Directive 2014/31/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 non-automatic weighing instruments (recast) (Text with EEA relevance)

CHAPTER 1

GENERAL PROVISIONS

Article 1

Scope

1 This Directive shall apply to all non-automatic weighing instruments.

2 For the purposes of this Directive, the following categories of use of non-automatic weighing instruments shall be distinguished:

a determination of mass for commercial transactions;

b determination of mass for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment;

c determination of mass for the application of laws or regulations or for an expert opinion given in court proceedings;

d determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment;

e determination of mass for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories;

f determination of price on the basis of mass for the purposes of direct sales to the public and the making-up of prepackages;

g all applications other than those listed in points (a) to (f).

Article 2

Definitions

For the purposes of this Directive, the following definitions shall apply:

(1) ‘weighing instrument’ means a measuring instrument serving to determine the mass of a body by using the action of gravity on that body. A weighing instrument may also serve to determine other mass-related magnitudes, quantities, parameters or characteristics;

(2) ‘non-automatic weighing instrument’ or ‘instrument’ means a weighing instrument requiring the intervention of an operator during weighing;

(3) ‘making available on the market’ means any supply of an instrument for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(4) ‘placing on the market’ means the first making available of an instrument on the Union market;

(5) ‘manufacturer’ means any natural or legal person who manufactures an instrument or has an instrument designed or manufactured, and markets that instrument under his name or trade mark;

(6) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

(7) ‘importer’ means any natural or legal person established within the Union who places an instrument from a third country on the Union market;

(8) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an instrument available on the market;

(9) ‘economic operators’ means the manufacturer, the authorised representative, the importer and the distributor;

(10) ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by an instrument;

(11) ‘harmonised standard’ means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;

(12) ‘accreditation’ means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;

(13) ‘national accreditation body’ means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;

(14) ‘conformity assessment’ means the process demonstrating whether the essential requirements of this Directive relating to an instrument have been fulfilled;

(15) ‘conformity assessment body’ means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

(16) ‘recall’ means any measure aimed at achieving the return of an instrument that has already been made available to the end-user;

(17) ‘withdrawal’ means any measure aimed at preventing an instrument in the supply chain from being made available on the market;

(18) ‘Union harmonisation legislation’ means any Union legislation harmonising the conditions for the marketing of products;

(19) ‘CE marking’ means a marking by which the manufacturer indicates that the instrument is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

Article 3

Making available on the market and putting into service

1 Member States shall take all steps to ensure that only instruments that meet the applicable requirements of this Directive may be made available on the market.

2 Member States shall take all steps to ensure that instruments may not be put into service for the uses referred to in points (a) to (f) of Article 1(2) unless they meet the requirements of this Directive.

3 Member States shall take all steps to ensure that instruments put into service for the uses referred to in points (a) to (f) of Article 1(2) continue to conform to the applicable requirements of this Directive.

Article 4

Essential requirements

Instruments used or intended to be used for the applications listed in points (a) to (f) of Article 1(2) shall satisfy the essential requirements set out in Annex I.

Where the instrument includes, or is connected to, devices which are not used or intended to be used for the applications listed in points (a) to (f) of Article 1(2), such devices shall not be subject to those essential requirements.

Article 5

Free movement of instruments

1 Member States shall not impede the making available on the market of instruments which meet the requirements of this Directive.

2 Member States shall not impede the putting into service, for the uses referred to in points (a) to (f) of Article 1(2), of instruments which meet the requirements of this Directive.

CHAPTER 2

OBLIGATIONS OF ECONOMIC OPERATORS

Article 6

Obligations of manufacturers

1 When placing on the market their instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Annex I.

2 For the instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall draw up the technical documentation referred to in Annex II and carry out the relevant conformity assessment procedure referred to in Article 13 or have it carried out.

Where compliance of an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) with the applicable requirements 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 For the instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the 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 instrument design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of an instrument is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall carry out sample testing of instruments made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming instruments and instrument recalls, and shall keep distributors informed of any such monitoring.

