

STATUTORY INSTRUMENTS.

S.I. No. 2 of 2018

LEGAL METROLOGY (EUROPEAN CONFORMITY ASSESSMENT OF MEASURING INSTRUMENTS) REGULATIONS 2018

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I, HEATHER HUMPHREYS, Minister for Business, Enterprise and Innovation, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014¹ on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast) (amended by Commission Delegated Directive (EU) 2015/13 of 31 October 2014 amending Annex III to Directive 2014/32/EU of the European Parliament and of the Council, as regards the flowrate range of water meters²), hereby make the following regulations:

PART 1

GENERAL PROVISIONS

Citation

1. (1) These Regulations may be cited as the Legal Metrology (European Conformity Assessment of Measuring Instruments) Regulations 2018.

(2) These Regulations come into operation on 8 January 2018.

Interpretation

2. (1) In these Regulations—

"annex" means an annex of the Directive;

"appeal panel" means a panel established by the Minister under Regulation 27;

"authorised officer" means a person appointed under Regulation 34;

"authorised representative" means an authorised representative appointed under Regulation 10;

"Commission" means the European Commission;

"competent authority" means-

(*a*) in relation to the State, the Director, and ¹OJ No. L 96, 29.3.2014, p. 149. ²OJ No. L 3, 7.1.2015, p. 42.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 9th January, 2018. (b) in relation to another Member State, the competent authority under the Directive, of that State;

"Directive" means Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014³ on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast) (amended by Commission Delegated Directive (EU) 2015/13 of 31 October 2014 amending Annex III to Directive 2014/32/EU of the European Parliament and of the Council, as regards the flowrate range of water meters⁴);

"Director" means the Director of Legal Metrology;

"EC Regulation" means Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008⁵ setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93;

"instrument-specific Annexes" means Annexes III to XII of the Directive;

"mandate" has the meaning assigned to it by Regulation 10(1);

"Minister" means the Minister for Business, Enterprise and Innovation;

"Regulations of 2007" means the Legal Metrology (European Conformity Assessment of Measuring Instruments) Regulations 2007 (S.I. No. 160 of 2007);

(2) A word or expression which is used in these Regulations and is also used in the Directive has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Directive.

(3) For the purposes of these Regulations, the Director of Legal Metrology is the market surveillance authority in the State.

Application

3. (1) These Regulations shall apply to the measuring instruments defined in the instrument-specific Annexes III to XII (in these Regulations referred to as the 'instrument-specific Annexes') concerning water meters (MI-001), gas meters and volume conversion devices (MI-002), active electrical energy meters (MI-003), thermal energy meters (MI-004), measuring systems for the continuous and dynamic measurement of quantities of liquids other than water (MI-005), automatic weighing instruments (MI-006), taximeters (MI-007), material measures (MI-008), dimensional measuring instruments (MI-009) and exhaust gas analysers (MI-010).

(2) Where instrument-specific Annexes lay down essential requirements for sub-assemblies, these Regulations apply to such sub-assemblies as if such sub-assemblies were measuring instruments.

³OJ No. L 96, 29.3.2014, p. 149. ⁴OJ No. L 3, 7.1.2015, p. 42.

⁵OJ No. L 218, 13.8.2008, p. 30.

(3) Sub-assemblies and measuring instruments may be assessed independently and separately for the purpose of establishing their conformity with the requirements of these Regulations.

(4) The use of a measuring instrument is, for the purposes of these Regulations and the Directive, prescribed for the measuring tasks specified in section 3 of, and Schedule to, the Legal Metrology (Measuring Instruments) Act 2017 (No. 31 of 2017).

Making available on the market of measuring instruments

4. (1) A person shall not make available on the market or put into use any measuring instrument referred to in Regulation 3(1) unless the instrument satisfies the requirements of these Regulations.

(2) Nothing in the Metrology Act 1996 (No. 27 of 1996) or any other enactment or rule of law shall impede the making available on the market or putting into use of a measuring instrument for the purpose of legal metrological control where such measuring instrument complies with the Directive.

Exception for trade fairs, exhibitions and demonstrations

5. Nothing in these Regulations shall prevent the showing of measuring instruments that are not in conformity with these Regulations at trade fairs, exhibitions, demonstrations or similar events, provided that a clearly visible sign is displayed indicating—

- (a) that the instruments concerned do not conform with these Regulations, and
- (b) that the instruments concerned are not made available on the market or put into use until they are brought into conformity with these Regulations.

Essential requirements

6. (1) A measuring instrument referred to in Regulation 3 shall meet the essential requirements set out in Annex I and in the relevant instrument-specific Annex.

(2) The information referred to in point 9 of Annex I or in the relevant instrument-specific Annexes shall be provided, if needed for the correct use of the instrument, in the English language.

PART 2

Obligations of Economic Operators

Obligations of manufacturers

7. (1) A manufacturer shall ensure that measuring instruments placed on the market or put into use have been designed and manufactured in accordance with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes applicable to the category of measuring instrument concerned.

(2) Before placing a measuring instrument on the market or putting a measuring instrument into use, the manufacturer of the measuring instrument shall—

- (a) draw up the technical documentation referred to in Regulation 17,
- (b) carry out or have carried out the relevant conformity assessment in accordance with Regulation 16,
- (c) where compliance of a measuring instrument with the applicable requirements has been demonstrated by the conformity assessment procedure, draw up an EU declaration of conformity in accordance with Regulation 18,
- (d) affix a CE marking and the supplementary metrology marking to the measuring instrument in accordance with Regulation 20,
- (e) retain the technical documentation and EU declaration of conformity for 10 years after the measuring instrument has been placed on the market,
- (f) ensure that procedures are in place for series production to remain in conformity with these Regulations, and having regard to any 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,
- (g) when deemed appropriate with regard to the performance of a measuring instrument—
 - (i) carry out sample testing of measuring instruments made available on the market,
 - (ii) investigate and, if necessary, keep a register of complaints, of nonconforming measuring instruments and measuring instrument recalls, and
 - (iii) keep distributors informed of any such monitoring,
- (*h*) mark the measuring instrument in accordance with Regulation 8, as appropriate,
- (*i*) ensure that the measuring instrument is accompanied by an EU declaration of conformity and instructions and information on its operation in accordance with point 9.3 of Annex I, and
- (*j*) ensure that the instructions and information referred to in paragraph(*i*) and any labelling accompanying that measuring instrument is clear, understandable and intelligible.

(3) A manufacturer who considers or has reason to believe that a measuring instrument which he or she has placed on the market is not in conformity with these Regulations shall immediately take the corrective measures necessary to—

- (a) bring the measuring instrument into conformity,
- (b) withdraw the measuring instrument, or
- (c) recall the measuring instrument.

