

Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast) (Text with EEA relevance)

CHAPTER 2

OBLIGATIONS OF ECONOMIC OPERATORS

Article 8

Obligations of manufacturers

1 When placing their measuring instruments on the market and/or putting them into use, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes.

2 Manufacturers shall draw up the technical documentation referred to in Article 18 and carry out the relevant conformity assessment procedure referred to in Article 17 or have it carried out.

Where compliance of a measuring instrument with the applicable requirements of this Directive has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking and the supplementary metrology marking.

3 Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the measuring instrument has been placed on the market.

4 Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in measuring instrument design or characteristics and changes in the harmonised standards, normative documents or in other technical specifications by reference to which conformity of a measuring instrument is declared shall be adequately taken into account.

When deemed appropriate with regard to the performance of a measuring instrument, manufacturers shall carry out sample testing of measuring instruments made available on the market, investigate and, if necessary, keep a register of complaints, of non-conforming measuring instruments and measuring instrument recalls, and shall keep distributors informed of any such monitoring.

5 Manufacturers shall ensure that measuring instruments which they have placed on the market bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the measuring instrument does not allow it, that the required information is provided in a document accompanying the measuring instrument and on the packaging, if any, in accordance with point 9.2 of Annex I.

6 Manufacturers shall indicate on the measuring instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, in a document accompanying the measuring instrument and on the packaging, if any, in accordance with point 9.2 of Annex I. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

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7 Manufacturers shall ensure that the measuring instrument which they have placed on the market is accompanied by a copy of the EU Declaration of conformity and by instructions and information in accordance with point 9.3 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

8 Manufacturers who consider or have reason to believe that a measuring instrument which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that measuring instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the measuring instrument presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the measuring instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9 Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the measuring instrument with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by measuring instruments which they have placed on the market.

Article 9

Authorised representatives

1 A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 8(1) and the obligation to draw up technical documentation referred to in Article 8(2) shall not form part of the authorised representative's mandate.

2 An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

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

Article 10

Obligations of importers

1 Importers shall place only compliant measuring instruments on the market.

2 Before placing a measuring instrument on the market and/or putting a measuring instrument into use importers shall ensure that the appropriate conformity assessment procedure referred to in Article 17 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the measuring instrument bears

the CE marking and the supplementary metrology marking and is accompanied by a copy of the EU declaration of conformity and the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).

Where an importer considers or has reason to believe that a measuring instrument is not in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes, he shall not place the measuring instrument on the market or put it into use until it has been brought into conformity. Furthermore, where the measuring instrument presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3 Importers shall indicate on the measuring instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, in a document accompanying the measuring instrument and on its packaging, if any, in accordance with point 9.2 of Annex I. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4 Importers shall ensure that the measuring instrument is accompanied by instructions and information in accordance with point 9.3 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State concerned.

5 Importers shall ensure that, while a measuring instrument is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes.

6 When deemed appropriate with regard to the performance of a measuring instrument, importers shall carry out sample testing of measuring instruments made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming measuring instruments and measuring instrument recalls, and shall keep distributors informed of any such monitoring.

7 Importers who consider or have reason to believe that a measuring instrument which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that measuring instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the measuring instrument presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the measuring instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8 Importers shall, for 10 years after the measuring instrument has been 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.

9 Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a measuring instrument in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by measuring instruments which they have placed on the market.

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Article 11

Obligations of distributors

1 When making a measuring instrument available on the market and/or putting it into use, distributors shall act with due care in relation to the requirements of this Directive.

2 Before making a measuring instrument available on the market and/or putting a measuring instrument into use distributors shall verify that the measuring instrument bears the CE marking and the supplementary metrology marking, that it is accompanied by the EU declaration of conformity, by the required documents and by instructions and information in accordance with point 9.3 of Annex I, in a language which can be easily understood by end-users in the Member State in which the measuring instrument is to be made available on the market and/or put into use, and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3) respectively.

Where a distributor considers or has reason to believe that a measuring instrument is not in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes, he shall not make the measuring instrument available on the market or put it into use, until it has been brought into conformity. Furthermore, where the measuring instrument presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3 Distributors shall ensure that, while a measuring instrument is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes.

4 Distributors who consider or have reason to believe that a measuring instrument which they have made available on the market or put into use is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that measuring instrument into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the measuring instrument presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the measuring instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5 Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a measuring instrument. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by measuring instruments which they have made available on the market.

Article 12

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 8, where he places a measuring instrument on the market under his name or trade mark or modifies a measuring instrument already placed on the market in such a way that compliance with this Directive may be affected.

Article 13

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

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

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the measuring instrument and for 10 years after they have supplied the measuring instrument.