
STATUTORY INSTRUMENTS

2016 No. 1153

The Measuring Instruments Regulations 2016

PART 2

REGULATED MEASURING INSTRUMENTS –
OBLIGATIONS OF ECONOMIC OPERATORS

CHAPTER 1

OBLIGATIONS OF MANUFACTURERS AND
PERSONS TO BE TREATED AS MANUFACTURERS

Introductory

6.—(1) This Chapter applies in relation to the placing on the market or the putting into use of a regulated measuring instrument by a manufacturer.

(2) The obligations in this Chapter also apply to an importer or distributor who—

- (a) places a regulated measuring instrument on the market under the name or trade mark of that importer or distributor; or
- (b) modifies a regulated measuring instrument already placed on the market in such a way that compliance with these Regulations may be affected,

and the expression “manufacturer” is to be construed accordingly.

Manufacturers' responsibilities – design, conformity assessment and marking of regulated measuring instruments **E+W+S**

7.—^[F1](1) A manufacturer must not place on the market or put into use a regulated measuring instrument unless the manufacturer has—

- (a) designed and manufactured the instrument in accordance with the essential requirements;
- (b) drawn up technical documentation in relation to the instrument;
- (c) carried out (or procured the carrying out of) the relevant conformity assessment procedure which has demonstrated compliance of the instrument with the applicable requirements;
- (d) drawn up ^[F2]a declaration of conformity; and
- (e) affixed to the instrument ^[F3]or where paragraph (2) applies in respect of the UK marking, to a label affixed to a product or to a document accompanying the product—
 - (i) the ^[F4]UK marking; and
 - (ii) the M marking.

^[F5](2) For a period of ^[F6]seven years beginning with IP completion day, the UK marking may be affixed to—

- (a) a label affixed to the instrument; or

(b) to a document accompanying the instrument.]

Extent Information

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

Textual Amendments

- F1** Reg. 7 renumbered as reg. 7(1) (E.W.S) by S.I. 2019/696, Sch. 27 para. 5(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. 19(3)**)
- F2** Word in reg. 7(1)(d) substituted (E.W.S) (31.12.2020) by S.I. 2019/696, Sch. 27 para. 5(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. 19(3)**)
- F3** Words in reg. 7(1)(e) inserted (E.W.S) (31.12.2020) by S.I. 2019/696, Sch. 27 para. 5(c)(i) (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. 19(3)**)
- F4** Word in reg. 7(1)(e) substituted (E.W.S) (31.12.2020) by S.I. 2019/696, Sch. 27 para. 5(c)(ii) (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. 19(3)**)
- F5** Reg. 7(2) inserted (E.W.S) by S.I. 2019/696, **Sch. 27 para. 5(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. 19(3)**)
- F6** Words in reg. 7(2) 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. (p)**

Manufacturers' responsibilities – design, conformity assessment and marking of regulated measuring instruments **N.I.**

7. A manufacturer must not place on the market or put into use a regulated measuring instrument unless the manufacturer has—

- (a) designed and manufactured the instrument in accordance with the essential requirements;
- (b) drawn up technical documentation in relation to the instrument;
- (c) carried out (or procured the carrying out of) the relevant conformity assessment procedure which has demonstrated compliance of the instrument with the applicable requirements;
- (d) drawn up an EU declaration of conformity; and
- (e) affixed to the instrument—
 - (i) the CE marking; and
 - (ii) the M marking.

Extent Information

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

Manufacturers – obligations in respect of records

8. A manufacturer must keep the technical documentation and the [F7EU] declaration of conformity for a period of 10 years beginning with the day after the day on which the regulated measuring instrument to which it relates has been placed on the market.

Textual Amendments

F7 Word in reg. 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. 27 para. 6 (with Sch. 27 para. 50(a)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Manufacturers' obligations to ensure continuing conformity with essential requirements **E** **+W+S**

9.—(1) Manufacturers must have procedures in place for series production of regulated measuring instruments by them to ensure that instruments so manufactured continue to meet the essential requirements.

(2) The procedures mentioned in paragraph (1) must adequately take into account changes in—

- (a) measuring instrument design or characteristics; and
- (b) changes in the [F8designated] standards, normative documents or in other technical specifications by reference to which the conformity of the regulated measuring instrument is declared.

(3) When deemed appropriate with regard to the performance of a regulated measuring instrument, manufacturers must—

- (a) carry out sample testing of regulated measuring instruments manufactured by them made available on the market;
- (b) investigate complaints about regulated measuring instruments manufactured by them;
- (c) if necessary, keep a register of—
 - (i) such complaints;
 - (ii) non-conforming measuring instruments; and
 - (iii) measuring instrument recalls; and
- (d) keep distributors informed of any monitoring undertaken by them.

Extent Information

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

Textual Amendments

F8 Word in reg. 9(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. 27 para. 7 (with Sch. 27 para. 50(a)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Manufacturers' obligations to ensure continuing conformity with essential requirements **N.I.**

9.—(1) Manufacturers must have procedures in place for series production of regulated measuring instruments by them to ensure that instruments so manufactured continue to meet the essential requirements.

(2) The procedures mentioned in paragraph (1) must adequately take into account changes in—

- (a) measuring instrument design or characteristics; and
- (b) changes in the harmonised standards, normative documents or in other technical specifications by reference to which the conformity of the regulated measuring instrument is declared.