(4) Where the measuring instrument presents a risk to aspects of public interest protection covered by these Regulations, a manufacturer shall immediately inform the competent authorities of the Member States in which he or she made the measuring instrument available on the market in writing to that effect, giving details of—

- (a) the non-compliance of the measuring instrument, and
- (b) any corrective measures taken.
- (5) (a) A manufacturer shall, 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 measuring instrument in English or, in the case of a competent national authority, in a language which can be easily understood by that authority.
 - (b) A manufacturer shall cooperate with a competent authority, at its request, on any action taken to eliminate the risks posed by measuring instruments which they have placed on the market.

Marking and indication of instruments

8. (1) A manufacturer shall ensure, in respect of measuring instruments which they have placed on the market that-

- (*a*) the instrument bears a type, batch or serial number or other element allowing their identification, or
- (b) where the size or nature of the measuring instrument does not allow such identification referred to in paragraph (a), the required information is provided in a document accompanying the measuring instrument and on the packaging, if any, in accordance with Regulation 9.

(2) Before placing a measuring instrument on the market or putting the measuring instrument into use, the manufacturer of the measuring instrument shall indicate on the measuring instrument-

- (a) their name, registered trade name or registered trade mark, and
- (b) the postal address at which they can be contacted.

(3) The address referred to in paragraph (2) shall indicate a single point at which the manufacturer can be contacted, and the contact details shall be in a language that is easily understood by end-users and the market surveillance authority.

(4) Where it is not possible to indicate the information specified in paragraph (2) on the measuring instrument, the manufacturer shall indicate the information in a document accompanying the measuring instrument or on the packaging, if any, in accordance with Regulation 9.

Marking of packaging and information

9. A measuring instrument of dimensions too small or of too sensitive a composition to allow it to bear the relevant information shall have its packaging, if any, and the accompanying documents required by the provisions of these Regulations suitably marked.

Authorised representatives

10. (1) Subject to paragraphs (2) and (3), a manufacturer may, by a written mandate (in this Regulation referred to as a "mandate"), appoint an authorised representative.

(2) The obligations laid down in Regulation 7(1) and the obligation to draw up technical documentation referred to in Regulation 7(2)(a) shall not be included in the authorised representative's mandate.

(3) An authorised representative shall perform the tasks specified in a mandate received from the manufacturer.

(4) The mandate shall allow the authorised representative to—

- (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 authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a measuring instrument,
- (c) cooperate with each such competent authority at its request, on any action taken to eliminate the risks posed by measuring instruments covered by their mandate, and
- (d) such other matter as is provided for in a mandate.

(5) An authorised representative shall provide the Director with a copy of the mandate, if requested to do so.

Obligations of importers

11. (1) An importer shall not place a measuring instrument on the market or put such instrument into use unless the instrument complies with these Regulations.

(2) Before placing a measuring instrument on the market or putting a measuring instrument into use, an importer shall ensure that-

- (*a*) the appropriate conformity assessment procedure has been carried out by the manufacturer in accordance with Regulation 16,
- (b) the manufacturer has drawn up the technical documentation referred to in Regulation 17,
- (c) 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
- (*d*) the manufacturer has complied with the requirements set out in Regulation 8.

(3) 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, the importer shall not place the measuring instrument on the market or put it into use until it has been brought into conformity.

(4) Where the measuring instrument presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

- (5) An importer shall indicate on the measuring instrument—
 - (a) the name, registered trade name or registered trade mark of the importer, and
 - (b) a postal address at which they can be contacted.

(6) The information referred to in paragraph (5) shall be in a language easily understood by end-users and the market surveillance authority in the Member State in which it is to be made available.

(7) Where it is not possible to indicate the information specified in paragraph (5) on the measuring instrument, the importer shall indicate the information in a document accompanying the measuring instrument or on the packaging, if any, in accordance with Regulation 9.

(8) An importer 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. (9) An importer shall ensure that, while a measuring instrument is under his or her 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.

(10) When deemed appropriate with regard to the performance of a measuring instrument, an importer shall—

- (a) carry out sample testing of measuring instruments made available on the market,
- (b) investigate, and, if necessary, keep a register of complaints of nonconforming measuring instruments and measuring instrument recalls, and
- (c) shall keep distributors informed of any such monitoring.

(11) An importer who considers or has reason to believe that a measuring instrument which he or she has placed on the market is not in conformity with these Regulations shall immediately take the corrective measures necessary to—

- (a) bring the measuring instrument into conformity,
- (b) withdraw the measuring instrument, or
- (c) recall the measuring instrument.

(12) Where the measuring instrument presents a risk, an importer shall immediately inform the competent authorities of the Member States in which he or she made the measuring instrument available on the market to that effect, giving details of—

- (a) the non-compliance of the measuring instrument, and
- (b) any corrective measures taken.

(13) An importer shall, for 10 years after a measuring instrument has been placed on the market—

- (*a*) keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities, and
- (b) ensure that the technical documentation can be made available to those authorities, upon request.
- (14) (a) An importer shall, 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 measuring instrument in English, or in the case of a competent national authority, in a language which can be easily understood by that authority.

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 - (b) An importer shall cooperate with a competent authority, at its request, on any action taken to eliminate the risks posed by a measuring instrument which the importer has placed on the market.

Obligations of distributors

12. (1) A distributor shall not make a measuring instrument available on the market or put such instrument into use without acting with due care in relation to the requirements of these Regulations.

(2) Before making a measuring instrument available on the market or putting such instrument into use, a distributor shall verify that—

- (a) the measuring instrument—
 - (i) bears the CE marking and the supplementary metrology marking,
 - (ii) is accompanied by the EU declaration of conformity and the required documents, and
 - (iii) 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 in the Member State in which the measuring instrument is to be made available on the market or put into use,
- (b) the manufacturer has complied with the requirements set out in Regulation 8, and
- (c) the importer has complied with the requirements set out in Regulation 11(5).

(3) 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, the distributor—

- (a) shall not make the measuring instrument available on the market or put such instrument into use until it has been brought into conformity, and
- (b) where the measuring instrument presents a risk, shall inform the manufacturer or the importer and also the Director and the market surveillance authorities of the other Member States to that effect.

(4) A distributor shall ensure that, while a measuring instrument is under the responsibility of the distributor, 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.

(5) A distributor who considers or has reason to believe that a measuring instrument which he or she has made available on the market or put into use is not in conformity with these Regulations shall ensure the corrective measures necessary are taken to—

- (a) bring the measuring instrument into conformity,
- (b) withdraw the measuring instrument, or
- (c) recall the measuring instrument.

