Regulations, against the relevant economic operator in respect of the non-compliance referred to in paragraph (1).
- (3) Where the non-compliance referred to in paragraph (1) persists, the enforcing authority must take appropriate measures to—
- (a) restrict or prohibit the apparatus being made available on the market;
  - (b) ensure that the apparatus is recalled;
  - (c) ensure that the apparatus is withdrawn from the market.
- (4) Where the non-compliance referred to in paragraph (1) persists and the apparatus has been imported for the person's own use, the enforcing authority must take appropriate measures to ensure that the apparatus is prohibited or restricted.
- (5) This regulation does not apply where apparatus presents a risk.

#### Extent Information

- E32** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only
- F106** Word in [reg. 59\(1\)\(a\)](#) 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. 32\(a\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F107** Word in [reg. 59\(1\)\(b\)](#) 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. 32\(b\)\(i\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F108** Word in [reg. 59\(1\)\(b\)](#) 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. 32\(b\)\(ii\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

#### Enforcement action in respect of formal non-compliance **N.I.**

**59.**—(1) Where an enforcing authority makes one of the following findings relating to apparatus, it must require a relevant economic operator to put an end to the non-compliance within a specified period—

- (a) the CE marking
  - (i) has not been affixed; or
  - (ii) has been affixed otherwise than in accordance with regulations 35 (prohibition on improper use of CE marking) and 42 (CE marking);
- [<sup>F229</sup>(aa) the UK(NI) indication—
  - (i) has not been affixed, in contravention of regulation 42A; or
  - (ii) has been affixed other than in accordance with regulation 42A;]
- (b) the EU declaration of conformity—
  - (i) has not been drawn up; or

- (ii) has been drawn up otherwise in accordance with regulation 10 (EU declaration of conformity and CE marking) and 41 (EU declaration of conformity);
  - (c) the technical documentation is either not available or not complete;
  - (d) the information set out in regulation 13 (information identifying manufacturer) is absent, false or incomplete;
  - (e) any other administrative requirement imposed on the manufacturer or importer under Part 2 has not been fulfilled.
- (2) Until the specified period has elapsed, the enforcing authority must not commence proceedings under these Regulations, or take any other enforcement action under these Regulations, against the relevant economic operator in respect of the non-compliance referred to in paragraph (1).
- (3) Where the non-compliance referred to in paragraph (1) persists, the enforcing authority must take appropriate measures to—
- (a) restrict or prohibit the apparatus being made available on the market;
  - (b) ensure that the apparatus is recalled;
  - (c) ensure that the apparatus is withdrawn from the market.
- (4) Where the non-compliance referred to in paragraph (1) persists and the apparatus has been imported for the person's own use, the enforcing authority must take appropriate measures to ensure that the apparatus is prohibited or restricted.
- (5) This regulation does not apply where apparatus presents a risk.

**F229** Reg. 59(1)(aa) inserted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(UK\(NI\) Indication\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1460\)](#), reg. 1(2), **Sch. 2 para. 7(4)**

### Restrictive measures

**60.** When enforcing these Regulations, an enforcing authority must comply with the requirements of Article 21 of RAMS in relation to any measure to—

- (a) prohibit or restrict apparatus being made available on the market;
- (b) withdraw apparatus; or
- (c) recall apparatus.

### Offences

**61.—(1)** It is an offence for a person to contravene or fail to comply with any requirement of regulations 7 to 15, 16(4), 17 to 24, 25(4), 26 to 30, 31(4), 33, 35 and 37.

(2) It is an offence for any person to contravene or fail to comply with any requirement of a withdrawal or recall notice served on that person by an enforcing authority under these Regulations.

### Penalties

**62.—(1)** Subject to paragraph (2) [<sup>F109</sup>and (3)], a person guilty of an offence under regulation 61 (offences) is liable on summary conviction—

- (a) in England and Wales—
  - (i) to imprisonment for a term not exceeding 3 months; or
  - (ii) a fine; or
  - (iii) to both.

- (b) in Scotland and Northern Ireland—
  - (i) to imprisonment for a term not exceeding 3 months; or
  - (ii) a fine not exceeding level 5 on the standard scale; or
  - (iii) to both.
- (2) A person guilty of an offence by reason of a contravention or failure to comply with regulations 11, 16, 24 and 31 is liable on summary conviction—
  - (a) in England and Wales, to a fine;
  - (b) in Scotland and Northern Ireland, to a fine not exceeding level 5 on the standard scale.
- [<sup>F110</sup>(3) A person guilty of an offence under regulation 61(2) insofar as the requirement relates to a UK(NI) indication is liable on summary conviction to a fine not exceeding level 5 on the standard scale.]

**F109** Words in [reg. 62\(1\)](#) inserted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(UK\(NI\) Indication\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1460\)](#), [reg. 1\(2\)](#), [Sch. 2 para. 7\(5\)\(a\)](#)

**F110** [Reg. 62\(3\)](#) inserted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(UK\(NI\) Indication\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1460\)](#), [reg. 1\(2\)](#), [Sch. 2 para. 7\(5\)\(b\)](#)

## Defence of due diligence

**63.**—(1) Subject to paragraph (2), (4) and (6), in proceedings for an offence under regulation 61 (offences), it is a defence for a person (“P”) to show that P took all reasonable steps and exercised all due diligence to avoid committing the offence.

(2) P may not rely on a defence under paragraph (1) which involves a third party allegation unless P has—

- (a) served a notice in accordance with paragraph (3); or
  - (b) obtained the leave of the court.
- (3) The notice must—
- (a) give any information in P's possession which identifies or assists in identifying the person who—
    - (i) committed the act or default; or
    - (ii) supplied the information on which P relied; and
  - (b) be served on the person bringing the proceedings not less than 7 clear days before—
    - (i) in England, Wales and Northern Ireland, the hearing of the proceedings;
    - (ii) in Scotland, the trial diet.

(4) P may not rely on a defence under paragraph (1) which involves an allegation that the commission of the offence was due to reliance on information supplied by another person unless it was reasonable for P to have relied upon the information, having regard in particular—

- (a) to the steps that P took, and those which might reasonably have been taken, for the purpose of verifying the information; and
- (b) to whether P had any reason to disbelieve the information.

(5) In this regulation, “third party allegation” means an allegation that the commission of the offence was due—

- (a) to the act or default of another person; or

- (b) to reliance on information supplied by another person.

### **Liability of persons other than the principal offender**

**64.**—(1) Where the commission of an offence by one person (“A”) under regulation 61 is due to anything which another person (“B”) did or failed to do in the course of any business, B is guilty of the offence and may be proceeded against and punished, whether or not proceedings are taken against A.

(2) Where a body corporate commits an offence, a relevant person is also guilty of the offence where the body corporate's offence was committed—

- (a) with the consent or connivance of the relevant person; or
  - (b) as a result of the negligence of the relevant person.
- (3) In paragraph (2), “relevant person” means—
- (a) a director, manager, secretary or other similar officer of the body corporate;
  - (b) in relation to a body corporate managed by its members, a member of that body corporate performing managerial functions;
  - (c) in relation to a Scottish partnership, a partner; or
  - (d) a person purporting to act as a person described in sub-paragraphs (a), (b) or (c).