(3) When deemed appropriate with regard to the performance of a regulated measuring instrument, manufacturers must—

- (a) carry out sample testing of regulated measuring instruments manufactured by them made available on the market;
- (b) investigate complaints about regulated measuring instruments manufactured by them;
- (c) if necessary, keep a register of—
 - (i) such complaints;
 - (ii) non-conforming measuring instruments; and
 - (iii) measuring instrument recalls; and
- (d) keep distributors informed of any monitoring undertaken by them.

Extent Information

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

Manufacturers' obligations in relation to the marking of regulated measuring instruments with serial numbers etc.

10.—(1) A manufacturer must ensure that a regulated measuring instrument, which that manufacturer has placed on the market, bears a type, batch or serial number or other element allowing identification of that instrument.

(2) Paragraph (1) does not apply where the dimensions of the regulated measuring instrument are too small or it is of too sensitive a composition to allow it to bear the information required by that paragraph and in such a case the information must be marked on the instrument's packaging (if any) and the accompanying documents required by these Regulations.

Manufacturers to mark contact details on regulated measuring instruments where possible **E+W+S**

11.—(1) A manufacturer must indicate on every regulated measuring instrument manufactured by that manufacturer, the manufacturer's name, registered trade name or registered trade mark and the postal address at which the manufacturer can be contacted.

(2) Paragraph (1) does not apply where the dimensions of the regulated measuring instrument are too small or it is of too sensitive a composition to allow it to bear the information required by that paragraph and in such a case the information must be marked on the instrument's packaging (if any) and the accompanying documents required by these Regulations.

(3) The address required by this regulation must indicate a single point at which the manufacturer can be contacted.

[^{F9}(4) The contact details required by this regulation must be clear, legible and in easily understandable English.]

Extent Information

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

Textual Amendments

F9 Reg. 11(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. 27 para. 8** (with Sch. 27 para. 50(a)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, **Sch. 5 para. 1(1)**

Manufacturers to mark contact details on regulated measuring instruments where possible **N.I.**

11.—(1) A manufacturer must indicate on every regulated measuring instrument manufactured by that manufacturer, the manufacturer's name, registered trade name or registered trade mark and the postal address at which the manufacturer can be contacted.

(2) Paragraph (1) does not apply where the dimensions of the regulated measuring instrument are too small or it is of too sensitive a composition to allow it to bear the information required by that paragraph and in such a case the information must be marked on the instrument's packaging (if any) and the accompanying documents required by these Regulations.

(3) The address required by this regulation must indicate a single point at which the manufacturer can be contacted.

(4) The contact details required by this regulation must be in a language easily understood by end-users and market surveillance authorities and, in the case of regulated measuring instruments made available in [^{F38}Northern Ireland], they must be in English.

Extent Information

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

Textual Amendments

F38 Words in [reg. 11\(4\)](#) 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. 14 para. 3(1)**

Documentation to accompany regulated measuring instruments **E+W+S**

12.—(1) A manufacturer must ensure that regulated measuring instruments that the manufacturer has placed on the market are accompanied by—

- (a) a copy of the ^{F10}... declaration of conformity relating to the instruments;
- (b) information on the operation of the instruments including, where relevant, the following—
 - (i) rated operating conditions;

- (ii) mechanical and electromagnetic environment classes;
- (iii) the upper and lower temperature limit, whether condensation is possible or not, open or closed location;
- (iv) instructions for installation, maintenance, repairs, permissible adjustments;
- (v) instructions for correct operation and any special conditions of use; and
- (vi) conditions for compatibility with interfaces, sub-assemblies or measuring instruments.

(2) Paragraph (1) (b) does not apply where the simplicity of the regulated measuring instrument makes the supply of the information referred to in that paragraph unnecessary.

^{F11}(3)

(4) Such instructions and information (and any labelling) relating to a regulated measuring instrument must be clear, [^{F12}legible and in easily understandable English].

Extent Information

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

Textual Amendments

- F10** Word in reg. 12(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. 27 para. 9(a)** (with [Sch. 27 para. 50\(a\)](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F11** Reg. 12(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. 27 para. 9(b)** (with [Sch. 27 para. 50\(a\)](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F12** Words in reg. 12(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. 27 para. 9(c)** (with [Sch. 27 para. 50\(a\)](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Documentation to accompany regulated measuring instruments **N.I.**

12.—(1) A manufacturer must ensure that regulated measuring instruments that the manufacturer has placed on the market are accompanied by—

- (a) a copy of the EU declaration of conformity relating to the instruments;
- (b) information on the operation of the instruments including, where relevant, the following—
 - (i) rated operating conditions;
 - (ii) mechanical and electromagnetic environment classes;
 - (iii) the upper and lower temperature limit, whether condensation is possible or not, open or closed location;
 - (iv) instructions for installation, maintenance, repairs, permissible adjustments;
 - (v) instructions for correct operation and any special conditions of use; and
 - (vi) conditions for compatibility with interfaces, sub-assemblies or measuring instruments.

(2) Paragraph (1) (b) does not apply where the simplicity of the regulated measuring instrument makes the supply of the information referred to in that paragraph unnecessary.

(3) Information supplied in accordance with this regulation must be in a language that can easily be understood by end-users and where the end users are in [^{F39}Northern Ireland], the information must be in English.

(4) Such instructions and information (and any labelling) relating to a regulated measuring instrument must be clear, understandable and intelligible.