5 Manufacturers shall ensure that instruments which they have placed on the market bear a type, batch or serial number or other element allowing their identification, as set out in Annex III.

For the instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall affix the inscriptions provided for in point 1 of Annex III.

For the instruments not intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall affix the inscriptions provided for in point 2 of Annex III.

Where an instrument which is intended to be used for any of the applications listed in points (a) to (f) of Article 1(2) includes, or is connected to, devices which are not used or intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall affix to each of those devices the restrictive use symbol as provided for in Article 18 and in point 3 of Annex III.

6 Manufacturers shall indicate on the instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted. 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.

7 Manufacturers shall ensure that the instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is accompanied by instructions and information 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 an 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 instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the instrument presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the 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 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 instruments which they have placed on the market.

Article 7

Authorised representatives

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

The obligations laid down in Article 6(1) and the obligation to draw up technical documentation referred to in Article 6(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 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 an instrument;

c cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by instruments covered by the authorised representative's mandate.

Article 8

Obligations of importers

1 Importers shall place only compliant instruments on the market.

2 Before placing on the market an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2), importers shall ensure that the appropriate conformity assessment procedure referred to in Article 13 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the instrument bears the CE marking and the supplementary metrology marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

Where an importer considers or has reason to believe that an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is not in conformity with the essential requirements set out in Annex I, he shall not place the instrument on the market until it has been brought into conformity. Furthermore, where the instrument presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

Before placing on the market an instrument not intended to be used for the applications listed in points (a) to (f) of Article 1(2) importers shall ensure that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

3 Importers shall indicate on the instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted. Where this would

require the packaging to be opened, those indications may be given on the packaging and in a document accompanying the instrument. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4 Importers shall ensure that the instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is accompanied by instructions and information in a language which can be easily understood by end-users, as determined by the Member State concerned.

5 Importers shall ensure that, while an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I.

6 When deemed appropriate with regard to the risks presented by an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2), importers shall carry out sample testing of instruments made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming instruments and instrument recalls, and shall keep distributors informed of any such monitoring.

7 Importers who consider or have reason to believe that an 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 instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the instrument presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8 For the instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), importers shall, for 10 years after the 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 an 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 instruments which they have placed on the market.

Article 9

Obligations of distributors

1 When making an instrument available on the market distributors shall act with due care in relation to the requirements of this Directive.

2 Before making an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) available on the market, distributors shall verify that the instrument bears the CE marking, and the supplementary metrology marking, that it is accompanied by the required documents and by instructions and information in a language which can be easily understood by end-users in the Member State in which the instrument is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.

Where a distributor considers or has reason to believe that an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is not in conformity

with the essential requirements set out in Annex I, he shall not make the instrument available on the market until it has been brought into conformity. Furthermore, where the instrument presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

Before making an instrument not intended to be used for the applications listed in points (a) to (f) of Article 1(2) available on the market, distributors shall verify that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.

3 Distributors shall ensure that, while an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I.

4 Distributors who consider or have reason to believe that an instrument which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that instrument into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the instrument presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the 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 an instrument. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by instruments which they have made available on the market.

Article 10

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 6, where he places an instrument on the market under his name or trade mark or modifies an instrument already placed on the market in such a way that compliance with this Directive may be affected.

Article 11

Identification of economic operators

For instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), economic operators shall, on request, identify the following to the market surveillance authorities:

(a) any economic operator who has supplied them with an instrument;

(b) any economic operator to whom they have supplied an 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 instrument and for 10 years after they have supplied the instrument.

CHAPTER 3

CONFORMITY OF INSTRUMENTS

Article 12

Presumption of conformity of instruments

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 covered by those standards or parts thereof.

Article 13

Conformity assessment procedures

1 The conformity of instruments to the essential requirements set out in Annex I may be established by either of the following conformity assessment procedures as selected by the manufacturer:

a Module B as set out in point 1 of Annex II, followed either by Module D as set out in point 2 of Annex II, or by Module F as set out in point 4 of Annex II.