(6) Where the measuring instrument presents a risk, the distributor shall immediately inform the competent authorities of the Member States in which the distributor made the measuring instrument available on the market to that effect, giving details of—

- (a) the non-compliance of the measuring instrument, and
- (b) any corrective measures taken.
- (7) (a) A distributor shall, further to a reasoned request from a competent authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a measuring instrument with these Regulations.
 - (b) A distributor shall cooperate with a competent authority, at its request, on any action taken to eliminate the risks posed by a measuring instrument which the distributor has made available on the market.

Cases in which obligations of manufacturers apply to importers and distributors 13. An importer or distributor shall be considered a manufacturer for the purposes of these Regulations, and shall be subject to the obligations of the manufacturer under Regulations 7 and 8, where he or she places a measuring instrument on the market under his or her name or trade mark or modifies a measuring instrument already placed on the market in such a way that compliance with these Regulations may be affected.

Identification of economic operators

14. (1) An economic operator shall, on request, identify to the Director or the market surveillance authority of another Member State—

- (a) any other economic operator who has supplied the operator with a measuring instrument, or
- (b) any other economic operator to whom the operator has supplied a measuring instrument.
- (2) An economic operator shall retain—
 - (a) the information referred to in paragraph (1)(a) for a period of 10 years after the operator has been supplied with the measuring instrument, and
 - (b) the information referred to in paragraph (1)(b) for a period of 10 years after the operator supplied the measuring instrument.

PART 3

CONFORMITY OF MEASURING INSTRUMENTS

Presumption of conformity of measuring instruments

15. (1) A measuring instrument which is in conformity with harmonised standards (or part of such a standard) the references to which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential requirements referred to in Annex I and in the relevant instrument-specific Annexes covered by that standard (or part of that standard).

(2) A measuring instrument which is in conformity with parts of normative documents, the list of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the essential requirements referred to 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.

(4) A manufacturer shall correctly apply solutions mentioned either in the relevant harmonised standards or in the normative documents referred to in paragraphs (1) and (2) in order for a measuring instrument to benefit from the presumption of conformity.

(5) A measuring instrument shall be presumed to comply with the appropriate tests referred to in Regulation 17(3)(i), where the corresponding test programme has been performed in accordance with the documents referred to in paragraphs (1), (2) and (3) and where the test results ensure compliance with the essential requirements.

Conformity assessment procedures

16. (1) The 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.

(2) The conformity assessment procedures are set out in Annex II.

(3) Records and correspondence relating to conformity assessment procedures in the State shall be drawn up in the English language.

Technical documentation

17. (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 these Regulations.

(2) The technical documentation shall be sufficiently detailed to ensure compliance with—

- (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, and
- (c) the integrity of the measuring instrument.

(3) The technical documentation shall insofar as relevant for assessment and identification of the type or measuring instrument include-

- (a) a general description of the measuring instrument,
- (b) conceptual design and manufacturing drawings and plans of components, sub-assemblies and 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 subparagraphs (b), (c) and (d), including the operation of the measuring instrument,
- (f) a list of the harmonised standards and normative documents referred to in Regulation 15, applied in full or in part,
- (g) descriptions of the solutions adopted to meet the essential requirements where the harmonised standards and normative documents referred to in Regulation 15 have not been applied, including a list of other relevant technical specifications applied,
- (h) results of design calculations and examinations,
- (*i*) the appropriate test results where necessary to demonstrate that the type or the measuring instrument comply with—
 - (i) the requirements of these Regulations under declared rated operating conditions and under specified environmental disturbances, and
 - (ii) the durability specifications for gas meters, water meters, thermal energy-meters as well as meters for liquids other than water, and
- (*j*) the EU-type examination certificates or EU design examination certificates in respect of measuring instruments containing parts identical to those in the design.

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 - (4) A manufacturer shall—
 - (a) specify where seals and markings have been applied, and
 - (b) indicate the conditions for compatibility with interfaces and subassemblies where relevant.

EU declaration of conformity

18. (1) An EU declaration of conformity shall—

- (a) state that the fulfilment of the essential requirements set out in Annex I and in the relevant instrument-specific Annexes has been demonstrated in respect of the measuring instrument,
- (b) have the model structure as set out in Annex XIII,
- (c) contain the elements specified in the relevant modules set out in Annex II,
- (d) be continuously updated, and
- (e) 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.

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

(3) 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 these Regulations.

(4) In this Regulation—

"Act of 1972" means the European Communities Act 1972;

"European act" means-

- (a) a provision of the treaties governing the European Union, or
- (b) an act adopted by an institution of the European Union, an institution of the European Communities or any other body competent under those treaties;

"European Communities" has the same meaning as it has in the Act of 1972;

"European Union" has the same meaning as it has in the Act of 1972;

"treaties governing the European Union" has the same meaning as it has in the Act of 1972.

Conformity marking

19. The conformity of a measuring instrument with these Regulations shall be indicated by the presence of the CE marking and the supplementary metrology marking on it as specified by Regulation 20.

General principles of CE marking and supplementary metrology marking

20. (1) The general principles set out in Article 30 of the EC Regulation shall apply to—

(a) the CE marking, and

(b) the supplementary metrology marking.

(2) The supplementary metrology marking shall consist of the capital letter "M" and the last 2 digits of the year of its affixing, surrounded by a rectangle.

(3) The height of the rectangle referred to in paragraph (2) shall be equal to the height of the CE marking.

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

21. (1) A person who affixes the CE marking or the supplementary metrology marking to a measuring instrument shall comply with this Regulation.

(2) Subject to paragraph (3), the CE marking and the supplementary metrology marking shall be affixed visibly, legibly and indelibly to the measuring instrument or to its data plate.

(3) Where it is not possible or warranted, on account of the nature of the measuring instrument, to affix a CE marking or supplementary metrology marking in accordance with paragraph (2), it shall be affixed to the accompanying documents and to the packaging, if any.

(4) When a measuring instrument consists of a set of devices which are not sub-assemblies, operating together, the CE marking and the supplementary metrology marking shall be affixed on the instrument's main device.

(5) Subject to paragraph (6), the CE marking and the supplementary metrology marking shall be affixed before the measuring instrument is placed on the market.

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

(7) The supplementary metrology marking shall immediately follow the CE marking.

(8) 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.

(9) The identification number of the notified body shall—

- (a) be affixed by the body itself, or under its instructions, by the manufacturer or his or her authorised representative, and
- (b) be indelible or self-destructive upon removal.

(10) 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.

(11) A person shall not affix to any measuring instrument, a marking or inscription which may lead to confusion as to the meaning and form of the CE marking or the supplementary metrology marking.

PART 4

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Designation of Minister as notifying authority

22. The Minister is designated as the notifying authority in the State for the purposes of Article 24 of the Directive.

Requirements relating to notified bodies

23. (1) Subject to paragraph (2), a conformity assessment body shall meet the requirements of Article 27 of the Directive for the purposes of notification.

(2) Where a notified body subcontracts specific tasks connected with conformity assessment, it shall comply with Article 29 of the Directive.