Extent Information

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

Textual Amendments

F39 Words in [reg. 12\(3\)](#) 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. 14 para. 3\(1\)](#)

Action to be taken where regulated measuring instruments placed on the market are not in conformity with the essential requirements **E+W+S**

13.—(1) This regulation applies where a manufacturer considers or has reason to believe that a regulated measuring instrument placed on the market by that manufacturer is not in conformity with the requirements of these Regulations.

(2) The manufacturer must immediately take the corrective measures necessary to bring the regulated measuring instrument into conformity or withdraw or recall it, if appropriate.

(3) Where the regulated measuring instrument presents a risk, the manufacturer must immediately inform the competent [^{F13}authority] to that effect giving details, in particular, of the non-compliance and of any corrective measures taken.

Extent Information

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

Textual Amendments

F13 Word in [reg. 13\(3\)](#) 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. 27 para. 10](#) (with [Sch. 27 para. 50\(a\)](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)

Action to be taken where regulated measuring instruments placed on the market are not in conformity with the essential requirements **N.I.**

13.—(1) This regulation applies where a manufacturer considers or has reason to believe that a regulated measuring instrument placed on the market by that manufacturer is not in conformity with the requirements of these Regulations.

(2) The manufacturer must immediately take the corrective measures necessary to bring the regulated measuring instrument into conformity or withdraw or recall it, if appropriate.

(3) Where the regulated measuring instrument presents a risk, the manufacturer must immediately inform the competent national authorities of the [^{F40}relevant] states in which the instrument has been

made available on the market to that effect giving details, in particular, of the non-compliance and of any corrective measures taken.

Extent Information

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

Textual Amendments

F40 Word in [reg. 13\(3\)](#) 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. 14 para. 3\(2\)](#)

Provision of information to the competent authority

14.—(1) A manufacturer must, further to a reasoned request from a competent authority, provide the competent authority with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a regulated measuring instrument manufactured by it with the requirements of these Regulations.

(2) Information and documentation supplied to a competent authority pursuant to this regulation must be supplied in English.

(3) A manufacturer must co-operate with a competent authority, at the request of that authority, on any action to eliminate the risks posed by regulated measuring instruments that the manufacturer has placed on the market.

Use of authorised representatives by manufacturers **E+W+S**

15.—(1) A manufacturer may, by a written mandate, appoint [^{F14}a person established in the United Kingdom as their] authorised representative to discharge the responsibilities under these Regulations in relation to the placing on the market of a regulated measuring instrument.

(2) A representative appointed under paragraph (1) may not discharge the manufacturer's obligations under regulation 7(a) and 7(b).

(3) An authorised representative shall be treated as being authorised to—

- (a) keep the ^{F15}... declaration of conformity and the technical documentation at the disposal of the market surveillance authority for 10 years beginning with the day after the day the regulated measuring instrument has been placed on the market;
- (b) provide a competent authority, further to a reasoned request from that authority, with all the information and documentation necessary to demonstrate the conformity of a regulated measuring instrument; and
- (c) cooperate with a competent authority, at its request on any action taken to eliminate the risks posed by regulated measuring instruments covered by its mandate.

Extent Information

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

Textual Amendments

- F14** Words in [reg. 15\(1\)](#) 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. 27 para. 11\(a\)](#) (with [Sch. 27 para. 50\(a\)](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F15** Word in [reg. 15\(3\)\(a\)](#) 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. 27 para. 11\(b\)](#) (with [Sch. 27 para. 50\(a\)](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Use of authorised representatives by manufacturers **N.I.**

15.—(1) A manufacturer may, by a written mandate, appoint an authorised representative to discharge the responsibilities under these Regulations in relation to the placing on the market of a regulated measuring instrument.

(2) A representative appointed under paragraph (1) may not discharge the manufacturer's obligations under regulation 7(a) and 7(b).

(3) An authorised representative shall be treated as being authorised to—

- (a) keep the EU declaration of conformity and the technical documentation at the disposal of the market surveillance authority for 10 years beginning with the day after the day the regulated measuring instrument has been placed on the market;
- (b) provide a competent authority, further to a reasoned request from that authority, with all the information and documentation necessary to demonstrate the conformity of a regulated measuring instrument; and
- (c) cooperate with a competent authority, at its request on any action taken to eliminate the risks posed by regulated measuring instruments covered by its mandate.

Extent Information

- E17** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

CHAPTER 2

OBLIGATIONS OF IMPORTERS

Introductory **E+W+S**

16. This Chapter applies to the placing on the market or the putting into use of a regulated measuring instrument from a country outside the ^{F16}... United Kingdom.

Extent Information

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

Textual Amendments

- F16** Words in [reg. 16](#) 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. 27 para. 12](#) (with [Sch. 27 para. 50\(a\)](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Introductory **N.I.**

16. This Chapter applies to the placing on the market or the putting into use of a regulated measuring instrument from a country outside the [^{F41}relevant market] that is imported into [^{F42}Northern Ireland].

Extent Information

E18 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F41 Words in [reg. 16](#) 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. 14 para. 3\(3\)](#)

F42 Words in [reg. 16](#) 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. 14 para. 3\(1\)](#)

Ensuring compliance of regulated measuring instruments **E+W+S**

17.—(1) An importer must only place compliant regulated measuring instruments on the market.