### **Service of documents**

**65.**—(1) Any document required or authorised by these Regulations to be served on a person may be served by—

- (a) delivering it to that person in person;
  - (b) leaving it at that person's proper address; or
  - (c) sending it by post or electronic means to that person's proper address.
- (2) In the case of a body corporate, a document may be served on a director of that body.
- (3) In the case of a partnership, a document may be served on a partner or a person having control or management of the partnership business.
- (4) For the purposes of this regulation, “proper address” means—
- (a) in the case of a body corporate or its director—
    - (i) the registered or principal office of that body; or
    - (ii) the email address of the secretary or clerk of that body;
  - (b) in the case of a partnership, a partner or person having control or management of the partnership business—
    - (i) the principal office of the partnership; or
    - (ii) the email address of a partner or person having that control or management;
  - (c) in any other case, a person's last known address, which includes an email address.
- (5) If a person to be served with a document has specified an address in the United Kingdom (other than that person's proper address) at which that person or someone on that person's behalf will accept service, that address must also be treated as that person's proper address.
- (6) In this regulation, “partnership” includes a Scottish partnership.

## Recovery of expenses of enforcement

**66.**—(1) This regulation applies where a person commits an offence under regulation 61 (offences).

(2) The court may (in addition to any other order it may make as to costs or expenses) order the person to reimburse the enforcing authority for any expenditure which the enforcing authority has incurred in investigating the offence.

## Action by enforcing authority

**67.**—(1) An enforcing authority may itself take any action which an economic operator could have been required to take by a notice served under these Regulations where the conditions for serving such a notice are met and either—

(a) the enforcing authority has been unable to identify any economic operator on whom to serve such a notice; or

(b) the economic operator on whom such a notice has been served has failed to comply with it.

(2) If the enforcing authority has taken action as a result of the condition in paragraph (1)(b) being met, the authority may recover from that person, as a civil debt, any costs or expenses reasonably incurred by the enforcing authority in taking the action.

(3) A civil debt recoverable under paragraph (2) may be recovered summarily—

(a) in England and Wales by way of a complaint pursuant to section 58 of the Magistrates' Courts Act 1980 <sup>M13</sup>;

(b) in Northern Ireland in proceedings under article 62 of the Magistrates' Courts (Northern Ireland) Order 1981 <sup>M14</sup>.

### Marginal Citations

**M13** 1980 c.43; section 58 was amended by the Crime and Courts Act 2013 (c.22), Schedule 10 paragraph 40.

**M14** S.I. 1981/1675 (NI 26).

## Appeals against notices

**68.**—(1) Any application for an order to vary or set aside the terms of a notice served under these Regulations may be made—

(a) by the economic operator on whom the notice has been served; and

(b) by a person having an interest in the apparatus in respect of which the notice has been served, unless the notice is a recall notice.

(2) An application must be made before the end of the period of 21 days beginning with the day on which the notice was served.

(3) The appropriate court may only make an order setting aside a notice served under these Regulations if satisfied—

(a) that the requirements of these Regulations and RAMS (in its application to apparatus) have been complied with in respect of the apparatus to which the notice relates; or

(b) that the enforcing authority failed to comply with regulation 55 (exercise of enforcement powers) when serving the notice.

(4) On an application to vary the terms of a notice served under these Regulations, the appropriate court may vary the terms of the notice as it considers appropriate.



(5) In this regulation—

- (a) the “appropriate court” is to be determined in accordance with regulation 69 (appropriate court for appeals against notices); and
- (b) “notice” means any notice served in accordance with Part 2 of Schedule 7.

#### **Appropriate court for appeals against notices**

**69.**—(1) In England and Wales or Northern Ireland, the appropriate court for the purposes of regulation 68 (appeals against notices) is—

- (a) the court in which proceedings have been brought in relation to the apparatus for an offence under regulation 61 (offences); or
- (b) in any other case, a magistrates' court.

(2) In Scotland, the appropriate court for the purposes of regulation 68 is the sheriff of the sheriffdom in which the person making the appeal resides or has a registered principal office;

(3) A person aggrieved by an order made by a magistrates' court in England and Wales or Northern Ireland pursuant to an application under regulation 68, or by a decision of such a court not to make such an order, may appeal against that order or decision—

- (a) in England and Wales, to the crown court;
- (b) in Northern Ireland, to the county court.

#### **Time limit for prosecution of offences**

**70.**—(1) Subject to paragraph (4), in England and Wales an information relating to an offence under regulation 61 that is triable by a magistrates' court may be so tried if it is laid within 12 months after the date on which evidence sufficient in the opinion of the prosecutor to justify the proceedings comes to the knowledge of the prosecutor.

(2) Subject to paragraph (4), in Scotland—

- (a) summary proceedings for an offence under regulation 61 (offences) may be commenced before the end of 12 months after the date on which evidence sufficient in the Lord Advocate's opinion to justify the proceedings came to the Lord Advocate's knowledge; and
- (b) section 136(3) of the Criminal Procedure (Scotland) Act 1995 <sup>M15</sup> (time limit for certain offences) applies for the purpose of this paragraph as it applies for the purpose of that section.

(3) Subject to paragraph (4), in Northern Ireland summary proceedings for an offence under regulation 61 may be instituted within 12 months after the date on which evidence sufficient in the opinion of the prosecutor to justify proceedings comes to the knowledge of the prosecutor.

(4) No proceedings may be brought more than 3 years after the commission of the offence.

(5) For the purposes of this regulation a certificate of the prosecutor (or in Scotland, the Lord Advocate) as to the date on which the evidence referred to paragraphs (1), (2) or (3) came to their notice, is conclusive evidence.

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#### **Marginal Citations**

**M15** 1995 c.46.

## Compensation

**71.—**(1) Where an enforcing authority serves a relevant notice in respect of apparatus, the enforcing authority is liable to pay compensation to a person having an interest in the apparatus for any loss or damage suffered by reason of the notice if both of the conditions in paragraph (2) are met.

(2) The conditions are that—

(a) the apparatus in respect of which the relevant notice was served neither—

(i) presents a risk; nor

(ii) contravenes any requirement of these Regulations; and

(b) the exercise of the power to serve the relevant notice was not attributable to neglect or default by a relevant economic operator.

(3) In this regulation, “relevant notice” means a suspension, withdrawal or recall notice served in accordance with these Regulations.

## Power of the court to require a matter to be remedied

**72.—**(1) Where a person is convicted of an offence in relation to the contravention or failure to comply with a requirement of Part 2 or Part 3 of these Regulations in respect of a matter that appear to the court to be a matter which it is within that person's power to remedy, the court may, in addition to or instead of imposing any punishment, order that person within such time as may be specified in that order, to take such steps as may be specified in the order for remedy the said matter.

(2) The time specified in an order made under paragraph (1) may be extended or further extended by order of the court on an application made before the end of the time that was originally specified in that order or extended under this paragraph, as the case may be.