(3) Application for notification by a conformity assessment body shall be in accordance with Article 31 of the Directive.

(4) The Minister may where—

- (a) a conformity assessment body has made an application under paragraph (3), and
- (b) he or she is satisfied that the conformity assessment body meets the requirements set out in this Regulation,

notify the conformity assessment body in accordance with Article 32 of the Directive.

(5) The Irish National Accreditation Board shall carry out the following activities on behalf of the Minister:

- (*a*) the setting up and carrying out the necessary procedures for the assessment and accreditation of conformity assessment bodies;
- (b) the monitoring of such notified bodies, including compliance with Article 29 of the Directive.

(6) Where the Minister has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 27 of the Directive or that it is failing to fulfil its obligations under Article 36 of the Directive or this Part, the Minister shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations.

- (7) The Minister shall—
 - (*a*) inform the notified body concerned in writing of his or her decision under paragraph (6) and allow the body an opportunity to make representation to him or her, and
 - (b) immediately inform the Commission and other Member States accordingly.

(8) Where the Minister has restricted, suspended or withdrawn notifications in accordance with paragraph (6) or where the notified body has ceased its activity, the Minister shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Presumption of conformity of notified bodies

24. Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards (or part of such a standard), the reference to which has been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in Article 27 of the Directive in so far as the relevant harmonised standards cover those requirements.

Accredited in-house bodies

25. (1) An accredited in-house body may be used to carry out conformity assessment activities for the undertaking of which it forms a part for the purpose of implementing the procedures set out in Module A2 and Module C2 of Annex II.

- (2) An accredited in-house body referred to in paragraph (1)—
 - (a) shall constitute a separate and distinct part of the undertaking,
 - (b) shall not, along with its personnel, participate or be responsible in the design, production, supply, installation, operation, use or maintenance of the measuring instruments it assesses,
 - (c) shall be accredited in accordance with the EC Regulation,

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 - (d) shall be organisationally identifiable, including the body and its personnel,
 - (e) shall have reporting methods within the undertaking of which they form a part which ensure their impartiality and demonstrate such impartiality to the Irish National Accreditation Board,
 - (*f*) shall not engage in any activity which might conflict with the independence of judgment of the body or the integrity of the body in relation to the assessment activities, and
 - (g) shall supply its services exclusively to the undertaking of which it forms a part.

(3) Subject to paragraph (4), an accredited in-house body shall not be notified to the Member States or the Commission.

(4) Information concerning the accreditation of an in-house body shall be given to the Minister when requested—

- (a) by the undertaking of which it forms a part, or
- (b) by the Irish National Accreditation Board.

Operational obligations of notified bodies

26. (1) A notified body shall carry out a conformity assessment procedure in accordance with the conformity assessment procedures provided for in Annex II and Article 36 of the Directive.

(2) A conformity assessment body shall perform its activities taking due account of—

- (a) the size of the undertaking,
- (b) the sector in which it operates,
- (c) the structure of the undertaking,
- (d) the degree of complexity of the measuring instrument technology, and
- (e) the mass or serial nature of the production process.

(3) Where a notified body finds that the essential requirements set out in Annex I and in the relevant instrument-specific Annexes or corresponding harmonised standards, normative documents or other technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate measures and shall not issue a certificate of conformity.

(4) Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a measuring instrument no longer

complies with these Regulations, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

(5) Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates as appropriate.

(6) A manufacturer whose notification has been suspended or revoked, as the case may be, under paragraph (5), may appeal the suspension or revocation to an appeal panel established under Regulation 27, not later than 14 days, or such longer period as the notifying authority may, for good and sufficient reason, determine, after service on the body concerned of the notice under paragraph (4).

Appeal panel

27. (1) This Regulation applies to—

- (*a*) an economic operator aggrieved by a decision by a notified body pursuant to Regulation 26 which affects the economic operator, and
- (b) a notified body aggrieved by a decision of the Minister pursuant to Regulation 23.

(2) The Minister shall, upon a request in writing from a person to whom this Regulation applies who is aggrieved by a decision referred to in subparagraph (a) or (b) of paragraph (1), establish a panel ("appeal panel") to consider an appeal by that person against the decision concerned.

(3) The Minister may establish more than one appeal panel to consider one or more appeals.

(4) An appeal panel shall consist of at least 3 but not more than 5 persons appointed by the Minister one of whom shall be designated by the Minister to be the chairperson of the panel.

(5) An appeal panel shall determine its own procedure.

(6) Upon appeal—

- (a) under Regulation 26, an appeal panel may—
 - (i) affirm or vary the refusal, restriction, suspension or withdrawal of a certificate, as the case may be, or
 - (ii) quash the decision of the notified body and direct the notified body, for stated reasons, to reconsider its decision,

(b) under Regulation 23, an appeal panel may—

- 20 **[2]**
- (i) affirm or vary the restriction, suspension or withdrawal of notification, as the case may be, or
- (ii) quash the decision of the notifying authority and direct the notifying authority, for stated reasons, to reconsider its decision.

(7) An appeal panel shall notify the person who made the request under paragraph (2) of its determination under subparagraph (a) or (b) as the case may be, of paragraph (6).

(8) The notifying authority or a notified body, as the case may be, shall comply with a determination of an appeal panel under this Regulation.

(9) A party to an appeal under this Regulation may, not later than 21 days after service on the party concerned of the determination of the appeal panel, appeal that determination to the High Court on a specified question of law.

(10) A decision of the High Court under this Regulation shall be final, save that, by leave of the court an appeal from the decision shall lie to the Court of Appeal on a specified question of law.

(11) All expenses reasonably incurred by the appellant under this Regulation in relation to an appeal before an appeal panel, the High Court or the Court of Appeal, as the case may be, shall be borne by the appellant where the appeal panel, the High Court or the Court of Appeal, as the case may be, affirms the decision of the notifying authority or notified body concerned.

(12) The notifying authority or notified body concerned, as the case may be, may recover the expenses referred to in paragraph (11) as a simple contract debt in any court of competent jurisdiction.

Information obligation on notified bodies

28. (1) Notified bodies shall inform the Minister of the following:

- (a) any refusal, restriction, suspension or withdrawal of a certificate;
- (b) any circumstances affecting the scope of or conditions for notification;
- (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
- (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

(2) Notified bodies shall provide the other bodies notified under the Directive carrying out similar conformity assessment activities covering the same measuring instruments with relevant information on issues relating to negative and, on request, positive conformity assessment results.

PART 5

UNION MARKET SURVEILLANCE, CONTROL OF MEASURING INSTRUMENTS ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

Union market surveillance and control of measuring instruments entering the Union market

29. (1) Articles 16 to 29 of the EC Regulation shall apply to measuring instruments.