(2) An importer must ensure that—

- (a) the appropriate conformity assessment procedure has been carried out by the manufacturer of the regulated measuring instrument (or by the importer where the importer is to be regarded as the manufacturer by virtue of regulation 6(2));
- (b) the manufacturer has drawn up the technical documentation (or that the importer has done so where the importer is treated as the manufacturer by virtue of regulation 6(2));
- (c) the regulated measuring instrument bears the [^{F17}UK] marking and the M marking;
- (d) the regulated measuring instrument is accompanied by a copy of the ^{F18}... declaration of conformity and the documents referred to in regulation 12 (documentation to accompany regulated measuring instruments); and
- (e) the manufacturer (or the importer where he is treated as the manufacturer) has complied with the requirements of regulations 10 (manufacturers' obligations in relation to the marking of regulated measuring instruments with serial numbers etc.) and 11 (manufacturers to mark contact details on regulated measuring instruments where possible).

Extent Information

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

Textual Amendments

F17 Word in [reg. 17\(2\)\(c\)](#) 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. 27 para. 13\(a\)](#) (with [Sch. 27 para. 50\(a\)](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)

F18 Word in reg. 17(2)(d) 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. 27 para. 13(b) (with Sch. 27 para. 50(a)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Ensuring compliance of regulated measuring instruments **N.I.**

17.—(1) An importer must only place compliant regulated measuring instruments on the market.

(2) An importer must ensure that—

- (a) the appropriate conformity assessment procedure has been carried out by the manufacturer of the regulated measuring instrument (or by the importer where the importer is to be regarded as the manufacturer by virtue of regulation 6(2));
- (b) the manufacturer has drawn up the technical documentation (or that the importer has done so where the importer is treated as the manufacturer by virtue of regulation 6(2));
- (c) the regulated measuring instrument bears the CE marking and the M marking;
- (d) the regulated measuring instrument is accompanied by a copy of the EU declaration of conformity and the documents referred to in regulation 12 (documentation to accompany regulated measuring instruments); and
- (e) the manufacturer (or the importer where he is treated as the manufacturer) has complied with the requirements of regulations 10 (manufacturers' obligations in relation to the marking of regulated measuring instruments with serial numbers etc.) and 11 (manufacturers to mark contact details on regulated measuring instruments where possible).

Extent Information

E19 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Importers duty to notify manufacturer and market surveillance authorities of non-compliant regulated measuring instruments that present a risk

18. Where an importer considers or has reason to believe that the regulated measuring instrument is not in conformity with the essential requirements and presents a risk, the importer must inform the manufacturer and the market surveillance authority.

Requirements to mark importers' details on regulated measuring instruments **E+W+S**

19.—(1) An importer must indicate on regulated measuring instruments imported by that importer, the importer's name, registered trade name or trademark and the postal address at which the importer can be contacted.

[^{F19}(2) Paragraph (1) does not apply where—

- (a) either—
 - (i) the regulated measuring instrument is too small or too sensitive a composition to allow it to bear the information required by paragraph (1); or
 - (ii) the importer has imported the regulated measuring instrument from an EEA state or Switzerland and places it on the market within the period of [^{F20}seven years] beginning with IP completion day, and

- (b) before placing the regulated measuring instrument on the market, the importer sets out the information referred to in paragraph (1)—
- (i) where sub-paragraph (a)(i) applies, on any packaging in which the instrument is supplied and in any accompanying documents;
 - (ii) where sub-paragraph (a)(ii) applies, in a document accompanying the instrument.]

[^{F21}(3) Any contact details required by this regulation must be clear, legible and in easily understandable English.]

Extent Information

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

Textual Amendments

- F19** Reg. 19(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. 27 para. 14(a)** (with Sch. 27 para. 50(a)) (as amended by: S.I. 2020/676, regs. 1(1), 2; S.I. 2019/1246, reg. 1(3), 5; S.I. 2020/852, reg. 2(2), 4(2), **Sch. 1 para. 1(p)(ii)**; and S.I. 2020/1460, **Sch. 3 para. 2(1)(k)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F20** Words in reg. 19(2)(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. (n)**
- F21** Reg. 19(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. 27 para. 14(b)** (with Sch. 27 para. 50(a)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Modifications etc. (not altering text)

- C1** Reg. 19 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 \(S.I. 2019/1246\)](#), reg. 1(2)(4), **2(3)** (with reg. 18))

Requirements to mark importers' details on regulated measuring instruments **N.I.**

19.—(1) An importer must indicate on regulated measuring instruments imported by that importer, the importer's name, registered trade name or trademark and the postal address at which the importer can be contacted.

(2) Where a regulated measuring instrument is too small or of too sensitive a composition to allow it to bear the information required by paragraph (1), such information must be marked on any packaging in which the instrument is supplied and on any accompanying documents.

(3) Any contact details required by this regulation must be in a language easily understood by end-users and market surveillance authorities and, in the case of regulated measuring instruments made available in [^{F43}Northern Ireland], they must be in English.

Extent Information

- E20** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F43 Words in [reg. 19\(3\)](#) 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. 14 para. 3\(1\)](#)

Modifications etc. (not altering text)

C2 [Reg. 19](#) 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 \(S.I. 2019/1246\)](#), [reg. 1\(2\)\(4\)](#), [2\(3\)](#) (with [reg. 18](#)))

Importers' duty to ensure that regulated measuring instruments are accompanied by relevant documentation **E+W+S**

20.—(1) An importer must ensure that regulated measuring instruments imported by that importer are, where relevant, accompanied by the following instructions and information ^{F22} ...—

- (a) rated operating conditions;
- (b) mechanical and electromagnetic environment classes;
- (c) the upper and lower temperature limit, whether condensation is possible or not, open or closed location;
- (d) instructions for installation maintenance, repairs, permissible adjustments;
- (e) instructions for correct operation and any special conditions of use; and
- (f) conditions for compatibility with interfaces, sub-assemblies or measuring instruments.