(3) Where a person is ordered under paragraph (1) to remedy any matter, that person is not guilty of an offence under these Regulations insofar as those offences continued until the date specified in the order under paragraph (1) or the date to which the period specified in that order is extended under paragraph (2).

# PART 6

## MISCELLANEOUS

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

**73.—**(1) The Secretary of State must from time to time—

(a) carry out a review of these Regulations;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the Directive is implemented in other member States.

(3) The report must, in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved by a system that imposes less regulation.

(4) The first report under this regulation must be published before the end of the period of 5 years beginning on the date these Regulations come into force.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding 5 years.

#### Extent Information

**E33** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Review **N.I.**

**73.**—(1) The Secretary of State must from time to time—

- (a) carry out a review of these Regulations;
- (b) set out the conclusions of the review in a report; and
- (c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the Directive is implemented in other [<sup>F230</sup>relevant states].

(3) The report must, in particular—

- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
- (b) assess the extent to which those objectives are achieved; and
- (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved by a system that imposes less regulation.

(4) The first report under this regulation must be published before the end of the period of 5 years beginning on the date these Regulations come into force.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding 5 years.

**F230** Words in [reg. 73\(2\)](#) 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. 6](#)

#### Transitional provision

**74.** Nothing in these Regulations prevents the making available on the market or the putting into service of equipment which—

- (a) is in conformity with the requirements of Directive [2004/108/EC](#) on the approximation of laws, regulations and administrative provisions of the Member States relating to electromagnetic compatibility <sup>F111</sup>; and
- (b) is placed on the market or put into service before the commencement date.

**F111** OJ L 390, 31.12.2004, p. 24.

#### [<sup>F112</sup>Transitional provision in relation to EU Exit

**74A.**—(1) In this regulation—

“pre-exit period” means the period beginning with 8th December 2016 and ending immediately before IP completion day;

“product” means electromagnetic equipment to which these Regulations apply.

(2) Subject to paragraph (3) where a product was made available on the market during the pre-exit period, despite the amendments made by Schedule 20 of the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, any obligation to which a person was subject under these Regulations as they had effect immediately before IP completion day, continues to have effect as it did immediately before IP completion day, in relation to that product.

(3) Paragraph (2) does not apply to—

- (a) any obligation to any enforcing authority to inform the European Commission or the member States of any matter; or
- (b) any obligation to take action outside of the United Kingdom in respect of that product.

(4) Where during the pre-exit period—

- (a) a product has not been placed on the market; and
- (b) a manufacturer has taken any action under regulation 40 as it had effect immediately before IP completion day;

that action has effect as if it had been done under regulation 40 as it has effect on and after IP completion day.]

[<sup>F113</sup>(5) Subject to paragraph (6), where before 11pm on 31st December 2024—

- (a) a product has not been placed on the market or put into service; and
- (b) a manufacturer has taken any action under the conformity assessment procedure that applies to that product in accordance with Article 14 of the Directive

that action has effect as if it had been done under the applicable conformity assessment procedure referred to in regulation 40.

(6) Paragraph (5) does not apply—

- (a) after the expiry of the validity of any certificate issued pursuant to the applicable conformity assessment procedure; and
- (b) in any event, after 31st December 2027.]

**F112** Reg. 74 inserted (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. 33** (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(i)(vi)**); 2020 c. 1, **Sch. 5 para. 1(1)**)

**F113** Reg. 74A(5)(6) inserted (31.12.2022) by [The Product Safety and Metrology \(Amendment and Transitional Provisions\) Regulations 2022](#) (S.I. 2022/1393), regs. 1(1), **12(2)**)

## Revocations and savings

**75.—**(1) Subject to paragraph (2), the 2006 Regulations are revoked.

(2) The 2006 Regulations continue to apply, [<sup>F114</sup>subject to the modifications in paragraph (2A),] as if they had not been revoked, to equipment placed on the market or put into service before the commencement date.

[<sup>F115</sup>(2A) The modifications referred to in paragraph (2) are that in the Electromagnetic Compatibility Regulations 2006—

- (a) any reference to “the Community” is to be read as including the United Kingdom;

(b) any reference to a “member State” is to be read as including the United Kingdom.]

(3) Accordingly, despite the repeals in regulation 76(4), the entries in paragraphs 10, 19(7)(a), 25(7) and 30(1) of Schedule 5 to the Consumer Rights Act 2015 <sup>M16</sup> relating to the 2006 Regulations are to continue to have effect in relation to equipment placed on the market or put into service before the commencement date.

(4) The Electromagnetic Compatibility (Amendment) Regulations 2006 <sup>M17</sup> are revoked.

(5) Nothing in these Regulations is to be construed as preventing the taking of any action in respect of any equipment under the provisions of any other enactment.

**F114** Words in [reg. 75\(2\)](#) 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. 34\(2\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))

**F115** [Reg. 75\(2A\)](#) 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. 34\(3\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))

#### Marginal Citations

**M16** [2015 c.15.](#)

**M17** [S.I. 2006/1449.](#)

#### Consequential amendments

**76.—**(1) In Schedule 1 to the Enterprise Act 2002 (Part 9 Restrictions on Disclosure of Information)(Specification) Order 2004 <sup>M18</sup> for “the Electromagnetic Compatibility Regulations 2006”, substitute “ the Electromagnetic Compatibility Regulations 2016 ”.

(2) The Legislative and Regulatory Reform (Regulatory Functions) Order 2007 <sup>M19</sup> is amended as follows—

(a) in Part 3 of the Schedule, under the heading “Consumer and business protection”, for “Electromagnetic Compatibility Regulations 2006”, substitute “ Electromagnetic Compatibility Regulations 2016 ”;

(b) in Part 8 of the Schedule, for “Electromagnetic Compatibility Regulations 2006”, substitute “ Electromagnetic Compatibility Regulations 2016 ”.

(3) In Part 4 of Schedule 1 to the Co-ordination of Regulatory Enforcement (Regulatory Functions in Scotland and Northern Ireland) Order 2009 <sup>M20</sup> for “the Electromagnetic Compatibility Regulations 2006”, substitute “ the Electromagnetic Compatibility Regulations 2016 ”.

(4) Subject to paragraph (3) of regulation 75, Schedule 5 to the Consumer Rights Act 2015 is amended as follows—

(a) in paragraph 10—

(i) omit the entry “regulation 37(1)(a)(ii) or (b)(ii) of the Electromagnetic Compatibility Regulations 2006 (S.I. 2006/3418);”;

(ii) at the appropriate place insert—

“regulation 52(1)(a)(ii) or (b)(ii) of the Electromagnetic Compatibility Regulations 2016 (S.I. 2016/1091);”;

(b) in paragraph 19(7)(a), for “the Electromagnetic Compatibility Regulations 2006 (S.I. 2006/3418)”, substitute “ the Electromagnetic Compatibility Regulations 2016 (S.I. 2016/1091) ”;

- (c) in paragraph 25(7), for “regulation 37(1)(a)(ii) or (b)(ii) of the Electromagnetic Compatibility Regulations (S.I. 2006/3418)”, substitute “ regulation 52(1)(a)(ii) or (b)(ii) of the Electromagnetic Compatibility Regulations (S.I. 2016/1091) ”; and
- (d) in paragraph 30(1), for “regulation 37(1)(a)(ii) or (b)(ii) of the Electromagnetic Compatibility Regulations (S.I. 2006/3418)”, substitute “ regulation 52(1)(a)(ii) or (b)(ii) of the Electromagnetic Compatibility Regulations (S.I. 2016/1091) ”.

