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 3

CONFORMITY OF MEASURING INSTRUMENTS

Article 14

Presumption of conformity of measuring instruments

1 Measuring instruments which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes covered by those standards or parts thereof.

2 Measuring instruments which are in conformity with parts of normative documents, the list of which has been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes covered by those parts of normative documents.

3 A manufacturer may choose to use any technical solution that complies with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes. In addition, to benefit from the presumption of conformity, the manufacturer must correctly apply solutions mentioned either in the relevant harmonised standards or in the normative documents referred to in paragraphs 1 and 2.

4 Member States shall presume compliance with the appropriate tests mentioned in point (i) of Article 18(3) if the corresponding test programme has been performed in accordance with the relevant documents mentioned in paragraphs 1, 2 and 3 and if the test results ensure compliance with the essential requirements.

Article 15

Publication of the references of normative documents

On request by a Member State or in its own initiative, the Commission shall, where appropriate:

(a) identify normative documents and, in a list, indicate the parts thereof that satisfy the requirements which they cover and which are set out in Annex I and in the relevant instrument-specific Annexes;

(b) publish the reference of the normative documents and the list referred to in point (a) in the *Official Journal of the European Union*.

Article 16

Withdrawal of the references of normative documents

1 When a Member State or the Commission considers that a normative document whose reference has been published or is intended to be published in the *Official Journal of the European Union* does not entirely satisfy the essential requirements which it covers and which are set out in Annex I and in the relevant instrument-specific Annexes, the Commission shall decide:

a to publish, not to publish or to publish with restriction the references to the normative documents concerned in the *Official Journal of the European Union*;

b to maintain, to maintain with restrictions or to withdraw the references to the normative documents concerned in or from the *Official Journal of the European Union*.

2 The decision referred to in point (a) of paragraph 1 of this Article shall be adopted in accordance with the advisory procedure referred to in Article 46(2).

3 The decision referred to in point (b) of paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 46(3).

Article 17

Conformity assessment procedures

Conformity assessment of a measuring instrument with the applicable essential requirements shall be carried out by the application, at the choice of the manufacturer, of one of the conformity assessment procedures listed in the relevant instrument-specific Annex.

The conformity assessment procedures are set out in Annex II.

Records and correspondence relating to conformity assessment procedures shall be drawn up in the official language(s) of the Member State where the notified body carrying out the conformity assessment procedures is established, or in a language accepted by that body.

Article 18

Technical documentation

1 The technical documentation shall render the design, manufacture and operation of the measuring instrument intelligible and shall permit an assessment of its conformity with the applicable requirements of this Directive.

2 The technical documentation shall be sufficiently detailed to ensure compliance with the following requirements:

a the definition of the metrological characteristics;

b the reproducibility of the metrological performances of produced measuring instruments when properly adjusted using appropriate intended means;

c the integrity of the measuring instrument.

3 The technical documentation shall insofar as relevant for assessment and identification of the type and/or the measuring instrument include the following information:

a a general description of the measuring instrument;

b conceptual design and manufacturing drawings and plans of components, sub-assemblies, circuits, etc.;

c manufacturing procedures to ensure consistent production;

d if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation;

e descriptions and explanations necessary for the understanding of the information referred to in points (b), (c) and (d), including the operation of the measuring instrument;

f a list of the harmonised standards and/or normative documents referred to in Article 14, applied in full or in part, the references of which have been published in the *Official Journal of the European Union*;

g descriptions of the solutions adopted to meet the essential requirements where the harmonised standards and/or normative documents referred to in Article 14 have not been applied, including a list of other relevant technical specifications applied;

h results of design calculations, examinations, etc.;

i the appropriate test results, where necessary, to demonstrate that the type and/or the measuring instruments comply with the following:

— the requirements of this Directive under declared rated operating conditions and under specified environmental disturbances,

— the durability specifications for gas-, water-, thermal energy-meters as well as for liquids other than water;

j the EU-type examination certificates or EU design examination certificates in respect of measuring instruments containing parts identical to those in the design.

4 The manufacturer shall specify where seals and markings have been applied.

5 The manufacturer shall indicate the conditions for compatibility with interfaces and sub-assemblies, where relevant.

Article 19

EU declaration of conformity

1 The EU declaration of conformity shall state that the fulfilment of the essential requirements set out in Annex I and in the relevant instrument-specific Annexes has been demonstrated.

2 The EU declaration of conformity shall have the model structure set out in Annex XIII, shall contain the elements specified in the relevant modules set out in Annex II and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the measuring instrument is placed or made available on the market.

3 Where a measuring instrument is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.

4 By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the measuring instrument with the requirements laid down in this Directive.

Article 20

Conformity marking

The conformity of a measuring instrument with this Directive shall be indicated by the presence on it of the CE marking and the supplementary metrology marking as specified in Article 21.

Article 21

General principles of the CE marking and of the supplementary metrology marking

1 The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

2 The supplementary metrology marking shall consist of the capital letter ‘M’ and the last two digits of the year of its affixing, surrounded by a rectangle. The height of the rectangle shall be equal to the height of the CE marking.

3 The general principles set out in Article 30 of Regulation (EC) No 765/2008 shall apply, mutatis mutandis, to the supplementary metrology marking.

Article 22

Rules and conditions for affixing the CE marking and the supplementary metrology marking

1 The CE marking and the supplementary metrology marking shall be affixed visibly, legibly and indelibly to the measuring instrument or to its data plate. Where that is not possible or not warranted on account of the nature of the measuring instrument, they shall be affixed to the accompanying documents and to the packaging, if any.

2 When a measuring instrument consists of a set of devices, not being sub-assemblies, operating together, the CE marking and the supplementary metrology marking shall be affixed on the instrument’s main device.

3 The CE marking and the supplementary metrology marking shall be affixed before the measuring instrument is placed on the market.

4 The CE marking and the supplementary metrology marking may be affixed to the instrument during the fabrication process, if justified.

5 The supplementary metrology marking shall immediately follow the CE marking.

The CE marking and the supplementary metrology marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase as set out in Annex II.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

The identification number of the notified body concerned shall be indelible or self destructive upon removal.

6 The CE marking, the supplementary metrology marking and, where applicable, the identification number of the notified body may be followed by any other mark indicating a special risk or use.

7 Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.