[^{F23}(2) The instructions and information referred to in paragraph (1) must be clear, legible and in easily understandable English.]

Extent Information

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

Textual Amendments

F22 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. 27 para. 15\(a\)](#) (with [Sch. 27 para. 50\(a\)](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)

F23 [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. 27 para. 15\(b\)](#) (with [Sch. 27 para. 50\(a\)](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)

Importers' duty to ensure that regulated measuring instruments are accompanied by relevant documentation **N.I.**

20.—(1) An importer must ensure that regulated measuring instruments imported by that importer are, where relevant, accompanied by the following instructions and information in a language easily understood by end-users—

- (a) rated operating conditions;
- (b) mechanical and electromagnetic environment classes;

- (c) the upper and lower temperature limit, whether condensation is possible or not, open or closed location;
- (d) instructions for installation maintenance, repairs, permissible adjustments;
- (e) instructions for correct operation and any special conditions of use; and
- (f) conditions for compatibility with interfaces, sub-assemblies or measuring instruments.

(2) Where the end users are in ^{F44}Northern Ireland], the instructions and information referred to in paragraph (1) must be in English.

Extent Information

E21 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F44 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. 14 para. 3\(1\)](#)

Duty of importers to ensure proper conditions of storage and transport

21. An importer must, in respect of regulated measuring instruments under the importer's responsibility ensure that the conditions of their storage or transport are not such as to jeopardise their continuing compliance with the essential requirements.

Duties of importers with regard to monitoring etc.

22.—(1) When deemed appropriate with regard to the performance of a regulated measuring instrument imported by an importer, the importer must—

- (a) carry out a sample testing of regulated measuring instruments made available on the market by the importer;
- (b) investigate complaints about regulated measuring instruments imported by the importer ; and
- (c) if necessary, keep a register of—
 - (i) such complaints;
 - (ii) non-conforming regulated measuring instruments; and
 - (iii) regulated measuring instrument recalls; and
- (d) where the importer is not also the distributor of the regulated measuring instrument, keep distributors to whom the importer has supplied regulated measuring instruments informed of any monitoring undertaken by that importer.

Action to be taken by importers where regulated measuring instruments placed on the market by them are not in conformity with essential requirements

23.—(1) This regulation applies where an importer considers, or has reason to believe, that a regulated measuring instrument placed on the market by the importer is not in conformity with the requirements of these Regulations.

(2) The importer must immediately take the corrective measures necessary to bring the regulated measuring instrument into conformity or withdraw or recall it, if appropriate.

(3) Where the regulated measuring instrument presents a risk, the importer must immediately inform the competent authority to that effect, giving details, in particular, of the non-compliance of the instrument and of the corrective measures taken by that importer.

Requirement for importer to keep copy of [F24EU] declaration of conformity

24. An importer must, for a period of 10 years beginning with the day after the day on which the regulated measuring instrument is placed on the market, keep a copy of the [F25EU] declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request.

Textual Amendments

- F24** Word in reg. 24 heading omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 27 para. 16** (with Sch. 27 para. 50(a)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F25** Word in reg. 24 omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 27 para. 16** (with Sch. 27 para. 50(a)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Provision of information to the competent authority

25.—(1) The importer must, further to a reasoned request from a competent authority, provide the competent authority with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the regulated measuring instrument with the requirements of these Regulations.

(2) Information and documentation supplied to a competent authority pursuant to this regulation must be supplied in English.

(3) An importer must co-operate with a competent authority, at its request, as regards any action to eliminate the risks posed by any regulated measuring instrument that the importer has placed on the market.

CHAPTER 3

OBLIGATIONS OF DISTRIBUTORS

Introductory

26. This Chapter applies in relation to the making available on the market or the putting into use of a regulated measuring instrument by a distributor.

Distributors – duty to act with due care

27. Before making the regulated measuring instrument available on the market or putting it into use, the distributor must act with due care in relation to the requirements of these Regulations.

Distributors – verification obligations **E+W+S**

28.—(1) The distributor must verify that the regulated measuring instrument bears the [F26UK] marking and the M marking.

(2) The distributor must verify that the regulated measuring instrument is accompanied by—

- (a) a copy of the F27... declaration of conformity relating to it; and

- (b) information on the operation of the instrument including where relevant the following—
- (i) rated operating conditions;
 - (ii) mechanical and electromagnetic environment classes;
 - (iii) the upper and lower temperature limit, whether condensation is possible or not, open and closed location
 - (iv) instructions for installation, maintenance, repairs, permissible adjustments;
 - (v) instructions for correct operation and any special conditions of use; and
 - (vi) conditions for compatibility with interfaces, sub-assemblies or measuring instruments.

(3) Paragraph (2) (b) does not apply where the simplicity of the regulated measuring instrument makes the supply of the information referred to in that paragraph unnecessary.

[^{F28}(4) Instructions and information supplied in accordance with this regulation must be clear, legible and in easily understandable English.]