(2) For the purposes of Article 19 of the EC Regulation, where pursuant to that Article, the Director considers it is necessary to do so, the Director may destroy or otherwise render inoperable a measuring instrument presenting a serious risk referred to in that said Article.

(3) Where a measuring instrument is destroyed, or rendered inoperable under paragraph (2), the costs of such destruction or the rendering inoperable of the measuring instrument may be charged to the economic operator or any other person making the instrument available on the market.

Procedure for dealing with measuring instruments presenting a risk at national level

30. (1) Where the Director has sufficient reasons to believe that a measuring instrument presents a risk to aspects of public interest protection covered by these Regulations, he or she shall carry out an evaluation in relation to the measuring instrument concerned covering all relevant requirements laid down in these Regulations.

(2) The relevant economic operators shall cooperate as necessary with the Director in carrying out an evaluation under paragraph (1).

(3) Where, in the course of the evaluation referred to in paragraph (1), the Director finds that the measuring instrument does not comply with the requirements laid down in these Regulations, he or she shall without delay require the relevant economic operator by notice in writing (a "risk compliance notice")—

- (a) to take all appropriate corrective actions to bring the measuring instrument into compliance with those requirements,
- (b) to withdraw the measuring instrument from the market, or
- (c) to recall it,

within a reasonable period stated in the notification commensurate with the nature of the risk, as the Director decides.

(4) Article 21 of the EC Regulation shall apply to the measures referred to in paragraph (3) and Regulation 37 shall apply to the notice.

(5) The Director shall inform the relevant notified body of the matters referred to in paragraph (3).

(6) Where the Director considers that non-compliance of the measuring instrument is not restricted to the State, the Director shall inform the Commission and the other Member States of the result of the evaluation referred to in paragraph (1) and of the actions which he or she has required the economic operator to take.

(7) The economic operator shall ensure that corrective action is taken in respect of all measuring instruments that are found to be non-compliant under paragraph (3) that it has made available on the market throughout the European Union unless the notice is withdrawn under Regulation 35(5) or annulled under Regulation 38 (6).

(8) Where the relevant economic operator does not take adequate corrective action as required under paragraph (3) within the period referred to in that notification, the Director shall take all appropriate provisional measures to-

- (a) prohibit or restrict the measuring instrument being made available on the market in the State,
- (b) withdraw the measuring instrument from that market, or
- (c) recall the measuring instrument.

(9) Where, pursuant to paragraph (8), the Director takes a measure specified in that paragraph, the Director shall notify the economic operator of the measure concerned, by notice in writing, and Regulation 37 shall apply to that notice.

(10) An economic operator shall comply with measures taken under paragraph (8) unless the notice in which they are specified is withdrawn or amended under Regulation 35(5) or annulled under Regulation 38 (6).

(11) The Director shall immediately inform the Commission and the other Member States of the measures taken under paragraph (8) and shall include all available details including—

- (a) the data necessary for the identification of the non-compliant measuring instrument,
- (b) the origin of the measuring instrument,
- (c) the nature of the non-compliance alleged and the risk involved,
- (d) the nature and duration of the measures taken by the Director, and
- (e) the arguments put forward by the relevant economic operator.

(12) The Director shall indicate in addition to the matters referred to in paragraph (11), whether the non-compliance is due to-

(*a*) the failure of the measuring instrument to meet requirements relating to aspects of public interest laid down in these Regulations, or

(b) shortcomings in the harmonised standards or normative documents referred to in Regulation 15 conferring a presumption of conformity.

(13) Where another Member State initiates the procedure under Article 42 of the Directive—

- (*a*) the Director shall without delay inform the Commission and the other Member States of—
 - (i) any measures adopted, and
 - (ii) any additional information at the disposal of the Director relating to the non-compliance of the measuring instrument concerned, and
- (b) where the Director disagrees with the adopted national measure, the objections of the Director.

(14) Where, within 3 months of receipt of the information referred to in paragraph (13) no objection has been raised by—

- (a) another Member State, or
- (*b*) the Commission,

in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

(15) The Director shall ensure that appropriate restrictive measures, such as

withdrawal of the measuring instrument from the market, are taken in respect of the measuring instrument concerned without delay.

Union safeguard procedure

31. Where, pursuant to Article 43 of the Directive, a national measure of a Member State-

- (a) is considered justified, the Director shall—
 - (i) take the necessary measures to ensure that the non-compliant measuring instrument is withdrawn from the market in the State, and
 - (ii) inform the Commission accordingly, or
- (b) is considered unjustified, the Director shall withdraw that measure.

Formal non-compliance

32. (1) Without prejudice to Regulation 30, where the Director makes one of the following findings, the Director shall, by notice in writing (a "formal non-compliance notice"), require the relevant economic operator to put an end to the non-compliance concerned:

- 24 **[2]**
 - (*a*) the CE marking or the supplementary metrology marking has been affixed in contravention of Article 30 of the EC Regulation or Regulation 21;
 - (b) the CE marking or the supplementary metrology marking has not been affixed;
 - (c) the identification number of the notified body, where that body is involved in the production control phase, has been affixed in violation of Regulation 21 or has not been affixed;
 - (d) the EU declaration of conformity does not accompany the measuring instrument;
 - (e) the EU declaration of conformity has not been drawn up correctly;
 - (f) technical documentation is either not available or not complete;
 - (g) the information referred to in Regulation 8(2), (3) and (4) or Regulation 11(5) is absent, false or incomplete;
 - (*h*) any other administrative requirement provided for in Regulations 7, 8 or 11 is not fulfilled.
 - (2) For the purposes of paragraph (1)—
 - (a) the Director, in a formal non-compliance notice, shall specify the measures to be taken to end the non-compliance concerned, and
 - (b) Regulation 37 shall apply to that notice.

(3) Where the non-compliance referred to in paragraph (1) persists, the Director shall take all appropriate measures to restrict or prohibit the measuring instrument being made available on the market or ensure that it is recalled or withdrawn from the market.

(4) Where, pursuant to paragraph (3), the Director takes a measure specified in that paragraph—

- (a) the Director shall notify the economic operator of the measure concerned, by notice in writing, and
- (b) Regulation 37 shall apply to that notice.

(5) A person to whom a formal non-compliance notice, or a notice under paragraph (4), is given shall comply with the notice unless the notice concerned is withdrawn or amended under Regulation 35(5) or is annulled under Regulation 38 (6).

Compliant measuring instruments which present a risk

33. (1) Where, having carried out an evaluation under Regulation 30(1), the Director finds that although a measuring instrument is in compliance with these

Regulations, it presents a risk to aspects of public interest protection covered by these Regulations, he or she shall require the relevant economic operator by a notice in writing—

- (a) to take all appropriate measures to ensure that the measuring instrument concerned, when placed on the market, no longer presents that risk,
- (b) to withdraw the measuring instrument from the market or,
- (c) to recall it,

within a reasonable period commensurate with the nature of the risk, as the Director decides.