However, Module B shall not be compulsory for instruments which do not use electronic devices and the load-measuring device of which does not use a spring to balance the load. For those instruments not submitted to Module B, Module D1 as set out in point 3 of Annex II or Module F1 as set out in point 5 of Annex II shall apply;

b Module G as set out in point 6 of Annex II.

2 The documents and correspondence relating to the conformity assessment procedures referred to in paragraph 1 shall be drawn up in one of the official languages of the Member State where those procedures are carried out, or in a language accepted by the body notified in accordance with Article 19.

Article 14

EU declaration of conformity

1 The EU declaration of conformity shall state that the fulfilment of the essential requirements set out in Annex I has been demonstrated.

2 The EU declaration of conformity shall have the model structure set out in Annex IV, 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 instrument is placed or made available on the market.

3 Where an 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 instrument with the requirements laid down in this Directive.

Article 15

Conformity marking

The conformity of an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) with this Directive shall be indicated by the presence, on the instrument, of the CE marking and the supplementary metrology marking as specified in Article 16.

Article 16

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 17

Rules and conditions for affixing the CE marking, the supplementary metrology marking and other markings

1 The CE marking and the supplementary metrology marking shall be affixed visibly, legibly and indelibly to the instrument or to its data plate.

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

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

4 The CE marking and the supplementary metrology marking shall be followed by the identification number(s) of the notified body or bodies 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.

5 The CE marking, the supplementary metrology marking and the identification number(s) of the notified body or bodies may be followed by any other mark indicating a special risk or use.

6 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.

Article 18

Restrictive use symbol

The symbol referred to in the fourth subparagraph of Article 6(5) and specified in point 3 of Annex III shall be affixed to the devices in a clearly visible and indelible form.

CHAPTER 4

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 19

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive.

Article 20

Notifying authorities

1 Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 25.

2 Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3 Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 21. In addition it shall have arrangements to cover liabilities arising out of its activities.

4 The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 21

Requirements relating to notifying authorities

1 A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2 A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3 A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4 A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5 A notifying authority shall safeguard the confidentiality of the information it obtains.

6 A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 22

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 23

Requirements relating to notified bodies

1 For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2 A conformity assessment body shall be established under the national law of a Member State and have legal personality.

3 A conformity assessment body shall be a third-party body independent of the organisation or the instrument it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of instruments which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4 A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the instruments which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed instruments that are necessary for the operations of the conformity assessment body or the use of such instruments for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those instruments, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5 Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6 A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex II and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of instruments in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

a personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

b descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

c procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the instrument technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7 The personnel responsible for carrying out conformity assessment tasks shall have the following:

a sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

b satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

c appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;

d the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8 The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9 Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10 The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex II or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11 Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 24

Presumption of conformity of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 23 in so far as the applicable harmonised standards cover those requirements.

Article 25

Subsidiaries of and subcontracting by notified bodies

1 Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 23 and shall inform the notifying authority accordingly.

2 Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3 Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4 Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex II.

Article 26

Application for notification

1 A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2 The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the instrument or instruments for which that body claims to be competent, as well as by an

accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 23.

3 Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 23.

Article 27

Notification procedure

1 Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 23.

2 They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3 The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and instrument or instruments concerned and the relevant attestation of competence.

4 Where a notification is not based on an accreditation certificate as referred to in Article 26(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 23.

5 The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6 The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

Article 28

Identification numbers and lists of notified bodies

1 The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2 The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

Article 29

Changes to notifications

1 Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 23, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2 In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State 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.

Article 30

Challenge of the competence of notified bodies

1 The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2 The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.

3 The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4 Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 41(2).

Article 31

Operational obligations of notified bodies

1 Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex II.

2 Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the instrument technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the instrument with this Directive.

3 Where a notified body finds that the essential requirements set out in Annex I or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective 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 an instrument no longer complies, 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.