(5) The distributor must verify that the manufacturer and the importer have complied with the requirements set out in regulation 10 (manufacturers' obligations in relation to the marking of regulated measuring instruments with serial numbers etc.), regulation 11 (manufacturers to mark contact details on regulated measuring instruments where possible) and regulation 19 (requirements to mark importers' details on regulated measuring instruments).

Extent Information

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

Textual Amendments

F26 Word in reg. 28(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. 27 para. 17(a)** (with Sch. 27 para. 50(a)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F27 Word in reg. 28(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. 27 para. 17(b)** (with Sch. 27 para. 50(a)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F28 Reg. 28(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. 27 para. 17(c)** (with Sch. 27 para. 50(a)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Distributors – verification obligations **N.I.**

28.—(1) The distributor must verify that the regulated measuring instrument bears the CE marking and the M marking.

- (2) The distributor must verify that the regulated measuring instrument is accompanied by—
- (a) a copy of the EU declaration of conformity relating to it; and
 - (b) information on the operation of the instrument including where relevant the following—
 - (i) rated operating conditions;
 - (ii) mechanical and electromagnetic environment classes;
 - (iii) the upper and lower temperature limit, whether condensation is possible or not, open and closed location
 - (iv) instructions for installation, maintenance, repairs, permissible adjustments;

- (v) instructions for correct operation and any special conditions of use; and
- (vi) conditions for compatibility with interfaces, sub-assemblies or measuring instruments.

(3) Paragraph (2) (b) does not apply where the simplicity of the regulated measuring instrument makes the supply of the information referred to in that paragraph unnecessary.

(4) Instructions and information supplied in accordance with this regulation must be in a language that can be easily understood by end-users and where those end users are in [^{F45}Northern Ireland] must be in English.

(5) The distributor must verify that the manufacturer and the importer have complied with the requirements set out in regulation 10 (manufacturers' obligations in relation to the marking of regulated measuring instruments with serial numbers etc.), regulation 11 (manufacturers to mark contact details on regulated measuring instruments where possible) and regulation 19 (requirements to mark importers' details on regulated measuring instruments).

Extent Information

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

Textual Amendments

F45 Words in [reg. 28\(4\)](#) 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. 14 para. 3\(1\)](#)

Distributors not to make non-conforming regulated measuring instruments available on the market etc.

29.—(1) This regulation applies where a distributor considers, or has reason to believe, that a regulated measuring instrument is not in conformity with the essential requirements.

(2) Where this regulation applies, the distributor must not make the regulated measuring instrument available on the market or put it into use until it has been brought into conformity.

(3) Where the regulated measuring instrument presents a risk, the distributor must immediately inform—

- (a) the manufacturer;
- (b) the importer (where the distributor is not also the manufacturer or importer); and
- (c) the market surveillance authorities,

to that effect, giving details, in particular, of the non-compliance of the instrument and of the corrective measures taken by that distributor.

Duty of distributors to ensure proper conditions of storage and transport

30. A distributor must, in respect of regulated measuring instruments under that distributor's responsibility, ensure that the conditions of their storage or transport are not such as to jeopardise their continuing compliance with the essential requirements.

Action to be taken by distributors where regulated measuring instruments placed on the market by them are not in conformity with essential requirements

31.—(1) This regulation applies where a distributor considers, or has reason to believe, that a regulated measuring instrument [^{F29}made available] on the market or put into use by that distributor is not in conformity with the requirements of these Regulations.

(2) The distributor must immediately take the corrective measures necessary to bring the regulated measuring instrument into conformity, or withdraw or recall it, if appropriate.

(3) Where the regulated measuring instrument presents a risk, the distributor must immediately inform the competent authority to that effect, giving details, in particular, of the non-compliance of the instrument and of the corrective measures taken by that distributor.

Textual Amendments

F29 Words in [reg. 31\(1\)](#) substituted (1.2.2019) by [The Weights and Measures etc. \(Miscellaneous\) \(Amendment\) Regulations 2019 \(S.I. 2019/5\)](#), [regs. 1, 8\(2\)](#)

Provision of information to the competent authority

32.—(1) The distributor must, further to a reasoned request from a competent authority, provide that authority with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the regulated measuring instrument with the requirements of these Regulations.

(2) Information and documentation supplied to a competent authority pursuant to this regulation must be supplied in English.

(3) A distributor must co-operate with a competent authority, at its request, as regards any action to eliminate the risks posed by any regulated measuring instrument that the distributor has placed on the market.

CHAPTER 4

IDENTIFICATION OF ECONOMIC OPERATORS

33.—(1) Economic operators must, on request, identify to the market surveillance authorities—

- (a) any economic operator who has supplied them with a regulated measuring instrument; and
- (b) any economic operator to whom they have supplied a regulated measuring instrument.

(2) Economic operators must be able to present the information referred to in paragraph (1) for 10 years beginning with the day after the day on which they have been supplied with the regulated measuring instrument and for 10 years day beginning with the day after the day they have supplied the instrument.

(3) The Secretary of State may impose a monetary penalty on an economic operator who fails to comply with an obligation imposed on it under this regulation.

(4) Schedule 7 has effect in relation to a monetary penalty imposed under paragraph (3).