(2) An economic operator shall ensure that corrective action required under paragraph (1) is taken in respect of all the measuring instruments concerned that he or she has made available on the market throughout the European Union.

(3) The Director shall immediately inform the Commission and other Member States of the matters referred to in paragraph (1) and shall include all available details including—

- (a) the data necessary for the identification of the measuring instrument,
- (b) the origin and the supply chain of the measuring instrument,
- (c) the nature of the risk involved, and
- (d) the nature and duration of the national measures taken.
- (4) Regulation 37 applies to the service of notices under this Regulation.

PART 6

Enforcement

Authorised officers

34. (1) The Director may appoint such and so many persons as he or she thinks fit to be authorised officers for the purposes of ensuring compliance with these Regulations and the Directive.

(2) An authorised officer shall be furnished with a warrant of his or her appointment and when exercising any power conferred on him or her under these Regulations an authorised officer shall, if requested by any person thereby affected, produce the warrant or a copy of it to that person for inspection.

(3) Subject to paragraph (7), an authorised officer may for the purpose of ensuring that these Regulations and the Directive are being complied with—

(a) at all reasonable times enter any premises or a place, at which there are reasonable grounds to believe that measuring instruments to

which these Regulations apply, are or are likely to be found, made available on the market or placed on the market or that books, documents or records relating to such a measuring instrument are kept, and search and inspect the premises or place and any measuring instrument or books, documents or records found therein,

- (b) secure for later inspection any premises or place or part of it in which such measuring instruments or books, documents or records are kept or there are reasonable grounds for believing that such measuring instruments or books, documents or records are kept,
- (c) require any person in charge of or employed in such premises or place to produce to the officer such books, documents or records (and in the case of such information in a non-legible form to reproduce it in a permanent legible form) that are in the person's power or control or to give to the officer such information as the officer may reasonably require in relation to any entries in such records,
- (d) inspect, and take copies of or extracts from, any such books, documents or records (including in the case of information in non-legible form a copy of or extract from such information in a permanent legible form),
- (e) remove and detain, where the officer has reasonable cause to suspect that there has been a contravention of these Regulations, the measuring instrument, device, part or component or books, documents or records for such period as may be reasonable for further examination or until the conclusion of any legal proceedings,
- (f) in or at the premises, seize any equipment or part thereof or any books, records or other documents relating to equipment that the officer may reasonably require;
- (g) as regards any measuring instrument or any article or device, part or component used in the manufacture of a measuring instrument the officer finds at or in a premises, require any person in charge of the premises, or any person who appears to the officer to be in possession of the measuring instrument or the article or device, part or component, to supply without payment, for test, examination or analysis sufficient samples thereof,
- (h) require any person to afford the officer such facilities and assistance within the person's control or responsibilities as are reasonably necessary to enable the officer to exercise any of the powers conferred on an authorised officer under this Regulation,
- (*i*) examine any procedure connected with the manufacture, import or distribution of a measuring instrument, and

(*j*) request the person in charge of a vehicle or vessel to bring that vehicle or vessel to the nearest appropriate test facility at which an inspection may be carried out.

(4) An authorised officer shall not, other than with the consent of the occupier, enter a private dwelling unless he or she has obtained a warrant from the District Court under paragraph (7) authorising such entry.

(5) Where an authorised officer in the exercise of the officer's powers under this Regulation is prevented from entering any premises, an application may be made to the District Court under paragraph (7) for a warrant authorising such entry.

(6) An authorised officer, where he or she considers it necessary, may be accompanied by a member of the Garda Síochána when performing any powers conferred on an authorised officer under this Regulation.

(7) If a judge of the District Court is satisfied on the sworn information of an authorised officer that there are reasonable grounds for suspecting that there is information required by an authorised officer under this Regulation held on any premises or any part of any premises or there is a measuring instrument or article, device, part or component of a measuring instrument which an authorised officer requires to inspect for the purposes of these Regulations or that such inspection is likely to disclose evidence of a contravention of these Regulations, the judge may issue a warrant authorising an authorised officer, accompanied by either or both authorised officers and members of the Garda Síochána, at any time or times within one month from the date of issue of the warrant, on production if so requested of the warrant, to enter, if need be by reasonable force, the premises and exercise all or any of the powers conferred on an authorised officer under this Regulation.

(8) An application under paragraph (7) shall be made to the judge of the District Court in whose District Court district the premises is situated.

- (9) A person shall not—
 - (a) obstruct or interfere with an authorised officer in the exercise of the officer's powers under this Regulation,
 - (b) without reasonable excuse, fail to comply with a request or a requirement of an authorised officer under this Regulation, or
 - (c) make a statement to such officer which the person knows is false or misleading.

(10) A person appointed as an authorised officer under Regulation 14 of the Regulations of 2007 who immediately before the making of these Regulations held office as such an officer continues to be an authorised officer under this Regulation.

(11) In this Regulation, premises or a place includes a vehicle or vessel.

Measures entailing prohibition or restriction

35. (1) Where the Director takes a measure referred to in Regulation 30, 31, 32 (3), or 33, he or she shall follow the procedures set out in this Regulation.

(2) A measure referred to in paragraph (1) shall be notified without delay to the person concerned, and the notification shall—

- (a) state the exact grounds on which the measure is based, and
- (b) inform the person concerned of his or her right to make representations under paragraph (3) and of his or her right of appeal under Regulation 38, and
- (c) explain the measures, and any time limits associated with them, that must be taken in order to remove the necessity for the prohibition or restriction.

(3) Subject to paragraph (4), a person concerned by a measure referred to in paragraph (1) shall have the opportunity to make representations to the Director in advance of the measure being taken.

(4) Where, due to the urgency of the measure referred to in paragraph (1), it is not possible to give the person concerned the opportunity to make representations in advance of the measure being taken, the Director shall give such opportunity, as soon as may be, thereafter.

(5) The Director may, where he or she considers it appropriate to do so, withdraw, or amend by a further notification in writing any notification given under this Regulation.

(6) Without prejudice to paragraph (5), the Director shall, where he or she is satisfied that the economic operator concerned has taken effective action, amend or withdraw the notice concerned.

(7) A notification under this Regulation may require that the measures concerned be undertaken—

- (a) immediately, because of the urgency of the matter,
- (b) from a specified date,
- (c) by a specified date, or
- (d) between specified dates.

(8) The Director shall cause the Commission to be notified of any relevant notification or other measures taken pursuant to paragraph (1).

(9) A person shall comply with a notification under this Regulation, or a requirement of a notification, unless and until the notification is annulled under Regulation 38 (6).

