
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

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.

Manufacturers – obligations in respect of records

8. A manufacturer must keep the technical documentation and the EU 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.

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Manufacturers' obligations to ensure continuing conformity with essential requirements

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.

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

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 the United Kingdom, they must be in English.

Documentation to accompany regulated measuring instruments

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 the United Kingdom, 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.

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

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 EEA 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.

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

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.

CHAPTER 2

OBLIGATIONS OF IMPORTERS

Introductory

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 European Economic Area that is imported into the United Kingdom.

Ensuring compliance of regulated measuring instruments

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).

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

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 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 the United Kingdom, they must be in English.

Importers' duty to ensure that regulated measuring instruments are accompanied by relevant documentation

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 the United Kingdom, the instructions and information referred to in paragraph (1) must be in English.

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—

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- (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 EU 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 EU 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.

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

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 the United Kingdom 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).

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 placed 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.

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).

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