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**Marginal Citations**

**M18** [S.I. 2004/693](#).

**M19** [S.I. 2007/3544](#).

**M20** [S.I. 2009/699](#).

Department for Business, Energy and Industrial  
Strategy

*Margot James*  
Parliamentary Under Secretary of State, Minister  
for Small Business, Consumers and Corporate  
Responsibility

## SCHEDULES

### SCHEDULE 1

Regulation 2(1)

#### Essential Requirements

##### General requirements

1. Equipment must be so designed and manufactured, having regard to the state of the art, as to ensure that—
  - (a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;
  - (b) it 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.

##### Specific requirements for fixed installations

2. A fixed installation must be installed applying good engineering practices and respecting the information on the intended use of its components, with a view to meeting the essential requirements set out in paragraph 1 of this Schedule.

### SCHEDULE 2

Regulation 9(b)(i)

#### Module A: internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2 to 5 of this Schedule, and ensures and declares on the manufacturer's sole responsibility that the apparatus concerned satisfies the requirements of these Regulations that apply to it.

#### *Electromagnetic compatibility assessment*

2. The manufacturer must perform an electromagnetic compatibility assessment of the apparatus, on the basis of the relevant phenomena, with a view to meeting the essential requirements set out in paragraph 1 of Schedule 1.
3. The electromagnetic compatibility assessment must take into account all normal intended operating conditions. Where the apparatus is capable of taking different configurations, the electromagnetic compatibility assessment must confirm whether the apparatus meets the essential requirements set out in paragraph 1 of Schedule 1 in all the possible configurations identified by the manufacturer as representative of its intended use.



### *Technical documentation*

4. The manufacturer must establish the technical documentation. The documentation must make it possible to assess the conformity of the apparatus to the relevant requirements, and must include an adequate analysis and assessment of the risks.

5. The technical documentation must specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the apparatus. The technical documentation must, wherever applicable, contain at least the following elements—

- (a) a general description of the apparatus;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus;
- (d) a list of the [F116designated] standards applied in full or in part <sup>F117</sup>... and, where those [F116designated] standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of a partly applied [F116designated] standard, the technical documentation must specify the parts of the standard that have been applied;
- (e) results of design calculations made, examinations carried out, etc.;
- (f) test reports.

### *Manufacturing*

6. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure the compliance of the manufactured apparatus with the technical documentation referred to in paragraphs 4 and 5 of this Schedule and the essential requirements set out in paragraph 1 of Schedule 1.

### *[F118CE][F118UK] marking and [F119EU] declaration of conformity*

**F118** Word in [Sch. 2 para. 7](#) 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. 35\(b\)\(i\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**F119** Word in [Sch. 2 para. 7](#) 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. 35\(b\)\(ii\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

7. The manufacturer must affix the [F120UK] marking to each individual apparatus that satisfies the applicable requirements of these Regulations,

8. The manufacturer must draw up a written [F121EU] declaration of conformity for an apparatus model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the apparatus has been placed on the market. The [F121EU] declaration of conformity must identify the apparatus model for which it has been drawn up.

**F121** Word in [Sch. 2 para. 8](#) 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. 35\(d\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

### Authorised Representative

9. The manufacturer's obligations set out in paragraphs 7 and 8 may be fulfilled by the authorised representative, on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate.

## SCHEDULE 3

Regulation 9(b)(i)

### Applicable conformity assessment procedures

## PART 1

### Module B: [F122EU-type][F122Type] Examination

**F122** Word in Sch. 3 Pt. 1 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. 36(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)

1. [F123Type] examination is the part of a conformity assessment procedure in which [F124an approved] body examines the technical design of an apparatus and verifies and attests that the technical design of the apparatus meets the essential requirements set out in paragraph 1 of Schedule 1.

2. [F125Type] examination must be carried out by an assessment of the adequacy of the technical design of the apparatus through examination of the technical documentation referred to in paragraphs 3 and 4 without examination of a specimen (design type). It may be restricted to some aspects of the essential requirements as specified by the manufacturer or the manufacturer's authorised representative.

3. The manufacturer must lodge an application for [F126Type] examination with a single [F127approved] body of the manufacturer's choice. The application must specify the aspects of the essential requirements for which examination is requested and must include—

- (a) the name and address of the manufacturer or, if the application is lodged by an authorised representative, the name and address of the authorised representative and of the manufacturer;
- (b) a written declaration that the same application has not been lodged with another [F127approved] body;
- (c) the technical documentation.

4. The technical documentation referred to in paragraph 3(c) of this Schedule must make it possible to assess the conformity of the apparatus with the applicable requirements of these Regulations and must include an adequate analysis and assessment of the risks posed by the apparatus. The technical documentation must specify the applicable requirements and cover, as far as is relevant for the assessment, the design, manufacture and operation of the apparatus. The technical documentation must contain, where applicable, at least the following elements—

- (a) a general description of the apparatus;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.

- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus;
  - (d) a list of the [<sup>F128</sup>designated] standards applied in full or in part <sup>F129</sup>... and, where the harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of a partly applied harmonised standard, the technical documentation must specify the parts of the standard that have been applied;
  - (e) results of design calculations made, examinations carried out, etc.;
  - (f) test reports.
5. The [<sup>F130</sup>approved] body must examine the technical documentation to assess the adequacy of the technical design of the apparatus in relation to the aspects of the essential requirements for which examination is requested.
6. The [<sup>F131</sup>approved] body must draw up an evaluation report which records the activities undertaken in accordance with paragraph 5 and their outcomes. Without prejudice to its obligations to the notifying authorities, the [<sup>F131</sup>approved] body must release the content of that report, in full or in part, only with the agreement of the manufacturer.
7. Where the type meets the requirements of these Regulations that apply to the apparatus concerned, the [<sup>F132</sup>approved] body must issue [<sup>F133</sup>a Type] examination certificate to the manufacturer.
8. The [<sup>F134</sup>Type] examination certificate, which may be accompanied by one or more annexes, must contain—
- (a) the name and address of the manufacturer;
  - (b) the conclusions of the examination of the apparatus;
  - (c) the aspects of the essential requirements covered by the examination;
  - (d) the conditions (if any) for the validity of the certificate; and
  - (e) the necessary data for the identification of the approved type.
9. The [<sup>F135</sup>Type] examination certificate and any annexes to that certificate must contain all relevant information to allow the conformity of manufactured apparatus with the examined type to be evaluated and to allow for in-service control.
10. Where the type does not satisfy the applicable requirements of these Regulations, the [<sup>F136</sup>approved] body must refuse to issue the [<sup>F137</sup>Type] examination certificate and must inform the applicant accordingly, giving detailed reasons for its refusal.
11. The [<sup>F138</sup>approved] body must keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of these Regulations and must determine whether such changes require further investigation. If so, the [<sup>F138</sup>approved] body must inform the manufacturer accordingly.
12. The manufacturer must inform the [<sup>F139</sup>approved] body that holds the technical documentation relating to the [<sup>F140</sup>Type] examination certificate of all modifications to the approved type that may affect the conformity of the apparatus with the essential requirements of these Regulations or the conditions for validity of that certificate. Such modifications must require additional approval in the form of an addition to the [<sup>F140</sup>Type] examination certificate.
13. Each [<sup>F141</sup>approved] body must inform its notifying authority of any [<sup>F142</sup>Type] examination certificates or any additions thereto, which it has issued or withdrawn and, must periodically or upon

request, make available to its notifying authority a list of such certificates and additions thereto that it has refused, suspended or otherwise restricted.