(10) Where a person fails to comply with a notification under this Regulation or a requirement of a notification, the Director may institute, in a court of competent jurisdiction, proceedings for an order requiring the person to comply with the terms of the notification.

Compliance notice

36. (1) Where an authorised officer is satisfied that a person has contravened Regulation 7, 10, 11, 12, 14 or 32, the authorised officer may serve a notice (in these Regulations referred to as a "compliance notice") on the person.

- (2) A compliance notice shall—
 - (a) state the grounds for the authorised officer being satisfied that there has been a contravention referred to in paragraph (1),
 - (b) for the purpose of ensuring compliance by the person concerned with any provision of these Regulations, require the person to do or refrain from doing such act or acts as is or are specified in the notice by such date as is so specified, and
 - (c) contain information regarding the bringing of an appeal under paragraph (5) against the notice, including the manner in which an appeal shall be brought.

(3) A compliance notice shall not specify a date in accordance with paragraph (2)(b) that falls on or before the date by which an appeal under paragraph (5) shall be brought.

- (4) An authorised officer may—
 - (a) withdraw a compliance notice at any time, as he or she considers appropriate, or
 - (b) where no appeal is brought under this Regulation, specify a date extending the period specified in the notice for the purposes of paragraph (2)(b), and notify the person in writing accordingly.

(5) A person may appeal a compliance notice served on him or her to the District Court not later than 21 days after the service of the compliance notice concerned.

(6) The authorised officer and the appellant concerned shall be entitled to be heard and to adduce evidence at the hearing of an appeal under this Regulation.

(7) The District Court shall, upon an appeal under this Regulation, do one of the following:

- (a) affirm the compliance notice concerned;
- (b) direct the authorised officer to withdraw the compliance notice concerned.

(8) An authorised officer shall comply with a direction under paragraph (7).

(9) A person shall comply with a compliance notice on or before the specified date.

(10) This Regulation shall not operate to prevent or restrict—

- (*a*) the entitlement of any person to bring proceedings for the purpose of securing compliance with these Regulations by a person, or
- (b) the bringing or prosecuting of any proceedings for an offence under these Regulations.

(11) In this Regulation "specified date" means, in relation to a compliance notice—

- (a) the date specified in the notice in accordance with paragraph (2)(b), where no appeal against the notice is brought under this Regulation, or
- (b) the day falling immediately after the expiration of the period of 7 days from the date on which the District Court so affirms the notice, where an appeal against the notice is brought under paragraph (5) and the District Court affirms the notice in accordance with paragraph (7)(a).

Service of notifications

37. (1) Subject to paragraph (2), a notification under Regulation 30, 32, 33 or 36 shall be addressed to the person concerned by name and may be given to the person in one of the following ways—

- (a) by delivering it to the person,
- (b) by leaving it at the address at which the person carries on business or ordinarily resides or, in the case in which an address for service has been furnished, at that address, or
- (c) by sending it by post in a prepaid registered letter to the address at which the person carries on business or ordinarily resides or, in a case in which an address for service has been furnished, to that address.

(2) For the purposes of this Regulation, a company within the meaning of the Companies Act 2014 (No. 38 of 2014) shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body shall be deemed to be ordinarily resident at its principal office or place of business.

Right of appeal against restriction or other measure

38. (1) A person aggrieved by a notification or other measure taken under Regulation 30, 32 (3), 33 or 35 may appeal to the appropriate court against the giving of the direction or taking of the measure.

(2) An appeal under this Regulation shall state the grounds on which the appeal is made and be made by written notice, which shall be lodged with the appropriate office of the court by the appellant not later than 14 days from the date upon which the notification concerned was given to him or her or the measure was taken.

(3) Where a person appeals a notice referred to in paragraph (1) he or she shall-

- (a) give the Director a copy of the notice of appeal at the same time he or she lodges the notice of appeal in accordance with paragraph (2), and
- (b) notify the Director in writing of the grounds of the appeal.

(4) The Director shall be entitled to appear, be heard and adduce evidence at the hearing of the appeal.

(5) Where an appeal is made under paragraph (1) the notification shall remain in force until the appeal is determined or withdrawn, subject to any decision to the contrary by the High Court.

(6) On the hearing of an appeal under this Regulation the appropriate court may, as it thinks fit, confirm the notification or measure concerned or annul the notification or measure and make any other such order as it considers appropriate.

- (7) In this Regulation "appropriate court" means—
 - (a) in case the estimated value of the measuring instrument concerned does not exceed €15,000, or such other amount as may stand specified for the time being by law as that Court's jurisdiction in tort, the District Court,
 - (b) in case the estimated value of the measuring instrument concerned does not exceed €75,000, or such other amount as may stand specified for the time being by law as that Court's jurisdiction in tort, the Circuit Court, and
 - (c) in any case, the High Court.

(8) If, in relation to an appeal under this Regulation to the District Court, that court becomes of opinion during the hearing of the appeal that the value of the measuring instrument, the subject of the appeal, exceeds that court's jurisdiction in tort, it may, if it so thinks fit, transfer the appeal to the Circuit Court or the High Court, whichever it considers appropriate having regard to its opinion of the value of the measuring instrument.

(9) If, in relation to an appeal under this Regulation to the Circuit Court, that court becomes of opinion during the hearing of the appeal that the value of the measuring instrument, the subject of the appeal, exceeds that court's jurisdiction in tort, it may, if it so thinks fit, transfer the appeal to the High Court.

(10) Paragraphs (8) and (9) are without prejudice to the jurisdiction of a court (being either the District Court or the Circuit Court) to determine an appeal under this Regulation in relation to which it was, at the time of the hearing of the appeal, the appropriate court.

(11) An appeal under this Regulation to the District Court shall be determined by the judge of the District Court for the District Court district in which the measuring instrument concerned was made available on the market or the appellant ordinarily resides.

(12) An appeal under this Regulation to the Circuit Court shall be determined by the judge of the Circuit Court for the circuit in which the measuring instrument concerned was made available on the market or the appellant ordinarily resides.

Offences

39. (1) A person who contravenes a provision or requirement of this Regulation or Regulation 4, 5, 6, 7, 8, 10(5),11, 12, 14(1), 14(2), 21, 30 (2), (7), (10), (11), 32(5), 33(2), 34 (9), 35 (9), 36 (9) or 40 commits an offence.

- (2) A person who—
 - (a) forges or counterfeits the CE marking or supplementary metrology marking,
 - (b) applies to any measuring instrument a marking which he or she knows to be forged or counterfeit,
 - (c) knowingly, makes available, places on the market or puts into use any measuring instrument with such forged or counterfeit mark, or any mark liable to be confused with marks authorised under these Regulations, or
 - (d) fails to comply with Regulation 21,

commits an offence.

(3) A person who knowingly alters a measuring instrument, device, part or component of a measuring instrument so as to affect its accuracy, commits an offence.

