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STATUTORY INSTRUMENTS

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**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.

**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.