14. Each [<sup>F143</sup>approved] body must inform the other [<sup>F143</sup>approved] bodies of any [<sup>F144</sup>Type] examination certificates or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted. Upon request from another [<sup>F143</sup>approved] body, [<sup>F145</sup>an approved] body must inform the requesting body of the [<sup>F144</sup>Type] examination certificates that it has issued.

15. [<sup>F146</sup>The Secretary of State] and the other [<sup>F147</sup>approved] bodies may, on request, obtain a copy of the [<sup>F148</sup>Type] examination certificate and any additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examination carried out by the [<sup>F147</sup>approved] body. The [<sup>F147</sup>approved] body must keep a copy of the [<sup>F148</sup>Type] examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

16. The manufacturer must keep a copy of the [<sup>F149</sup>Type] examination certificate, its annexes and additions, together with the technical documentation at the disposal of the national authorities for 10 years after the apparatus has been placed on the market.

17. The manufacturer's authorised representative may lodge the application referred to in paragraph 3 and fulfil the obligations set out in paragraphs 12 and 16 of this Schedule, provided that these obligations are specified in the authorised representative's written mandate.

## PART 2

### Module C: conformity to type based on internal production control

Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations set out in paragraphs 19 and 20 of this Schedule and ensures and declares that the apparatus concerned is in conformity with the type described in the [<sup>F150</sup>Type] Examination certificate and satisfies the requirements of these Regulations that apply to it.

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

19. The manufacturer must take all measures necessary to ensure that the manufacturing process and the monitoring of that process ensure the conformity of the manufactured apparatus with the approved type described in the [<sup>F151</sup>Type] examination certificate and with the requirements of these Regulations that apply to it.

#### Extent Information

**E53** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

**F151** Word in [Sch. 3 para. 19](#) 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. 37\(a\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

#### Manufacturing **N.I.**

19. The manufacturer must take all measures necessary to ensure that the manufacturing process and the monitoring of that process ensure the conformity of the manufactured apparatus with the

approved type described in the EU-type examination certificate and with the requirements of these Regulations that apply to it.

### **[<sup>F152</sup>UK] marking and <sup>F153</sup>... declaration of conformity **E+W+S****

**20.—**(1) The manufacturer must affix the [<sup>F154</sup>UK] marking to each individual apparatus that is in conformity with the type described on the [<sup>F155</sup>Type] examination certificate and satisfies the applicable requirements of these Regulations.

(2) The manufacturer must draw up a written <sup>F156</sup>... declaration of conformity for each apparatus model and keep it at the disposal of the national authorities for 10 years after the apparatus has been placed on the market. The <sup>F156</sup>... declaration of conformity must identify the apparatus model for which it has been drawn up.

(3) A copy of the <sup>F157</sup>... declaration of conformity must be made available to the relevant authorities upon request.

#### **Extent Information**

**E54** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

**F152** Word in [Sch. 3 para. 20](#) 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. 37\(b\)\(i\)](#) (with [Sch. 20 para. 33](#)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F153** Word in [Sch. 3 para. 20](#) 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. 37\(b\)\(ii\)](#) (with [Sch. 20 para. 33](#)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F154** Word in [Sch. 3 para. 20\(1\)](#) 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. 37\(c\)\(i\)](#) (with [Sch. 20 para. 33](#)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F155** Word in [Sch. 3 para. 20\(1\)](#) 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. 37\(c\)\(ii\)](#) (with [Sch. 20 para. 33](#)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F156** Word in [Sch. 3 para. 20\(2\)](#) 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. 37\(d\)](#) (with [Sch. 20 para. 33](#)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F157** Word in [Sch. 3 para. 20\(3\)](#) 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. 37\(d\)](#) (with [Sch. 20 para. 33](#)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

**20.—**(1) The manufacturer must affix the CE marking to each individual apparatus that is in conformity with the type described on the EU-type examination certificate and satisfies the applicable requirements of these Regulations.

(2) The manufacturer must draw up a written EU declaration of conformity for each apparatus model and keep it at the disposal of the national authorities for 10 years after the apparatus has been placed on the market. The EU declaration of conformity must identify the apparatus model for which it has been drawn up.

(3) A copy of the EU declaration of conformity must be made available to the relevant authorities upon request.

## Authorised representative

21. The manufacturer's obligations set out in paragraph 20 of this Schedule may be fulfilled by an authorised representative on behalf of the manufacturer and under the responsibility of the manufacturer provided that these responsibilities are set out in the authorised representative's written mandate.

## SCHEDULE 4

Regulation 41

### [<sup>F158</sup>EU declaration][<sup>F158</sup>Declaration] of conformity

**F158** Word in [Sch. 4](#) 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. 38\(a\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

### [<sup>F159</sup>EU declaration][<sup>F159</sup>Declaration] of conformity (No xxxx) <sup>M21</sup>

1. Apparatus model (apparatus, type, batch or serial number):

**F159** Word in [Sch. 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. 38\(b\)](#) (with [Sch. 20 para. 33](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

#### Marginal Citations

**M21** It is optional for the manufacturer to assign a number to the declaration of conformity.

2. Name and address of manufacturer or the manufacturer's authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of apparatus allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the apparatus):
5. The object of the declaration described above is in conformity with the relevant [<sup>F160</sup>statutory requirements]:
6. References to the relevant [<sup>F161</sup>designated] standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:
7. Where applicable, the [<sup>F162</sup>approved] body ... (name, number) performed ... (description of intervention) and issued the certificate:
8. Additional information:
  - Signed for and on behalf of:
  - (place and date of issue):
  - (name, function) (signature):

## SCHEDULE 5

Regulation 2(1)

### Requirements for [F163notified][F163approved] bodies

**F163** Word in Sch. 5 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. 39(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)

1. A conformity assessment body must be established in the United Kingdom and have legal personality.

2.—(1) A conformity assessment body must be a third party body independent of the organisation or the apparatus it assesses.

(2) A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of apparatus which it assesses may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered an independent body under sub-paragraph (1).

3. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the apparatus which the conformity assessment body assesses, nor the representative of any of those parties.