(4) A person who knowingly makes available on the market, places on the market or puts into use any instrument so altered commits an offence.

(5) Without prejudice to paragraph (3) a person who alters, adjusts or repairs an instrument so as to bring it into conformity with the Regulations does not commit an offence.

(6) Where a person is convicted of an offence under these Regulations, the court may order the forfeiture to the Director of any measuring instrument to which the offence relates.

(7) Summary proceedings for an offence under these Regulations may be brought and prosecuted by the Director.

(8) Unless it is satisfied that there are special and substantial reasons for not so doing, the court shall, where a person is convicted of an offence under these Regulations, order the person to pay to the prosecution the costs and expenses, measured by the court, incurred by the prosecution in relation to the prosecution of the offence.

Offence of providing false or misleading information

40. A person who provides to the Director information which the person knows or ought reasonably to know to be false or misleading (whether on the person's own behalf or on behalf of another person) in purported compliance with a requirement imposed by these Regulations, commits an offence.

Penalties

41. A person convicted of an offence under these Regulations is liable—

- (*a*) on summary conviction to a class B fine, or imprisonment for a term not exceeding 12 months, or to both, or
- (b) on conviction on indictment to a fine not exceeding €500,000 or imprisonment for a term not exceeding 2 years or both.

Offences by bodies corporate

42. (1) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent or connivance of, or to be attributable to any wilful neglect on the part of any person, being a director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person, as well as the body corporate, commits an offence and shall be liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

(2) Where the affairs of a body corporate are managed by its members, paragraph (1) applies in relation to the acts and defaults of a member in connection with his or her functions of management as if he or she were a director or manager of the body corporate.

Amendment of Water Services Act 2007

43. Section 5 of the Water Services Act 2007 (No. 30 of 2007) is amended by the substitution of the following paragraph for paragraph (a):

"(*a*) Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014⁶ on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast);".

Amendment of Waste Management (Collection Permit) Regulations 2007

44. The Waste Management (Collection Permit) Regulations 2007 (S.I. 820 of 2007) are amended in Article 20(2) by the substitution of the following paragraph for paragraph (g)(iii) (substituted by Regulation 2(n) of the Waste Management (Collection Permit) (Amendment) Regulations 2016 (S.I. No. 24 of 2016)):

"(iii) use an automatic weighing instrument that complies with the Metrology Act 1996 (No. 27 of 1996), Legal Metrology (Measuring Instruments) Act 2017 (No. 31 of 2017) and the Legal Metrology (European Conformity Assessment of Measuring Instruments) Regulations 2018 (S.I. No. 2 of 2018) to weigh household kerbside waste in accordance with (I) and where the automatic weighing instrument is an automatic catchweigher it must be of accuracy Class Y(b) or better,"

Transitional — measuring instruments placed on market under Regulations of 2007

45. (1) Measuring instruments which are in conformity with the Regulations of 2007 and which were placed or made available on the market or put into use before the coming into operation of these Regulations may continue to be made available on the market and where in use may be inspected in service in accordance with the Legal Metrology (General) Regulations 2008 (S.I. No. 323 of 2008).

(2) Certificates issued under the Regulations of 2007 shall be valid under these Regulations.

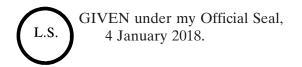
(3) A measuring instrument which was placed on the market or put into use in accordance with a type approval certificate issued under the Legal Metrology (Type Approval) Regulations 2006 (S I. No. 207 of 2006) shall continue to conform to the requirements of that certificate notwithstanding the termination of the certificate under the Regulations of 2007.

Revocations

46. The following are revoked:

- (a) Legal Metrology (European Conformity Assessment of Measuring Instruments) Regulations 2007 (S.I. No. 160 of 2007), and
- (b) Legal Metrology (European Conformity Assessment of Measuring Instruments) (Amendment) Regulations 2010 (S.I. No. 543 of 2010).

⁶OJ No.L 96, 29.3.2014, p.149.



HEATHER HUMPHREYS, Minister for Business Enterprise and Innovation.

EXPLANATORY NOTE

(This note is not part of the Regulations and does not purport to be a legal interpretation)

These Regulations give further effect to 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), (amended by Commission Delegated Directive (EU) 2015/13 of 31 October 2014 amending Annex III to Directive 2014/32/EU of the European Parliament and of the Council, as regards the flowrate range of water meters).

Articles 1 and 3 of Directive 2014/32/EU are transposed into Irish law by way of the Legal Metrology (Measuring Instruments) Act 2017 (No. 31 of 2017).

Directive 2014/32/EU (the Recast Measuring Instruments Directive) essentially aligns the existing Measuring Instruments Directive (2004/22/EC) with the New Legislative Framework.

The Regulations provide for the free movement within the Community of certain instruments and sets out essential requirements, which must be met for instruments intended for certain specified uses.

Part 1 of the Regulations contains definitions, application to the measuring instruments defined in the instrument-specific Annexes 111 to X11 referred to as the ("instrument-specific Annexes"); and an exemption from the requirements of the Regulations in relation to trade fairs, exhibitions and demonstrations.

Part 2 of the Regulations sets out the obligations of economic operators (manufacturers, importers and distributors) in relation to the marking and indication of regulated measuring instruments in the State, and, in particular to ensure that they meet the essential requirements applicable to those instruments.

Part 3 of the Regulations deals with the Conformity of Measuring Instruments. The Regulations provide that the essential requirements of the Directive may be met through the adoption by a manufacturer of the harmonised standards and/or appropriate normative documents, subject to the procedure stipulated in the Directive, containing technical specifications.

Part 4 of the Regulations provides for the appointment of a Notifying Authority and Notified Bodies to carry out the various functions such as typeapproval, verification and quality system approval and sets out the obligations on manufacturers and the conditions under which they may issue a declaration of conformity and attach the CE mark and the Supplementary Metrology Mark, to instruments. Part 5 of the Regulations deals with Union Market Surveillance, and Control of Measuring Instruments entering the Union Market and Union Safeguard Procedures for dealing with Measuring Instruments presenting a risk at national level.

Part 6 of the Regulations deals with Enforcement. The Regulations provide for an Appeals Procedure, market surveillance, powers of inspectors and authorised officers and penalties for Offences.

The Regulations amend:

Section 5 of the Water Services Act 2007 (No. 30 of 2007) and

Article 20(2) of the Waste Management (Collection Permit) Regulations 2007 (S.I. 820 of 2007).

The Regulations Revoke:

- (a) Legal Metrology (European Conformity Assessment of Measuring Instruments) Regulations 2007 (S.I. No. 160 of 2007), and
- (b) Legal Metrology (European Conformity Assessment of Measuring Instruments) (Amendment) Regulations 2010 (S.I. No. 543 of 2010).

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