[^{F30}Obligations which are met by complying with obligations in the Directive

33A.—(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 4(22);
 - (c) “Module B” means the conformity assessment procedure set out under the heading “MODULE B: EU-TYPE EXAMINATION” in Annex II;
 - (d) “Module H1” means the conformity assessment procedure set out under the heading “MODULE H1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION” in Annex II;
 - (e) “EU-design examination certificate” means an EU design certificate issued in accordance with Module H1;
 - (f) “EU-type examination certificate” means an EU-type examination certificate issued in accordance with Module B;
 - (g) “harmonised standard” has the meaning given to it in Article 4(14);
 - (h) “instrument-specific Annexes” means Annexes III to XII.
- (2) Paragraph (3) applies where, before placing a regulated measuring instrument on the market, the manufacturer—
- (a) ensures that the regulated measuring instrument has been designed and manufactured in accordance with the essential requirements set out in Annex I and in the relevant instrument-specific Annex which applies to the regulated measuring instrument;
 - (b) ensures that the one of the relevant conformity assessment procedures listed in the relevant instrument-specific Annex that apply to that regulated measuring instrument in accordance with Article 17 have been carried out;
 - (c) draws up the technical documentation referred to in Article 18;
 - (d) ensures that the technical documentation and other records and correspondence relating to the conformity assessment procedures are prepared in or translated into English;
 - (e) affixes a CE marking and the supplementary metrology marking, in accordance with Articles 21 and 22(1) to (6);
 - (f) draws up an EU declaration of conformity, in accordance with Article 19; 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 7(a) to (e), 48 and 52(2) are to be treated as being satisfied;
 - (b) regulations 8, 9(2), 51, 68(1)(a) to (e), 72, 73 and 75 apply subject to the modifications in paragraph (8); and
 - (c) regulations 36 to 39 do not apply.
- (4) Paragraph (5) applies where, before placing a regulated measuring instrument on the market, the importer ensures that—
- (a) the relevant conformity assessment procedures that apply to that measuring instrument in accordance with Article 17 have been carried out;
 - (b) the manufacturer has drawn up the technical documentation referred to in Article 18; and
 - (c) the measuring instrument bears the CE marking, and the supplementary metrology marking referred to in Article 21(2).
- (5) Where this paragraph applies—
- (a) the requirements of regulation 17(2)(a) to (c) are to be treated as being satisfied; and
 - (b) regulations 18, 21, 23, 51, 68(1)(a) to (e), 72, 73 and 75 apply subject to the modifications in paragraph (8).

(6) Paragraph (7) applies where, before making a regulated measuring instrument available on the market, a distributor ensures that the regulated measuring instrument bears the CE marking, and the supplementary metrology marking referred to in Article 21(2).

(7) Where this paragraph applies—

- (a) regulation 28(1) is to be treated as being satisfied; and
- (b) regulations 29(1), 30, 68(1)(a), 68(1)(b), 72 and 73 apply subject to the modifications in paragraph (8).

(8) The modifications referred to in paragraphs (3)(b), (5)(b) and (7)(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) [^{F31}except in relation to regulations 72 and 73,] any reference to “essential requirements” is to be read as a reference to the essential requirements referred to in Annex I and in the relevant instrument-specific Annex which applies to the regulated measuring instrument;
- (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 that apply to the regulated measuring instrument in accordance with Article 17;
- (f) any reference to “technical documentation” is a reference to the technical documentation referred to in Article 18;
- (g) any reference to “type examination certificate” is to be read as a reference to an EU-type examination certificate; and
- (h) any reference to “design examination certificate” is to be read as a reference to an EU-design examination certificate;
- (i) any reference to “M marking” is to be read as a reference to the supplementary metrology marking; and
- (j) any reference to “approved body” is to be read as a reference to the body that undertook any conformity assessment procedure in accordance with Article 13;
- (k) any reference to “authorised mark” includes the CE marking and the supplementary metrology marking.

Textual Amendments

F30 Regs. 33A33D 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. 27 para. 18** (with Sch. 27 para. 50(a)) (as amended by S.I. 2020/676, regs. 1(1), 2 and [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. 19(4)(b)**); 2020 c. 1, Sch. 5 para. 1(1)

F31 Words in reg. 33A(8)(c) inserted (E.W.S.) (9.12.2021) by [The Product Safety and Metrology etc. \(Amendment\) Regulations 2021](#) (S.I. 2021/1273), regs. 1, **12(2)**

Conformity assessment procedure obligation which is met by complying with the Directive

33B.—(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) “Module B” means the conformity assessment procedure set out under the heading “MODULE B: EU-TYPE EXAMINATION” in Annex II;
 - (c) “EU-type examination certificate” means an EU-type examination certificate issued in accordance with Module B;
 - (d) “harmonised standard” has the meaning given to it in Article 4(14);
 - (e) “instrument-specific Annexes” means Annexes III to XII.
- (2) Paragraph (3) applies where—
- (a) in accordance with Article 17, one of the conformity assessment procedures listed in the instrument-specific Annex that applies to the regulated measuring instrument is Module B; and
 - (b) before placing a regulated measuring instrument on the market, the manufacturer ensures that—
 - (i) the regulated measuring instrument has been designed in accordance with the essential requirements set out in Annex I and in the relevant instrument-specific Annex which applies to the regulated measuring instrument; and
 - (ii) Module B has been complied with in respect of that regulated measuring instrument.
- (3) Where this paragraph applies—
- (a) any reference in regulation 7(c) to “relevant conformity assessment procedure” includes Module B;
 - (b) any reference to “type examination certificate” in regulations 45(1)(j), 72(3)(b) and 73(3)(b) is to be read as a reference to “EU-type examination certificate”; and
 - (c) any reference to “designated standard” in regulation 45(1)(f) is to be read as a reference to “harmonised standard”.