4. Nothing in paragraph 3 of this Schedule precludes the use of assessed apparatus that is necessary for the operations of the conformity assessment body or the use of such apparatus for personal purposes.

5. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must not be directly involved in the design, manufacture or construction, marketing, installation, use or maintenance of the apparatus, or represent the parties engaged in those activities.

6. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must not engage in any activity, including consultancy services, that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are [F164approved].

7. A conformity assessment body must ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

8. A conformity assessment body and its personnel must carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

9. A conformity assessment body must be capable of carrying out all of the conformity assessment activities in relation to which it has been, or is to be, [F165approved], whether those activities are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

10. A conformity assessment body must have at its disposal—

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment activities;



- (b) descriptions of procedures in accordance with which conformity assessment is carried out ensuring the transparency and ability of reproduction of those procedures;
  - (c) policies and procedures in place to distinguish between tasks that it carries out as [<sup>F166</sup>an approved] body and other activities;
  - (d) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the apparatus in question and the mass or serial nature of the production process.
- 11.** A conformity assessment body must have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and must have access to all necessary equipment and facilities.
- 12.** The personnel responsible for carrying out the conformity assessment activities must have—
- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been [<sup>F167</sup>approved];
  - (b) satisfactory knowledge of the requirements of the assessments that they carry out and adequate authority to carry out those assessments;
  - (c) appropriate knowledge and understanding of the essential requirements, of the applicable [<sup>F168</sup>designated] standards and <sup>F169</sup>... of these Regulations;
  - (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.
- 13.** A conformity assessment body must be able to demonstrate the impartiality of its top level management and the personnel responsible for carrying out the conformity assessment activities.
- 14.** The remuneration of the top level management and the personnel responsible for carrying out the conformity assessment activities must not depend on the number of assessments carried out or on the results of those assessments.
- 15.** A conformity assessment body must have, and must satisfy the Secretary of State that it has, adequate civil liability insurance in respect of its activities.
- 16.** A conformity assessment body must ensure that its personnel observe professional secrecy with regard to all information obtained in carrying out their tasks in accordance with these Regulations and that proprietary rights are protected.
- 17.** Paragraph 16 does not prevent the personnel from providing information to the Secretary of State or an enforcing authority.
- 18.** A conformity assessment body must participate in, or ensure that its personnel who are responsible for carrying out the conformity assessment activities are informed of, the relevant standardisation activities and the activities of any [<sup>F170</sup>approved] body coordination group established [<sup>F171</sup>by the Secretary of State] and must apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

## SCHEDULE 6

Regulation 50

Operational obligations of [<sup>F172</sup>notified][<sup>F172</sup>approved] bodies

**F172** Word in Sch. 6 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. 40(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)

1. [<sup>F173</sup>An approved] body must carry out conformity assessments in accordance with the relevant conformity assessment procedures.
2. [<sup>F174</sup>An approved] body must carry out conformity assessments in a proportionate manner, avoiding unnecessary burdens for economic operators.
3. Conformity assessment bodies must perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the apparatus technology in question and the mass or serial nature of the production process.
4. Conformity assessment bodies must respect the degree of rigour and level of protection required for the compliance of the apparatus with these Regulations.
5. Where [<sup>F175</sup>an approved] body finds that the essential requirements or the corresponding [<sup>F176</sup>designated] standards or other technical specifications have not been met by a manufacturer, it must require that manufacturer to take appropriate corrective measures and must not issue a certificate.
6. Where, in the course of the monitoring of the conformity of apparatus following the issue of a certificate, [<sup>F177</sup>an approved] body finds that apparatus is no longer in conformity, it must require the manufacturer to take appropriate corrective measures and must suspend or withdraw the certificate if necessary.
7. Where corrective measures are not taken or do not have the required corrective effect, the [<sup>F178</sup>approved] body must restrict, suspend or withdraw any certificate as appropriate.
8. Paragraph 9 applies where [<sup>F179</sup>an approved] body is minded to—
  - (a) refuse to issue a certificate; or
  - (b) restrict, suspend or withdraw a certificate.
9. Where this paragraph applies, the [<sup>F180</sup>approved] body must—
  - (a) give the person applying for the certificate, or the person to whom the certificate was given, a notice in writing giving reasons and specifying the date on which the refusal, restriction, suspension or withdrawal is intended to take effect;
  - (b) give the person applying for the certificate, or the person to whom the certificate was given, an opportunity to make representations within a reasonable period from the date of the notice; and
  - (c) take account of any such representations before taking its decision.
10. [<sup>F181</sup>An approved] body must inform the Secretary of State of—
  - (a) any refusal, restriction, suspension or withdrawal of a certificate;
  - (b) any circumstances affecting the scope of, or conditions for, notification under regulation 44 (notification);
  - (c) any request for information which it has received from the market surveillance authority regarding conformity assessment activities; and

- (d) on request, conformity assessment activities performed within the scope of its notifications under regulation 44 and any other activity performed, including cross-border activities and subcontracting.
- 11. [<sup>F182</sup>An approved] body must make provision in its contracts with its clients enabling such clients to appeal against a decision—
  - (a) to refuse to issue a certificate; or
  - (b) to restrict, suspend or withdraw a certificate.
- 12. [<sup>F183</sup>An approved] body must provide other bodies [<sup>F184</sup>approved under these Regulations] carrying out similar conformity assessment activities covering the same type of apparatus with relevant information on issues relating to negative and, on request, positive conformity assessment results.
- 13. [<sup>F185</sup>An approved] body must participate in the work of [<sup>F186</sup>any approved] body coordination group established [<sup>F187</sup>by the Secretary of State], directly or by means of its designated representatives.

## SCHEDULE 7

Regulation 53

Enforcement and investigatory powers conferred on the enforcing authority and the market surveillance authority

## PART 1

### ENFORCEMENT AND INVESTIGATORY POWERS

#### Enforcement powers under the 1987 Act

1. For the purposes of enforcing these Regulations, the following sections of the 1987 Act apply subject to the modifications in paragraph 2—

- (a) section 13 (prohibition notices and notices to warn);
- (b) section 14 (suspension notices);
- (c) section 16 (forfeiture: England and Wales and Northern Ireland);
- (d) section 17 (forfeiture: Scotland);
- (e) section 18 (power to obtain information);
- (f) section 19 (interpretation of Part II);
- (g) section 29 (powers of search etc);
- (h) section 30 (provisions supplemental to s 29);
- (i) section 31 (powers of customs officer to detain goods);
- (j) section 33 (appeals against detention of goods);
- (k) section 34 (compensation for seizure and detention);
- (l) section 35 (recovery of expenses of enforcement);
- (m) section 37 (power of Commissioners for Revenue and Customs);
- (n) section 45 (interpretation);

- (o) section 46(1) (meaning of “supply”);
- (p) Schedule 2 (prohibition notices and notices to warn).

## **Modifications to the 1987 Act**

2. The sections of the 1987 Act referred to in paragraph 1 are to apply as if—
  - (a) in section 13—
    - (i) in subsection (1), for “unsafe” on each occasion that it appears, there were substituted “non-compliant”;
    - (ii) in subsection (1), “relevant” were omitted on each occasion that it appears;
    - (iii) in subsection (2), the words from “; and the Secretary of State may” to the end were omitted;
    - (iv) subsections (4) to (7) were omitted;
  - (b) in section 14—
    - (i) in subsection (1), after “any safety provision has been contravened in relation to any goods”, there were inserted “or that any goods present a risk”;
    - (ii) in subsection (2)(b), after “a safety provision has been contravened in relation to the goods”, there were inserted “or that the goods present a risk”;
    - (iii) in subsection (2)(c), “under section 15 below” were omitted; and
    - (iv) subsections (6) to (8) were omitted;
  - (c) in section 16—
    - (i) in subsection (1), after “a contravention in relation to the goods of a safety provision” there were inserted “or that the goods present a risk”;
    - (ii) for subsection 2(b) there were substituted—
      - “(b) where an application with respect to some or all of the goods has been made to a magistrates' court under regulation 68 (appeals against notices) of the Electromagnetic Compatibility Regulations 2016 or section 33, to that court; and”;
    - (iii) in subsection (3), after “a contravention in relation to the goods of a safety provision” there were inserted “or that the goods present a risk”;
    - (iv) after subsection (4), there were inserted—
      - “(4A) A court may infer for the purposes of this section that any goods present a risk if it is satisfied that such a risk is presented by goods which are representative of those goods (whether by reason of being of the same design or part of the same consignment or batch or otherwise).”;
    - (v) in subsection (6), for “Subject to subsection (7) below,” there were substituted “Where”; and
    - (vi) subsection (7) were omitted;
  - (d) in section 17—
    - (i) in subsection (1), after “a contravention of a safety provision”, there were inserted “or where the goods present a risk”;
    - (ii) in subsection (6), after “a contravention in relation to those goods of a safety provision” there were inserted “or that those goods present a risk”; and
    - (iii) after subsection (7), there were inserted—

“(7A) The sheriff may infer for the purposes of this section that any goods present a risk if satisfied that such a risk is presented by goods which are representative of those goods (whether by reason of being of the same design or part of the same consignment or batch or otherwise).”;

- (e) in section 18, subsections (3) and (4) were omitted;
- (f) in section 29—
  - (i) in subsection (4)(a), after “any contravention of any safety provision in relation to the goods” there were inserted “ or whether the goods present a risk ”;
  - (ii) in subsection (4)(b), after “any such contravention” there were inserted “ or whether the goods present a risk ”;
  - (iii) in subsection (7), after “a contravention of any safety provision”, there were inserted “ or prevent goods from presenting a risk ”;
- (g) in section 30—
  - (i) at the end of subsection (2)(a)(ii), for “and”, there were substituted “ or ”;
  - (ii) after subsection (2)(a)(ii), there were inserted—
    - “(iii) that any goods which any officer has power to inspect under section 29 are on any premises and their inspection is likely to demonstrate that they present a risk; and;” and
  - (iii) subsections (5), (7) and (8) were omitted;
- (h) in section 31(1), for “Part II of this Act”, there were substituted “ the Electromagnetic Compatibility Regulations 2016 ”;
- (i) in section 34(1), after paragraph (a), there were inserted—
  - “(aa) the goods do not present a risk;”;
- (j) in section 37(1), for “Part II of this Act”, there were substituted “ the Electromagnetic Compatibility Regulations 2016 ”;
- (k) in section 45(1)—
  - (i) the definitions of “conditional sale agreement”, “credit-sale agreement”, “gas”, “motor vehicle”, “personal injury”, “subordinate legislation” and “substance” were omitted;
  - (ii) for the definition of “enforcement authority” there were substituted—
    - ““enforcement authority” means an enforcing authority as defined in regulation 2(1) of the Electromagnetic Compatibility Regulations 2016;”;
  - (iii) for the definition of “goods” there were substituted—
    - ““goods” means apparatus within the scope of the Electromagnetic Compatibility Regulations 2016;”;
  - (iv) after the definition of “modifications” there were inserted—
    - ““non-compliant” in relation to any goods means that—
      - (a) a safety provision has been contravened in relation to the goods; or
      - (b) the goods present a risk;”;
  - (v) after the definition of “premises”, there were inserted—
    - ““present a risk” means present a risk within the meaning set out in regulation 2(3) of the Electromagnetic Compatibility Regulations 2016;”;
  - (vi) for the definition of “safety provision” there were substituted—

““safety provision” means any provision of the Electromagnetic Compatibility Regulations 2016;” and

(vii) for the definition of “safety regulations” there were inserted—

““safety regulations” means the Electromagnetic Compatibility Regulations 2016;”;

(l) in section 46(1), omit “and, in relation to gas or water, those references shall be construed as including references to providing the service by which the gas or water is made available for use”; and

(m) in Schedule 2—

(i) for “unsafe”, on each occasion that it appears, there were substituted “ non-compliant ”; and

(ii) for “safe” , on each occasion that it appears, there were substituted “ not non-compliant ”.

### **Application of Schedule 5 to the Consumer Rights Act 2015**

**3.** Schedule 5 to the Consumer Rights Act 2015 (investigatory powers etc) applies to OFCOM as if—

- (a) OFCOM were a domestic enforcer within the meaning of that Schedule;
- (b) the enforcer's legislation within the meaning of that Schedule, in relation to OFCOM, were the legislation and notices which, by virtue of regulation 52(1)(a)(i) or (b)(i), OFCOM has a duty or power to enforce; and
- (c) the references in paragraphs 25(7) and 30(1) of that Schedule to regulation 52(1)(a)(ii) or (b)(ii) were references to regulations 52(1)(a)(i) or (b)(i).

## **PART 2**

### **COMPLIANCE NOTICES, WITHDRAWAL NOTICES AND RECALL NOTICES**

#### **Compliance notice**

**4.** An enforcing authority may serve a compliance notice on a relevant economic operator in respect of apparatus if the authority has reasonable grounds for believing that there is non-compliance.

**5.** A compliance notice must—

- (a) require the relevant economic operator on which it is served to—
  - (i) end the non-compliance within such period as may be specified in the notice; or
  - (ii) provide evidence, within such period as may be specified in the notice, demonstrating to the satisfaction of the enforcing authority that the non-compliance has not in fact occurred; and
- (b) warn the economic operator that, if the non-compliance persists or if satisfactory evidence has not been produced under sub-paragraph (a) within the period specified in the notice, further action may be taken in respect of the apparatus or any apparatus of the same type made available on the market by that relevant economic operator.

**6.** A compliance notice may include directions as to the measures to be taken by the economic operator to secure compliance, including different ways of securing compliance.

7. Subject to paragraph 8, an enforcing authority may revoke or vary a compliance notice by serving a notification on the economic operator.

8. An enforcing authority may not vary a compliance notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

### **Withdrawal notice**

9. An enforcing authority may serve a withdrawal notice on a relevant economic operator in respect of apparatus if the authority has reasonable grounds for believing that—

- (a) the apparatus has been made available on the market; and
- (b) there is non-compliance.