Textual Amendments

F30 Regs. 33A33D 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. 27 para. 18** (with Sch. 27 para. 50(a)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2 and [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. 19(4)(b)**); 2020 c. 1, Sch. 5 para. 1(1)

Expiry of regulations 33A and 33B

33C.—(1) Subject to [^{F32}paragraphs (2) and (6)], regulation 33A ceases to have effect at the end of the period of [^{F33}four years] beginning with IP completion day.

(2) Notwithstanding the expiry of regulation 33A—

- (a) any regulated measuring instrument which was placed on the market pursuant to regulation 33A may continue to be made available on the market on or after the expiry of regulation 33A;
- (b) any obligation to which a person was subject under regulation 33A in respect of any regulated measuring instrument placed on the market pursuant to regulation 33A continues to have effect after the expiry of regulation 33A, in respect of that instrument.

(3) Subject to [^{F34}paragraphs (4) and (6)], regulation 33B ceases to have effect at the end of the period of [^{F35}four years] beginning with IP completion day.

(4) Where a conformity assessment procedure has been completed pursuant to regulation 33B in relation to a regulated measuring instrument prior to the expiry of regulation 33B, regulation 33B continues to apply in respect of that instrument where—

- (a) the manufacturer arranges for the EU-Type examination certificate and any annexes to be transferred to an approved body;
- (b) the approved body referred to in sub-paragraph (a) accepts responsibility for the EU-Type examination certificate; and
- (c) the approved body issues a Type-examination certificate relying, or relying in part, on any examinations or tests undertaken prior to the issue of the EU-Type examination certificate.

(5) In paragraph (4) “EU-Type examination certificate” has the meaning given to it in regulation 33B(1)(c).

[^{F36}(6) Regulations 72 and 73 continue to have effect in relation to any regulated measuring instrument—

- (a) placed on the market pursuant to 33A; or
- (b) in relation to which a manufacturer has undertaken a conformity assessment procedure in accordance with regulation 33B,

as if regulations 32A or 33B had not expired.]

Textual Amendments

- F30** Regs. 33A33D 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. 27 para. 18** (with Sch. 27 para. 50(a)) (as amended by S.I. 2020/676, regs. 1(1), 2 and 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. 19(4)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F32** Words in reg. 33C(1) substituted (E.W.S.) (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, **12(3)(a)**
- F33** Words in reg. 33C(1) 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), **2, Sch. 1 para. (q)**
- F34** Words in reg. 33C(3) substituted (E.W.S.) (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, **12(3)(b)**
- F35** Words in reg. 33C(3) 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), **2, Sch. 1 para. (q)**
- F36** Reg. 33C(6) inserted (E.W.S.) (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, **12(3)(c)**

Qualifying Northern Ireland Goods

33D.—(1) Where paragraph (2) applies—

- (a) a regulated measuring instrument is to be treated as being in conformity with the essential requirements; and
- (b) each relevant economic operator is to be treated as having complied or as complying with the obligations imposed on them under Part 2.

(2) This paragraph applies where—

- (a) a regulated measuring instrument is—

- (i) in conformity with the essential requirements, within the meaning of that term in regulation 2, as it applies in Northern Ireland; and
 - (ii) qualifying Northern Ireland goods; and
 - (b) each relevant economic operator has complied or is complying with the obligations imposed on them under Part 2, as that Part applies in Northern Ireland; and
 - (c) an importer has complied with the obligations set out in paragraph (3).
- (3) The obligations referred to in paragraph (2)(c) are that, before placing the non-automatic weighing instrument on the market, the importer—
- (a) complies with regulation 19;
 - (b) ensures that—
 - (i) the relevant conformity assessment procedure has been carried out.
 - (ii) the manufacturer has drawn up the technical documentation; and
 - (iii) the regulated measuring instrument bears the CE marking.

^{F37}(3A) After a regulated measuring instrument has been placed on the market pursuant to this regulation, regulations 72 and 73 are to be read in relation to that instrument subject to the following modifications—

- (a) the reference in regulation 72(2)(a) to “UK marking” is to be read as a reference to the CE marking, within the meaning of regulation 2(1) as it applies in Northern Ireland;
- (b) the reference in regulation 72(2)(b) to “M marking”, is to be read as a reference to the M Marking as defined in regulation 2(1) as it applies in Northern Ireland;
- (c) the reference in regulation 72(2)(c) to “approved body” is to be read as a reference to a “notified body” as defined in regulation 2(1) as it applies in Northern Ireland;
- (d) the references in regulations 72(3)(a) and 73(3)(a) to “essential requirements” are to be read as the essential requirements within the meaning of that term in regulation 2(1) as it applies in Northern Ireland; and
- (e) the references in regulations 72(3)(b) and 73(3)(b) to “type examination certificate” is to be read as a reference to an EU-type examination certificate as defined in regulation 2(1) as it applies in Northern Ireland.]

(4) In this regulation—

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

Textual Amendments

F30 Regs. 33A33D 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. 27 para. 18** (with Sch. 27 para. 50(a)) (as amended by S.I. 2020/676, regs. 1(1), 2 and 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. 19(4)(b)**); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: *There are currently no known outstanding effects for the The Measuring Instruments Regulations 2016, PART 2. (See end of Document for details)*

F37 Reg. 33D(3A) inserted (E.W.S) (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, **12(4)**

Changes to legislation:

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