10. A withdrawal notice must prohibit the relevant economic operator from making the apparatus available on the market without the consent of the enforcing authority.

11. A withdrawal notice may require the relevant economic operator to take action to alert end-users to any risk presented by the apparatus.

12. A withdrawal notice may require the relevant economic operator to keep the enforcing authority informed of the whereabouts of any apparatus referred to in the notice.

13. A consent given by the enforcing authority pursuant to a withdrawal notice, may impose such conditions on the making available on the market as the enforcing authority considers appropriate.

14. Subject to paragraph 15, an enforcing authority may revoke or vary a withdrawal notice by serving a notification on the economic operator.

15. An enforcing authority may not vary a withdrawal notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

16. A withdrawal notice has effect throughout the United Kingdom.

### **Recall notice**

17. The enforcing authority may serve a recall notice on a relevant economic operator in respect of apparatus if the authority has reasonable grounds for believing that—

- (a) the apparatus has been made available to end-users; and
- (b) there is non-compliance.

18. A recall notice must require the relevant economic operator to use reasonable endeavours to organise the return of the apparatus from end-users to the relevant economic operator or another person specified in the notice.

19. A recall notice may—

- (a) require the recall to be effected in accordance with a code of practice;
- (b) require the relevant economic operator to—
  - (i) contact end-users in order to inform them of the recall, to the extent that it is practicable to do so;
  - (ii) publish a notice in such form and such manner as is likely to bring to the attention of end-users any risk the apparatus poses and the fact of the recall; or
  - (iii) make arrangements for the collection or return of the apparatus from end-users or its disposal; or
- (c) impose such additional requirements on the relevant economic operator as are reasonable and practicable with a view to achieving the return of the apparatus.



**20.** In determining what requirements to include in a recall notice, the enforcing authority must take into consideration the need to encourage distributors and end-users to contribute to its implementation.

**21.** A recall notice may only be issued by the enforcing authority where—

- (a) other action which it may require under these Regulations would not suffice to address the non-compliance;
- (b) the action being undertaken by the relevant economic operator is unsatisfactory or insufficient to address the non-compliance;
- (c) the enforcing authority has given not less than 10 days' notice to the relevant economic operator of its intention to serve such a notice; and
- (d) the enforcing authority has taken account of any advice obtained under paragraph 22.

**22.** A relevant economic operator which has received notice from the enforcing authority of an intention to serve a recall notice may at any time prior to the service of the recall notice require the authority to seek the advice of such person as the Institute determines on the questions of—

- (a) whether there is non-compliance; and
- (b) whether the issue of a recall notice would be proportionate.

**23.** Paragraphs 21(b), (c) and (d) do not apply in the case of apparatus presenting a serious risk requiring, in the view of the enforcing authority, urgent action.

**24.** Where a relevant economic operator requires the enforcing authority to seek advice under paragraph 22, that relevant economic operator is to be responsible for the fees, costs and expenses of the Institute and of the person appointed by the Institute to advise the enforcing authority.

**25.** In this Schedule, “Institute” means the charitable organisation with registered number 803725 and known as the Chartered Institute of Arbitrators.

**26.** A recall notice served by the enforcing authority may require the relevant economic operator to keep the authority informed of the whereabouts of apparatus to which the recall notice relates, so far as the relevant economic operator is able to do so.

**27.** Subject to paragraph 28, an enforcing authority may revoke or vary a recall notice by serving a notification on the economic operator.

**28.** An enforcing authority may not vary a recall notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

**29.** A recall notice has effect throughout the United Kingdom.

## **Interpretation**

**30.** In this Schedule, “non-compliance” means that the apparatus—

- (a) presents a risk; or
- (b) is not in conformity with Part 2 or RAMS (in its application to apparatus).

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations transpose Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast) (OJ L 96, 29.3.2014, p.79) (“the Directive”).

The Directive repeals and replaces Directive [2004/108/EC](#) of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive [89/336/EEC](#) which was implemented in the United Kingdom by the Electromagnetic Compatibility Regulations 2006 (S.I. 2006/3418) (as amended). These Regulations revoke and replace S.I. 2006/3418.

Regulations 3 to 5 set out the application of the Regulations to apparatus and equipment, as defined in regulation 2.

Part 2 sets out the obligations of economic operators. Regulations 8 to 16 set out the obligations that are specific to manufacturers. Obligations include ensuring that apparatus has been designed and manufactured in accordance with the essential requirements set out in Schedule 1, having a relevant conformity assessment procedure carried out before the apparatus is placed on the market and affixing the CE marking. Regulation 38 sets out the obligations which an authorised representative, appointed by a manufacturer, may and may not perform on the manufacturer's behalf.

Regulations 17 to 25 set out the obligations that are specific to importers. These obligations include ensuring that the importer is not placing on the market apparatus which is not in conformity with the essential requirements, checking that the manufacturer has carried out a relevant conformity assessment procedure and ensuring the apparatus bears the name and address of the importer. Those regulations also include an obligation to ensure that, while the importer is responsible for apparatus, the storage and transport of the apparatus does not jeopardise its conformity with the essential requirements.

Regulations 26 to 31 set out the obligations that are specific to distributors. These obligations include acting with due care to ensure that apparatus is in conformity with Part 2 and checking that apparatus bears the CE marking. Those regulations also include an obligation to ensure that, while the distributor is responsible for apparatus, the storage and transport of the apparatus does not jeopardise its conformity with the essential requirements.

Regulations 32 to 37 set out obligations which apply to all economic operators. These obligations include making sure that the EU declaration of conformity is in English before apparatus is placed on the market. Those regulations also include an obligation to identify other economic operators in the supply chain, an obligation to provide information with apparatus, such as required precautions to ensure conformity with Part 1 of Schedule 1, and a prohibition on the improper use of the CE marking.

Part 3 contains provisions concerning the conformity assessment procedures, declarations of conformity and CE marking for apparatus.

Part 4 contains provisions concerning the bodies which carry out conformity assessment procedures under the Regulations.

Part 5 sets out provisions for market surveillance and enforcement of these Regulations.

Regulation 52 designates the enforcing authorities and regulation 53 designates the market surveillance authorities. Regulation 54 and Schedule 7 provide for the powers which the enforcement and market surveillance authorities are to have. Regulation 61 provides for the contravention of certain provisions of these Regulations to be an offence. Regulation 62 sets out the penalties that are to apply for offences under these Regulations.

Part 6 sets out a review provision and transitional provisions and consequential amendments. The Electromagnetic Compatibility Regulations 2006 (S.I. 2006/3418) (as amended) will continue to apply to apparatus placed on the market before the date on which these Regulations came into force. Regulation 75 makes consequential amendments.

A transposition note and full impact assessment of the impact that these Regulations will have on the costs of business, the voluntary sector and the public sector are available from the Single Market Product Safety Team, Department for Business, Energy and Industrial Strategy, 1 Victoria Street, London SW1H 0ET and are also published with the Explanatory Memorandum alongside these Regulations on [www.legislation.gov.uk](http://www.legislation.gov.uk).

**Changes to legislation:**

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