Article 32

Appeal against decisions of notified bodies

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

Article 33

Information obligation on notified bodies

1 Notified bodies shall inform the notifying authority 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 this Directive carrying out similar conformity assessment activities covering the same instruments with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 34

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article 35

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral or cross sectoral group or groups of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group or those groups, directly or by means of designated representatives.

CHAPTER 5

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

Article 36

Union market surveillance and control of instruments entering the Union market

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to instruments covered by Article 1 of this Directive.

Article 37

Procedure for dealing with instruments presenting a risk at national level

1 Where the market surveillance authorities of one Member State have sufficient reason to believe that an instrument covered by this Directive presents a risk to aspects of public interest protection covered by this Directive, they shall carry out an evaluation in relation to the instrument concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the instrument does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the instrument into compliance with those requirements, to withdraw the instrument from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2 Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3 The economic operator shall ensure that all appropriate corrective action is taken in respect of all the instruments concerned that it has made available on the market throughout the Union.

4 Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the instrument's being made available on their national market, to withdraw the instrument from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5 The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant instrument, the origin of the instrument, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

a failure of the instrument to meet requirements relating to the aspects of public interest protection laid down in this Directive; or

b shortcomings in the harmonised standards referred to in Article 12 conferring a presumption of conformity.

6 Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the instrument concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7 Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8 Member States shall ensure that appropriate restrictive measures, such as withdrawal of the instrument from the market, are taken in respect of the instrument concerned without delay.

Article 38

Union safeguard procedure

1 Where, on completion of the procedure set out in Article 37(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2 If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant instrument is withdrawn from their market,

and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3 Where the national measure is considered justified and the non-compliance of the instrument is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 37(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

Article 39

Compliant instruments which present a risk

1 Where, having carried out an evaluation under Article 37(1), a Member State finds that although an instrument is in compliance with this Directive, it presents a risk to aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the instrument concerned, when placed on the market, no longer presents that risk, to withdraw the instrument from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2 The economic operator shall ensure that corrective action is taken in respect of all the instruments concerned that he has made available on the market throughout the Union.

3 The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the instrument concerned, the origin and the supply chain of the instrument, the nature of the risk involved and the nature and duration of the national measures taken.

4 The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not, and where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 41(3).

5 The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

Article 40

Formal non-compliance

1 Without prejudice to Article 37, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

a the CE marking or the supplementary metrology marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 17 of this Directive;

b the CE marking or the supplementary metrology marking has not been affixed;

c the inscriptions provided for in Article 6(5) have not been affixed or have been affixed in violation of Article 6(5);

d the identification number of the notified body, where that body is involved in the production control phase, has been affixed in violation of Article 17 or has not been affixed;

e the EU declaration of conformity has not been drawn up;

f the EU declaration of conformity has not been drawn up correctly;

g technical documentation is either not available or not complete;

h the information referred to in Article 6(6) or 8(3) is absent, false or incomplete;

i any other administrative requirement provided for in Article 6 or 8 is not fulfilled.

2 Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the instrument being made available on the market or ensure that it is recalled or withdrawn from the market.

CHAPTER 6

COMMITTEE, TRANSITIONAL AND FINAL PROVISIONS

Article 41

Committee procedure

1 The Commission shall be assisted by the Committee on non-automatic weighing instruments. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2 Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3 Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4 The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

Article 42

Penalties

Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements

The penalties provided for shall be effective, proportionate and dissuasive.

Article 43

Transitional provisions

Member States shall not impede the making available on the market and/or the putting into service of instruments covered by Directive 2009/23/EC which are in conformity with that Directive and which were placed on the market before 20 April 2016.

Certificates issued under Directive 2009/23/EC shall be valid under this Directive.

Article 44

Transposition

1 Member States shall adopt and publish, by 19 April 2016 the laws, regulations and administrative provisions necessary to comply with points (3) to (19) of Article 2, Articles 6 to 17, Articles 19 to 43 and Annex II, III and IV. They shall forthwith communicate the text of those measures to the Commission.

They shall apply those measures from 20 April 2016.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 45

Repeal

Directive 2009/23/EC, as amended by the Regulation listed in Annex V, Part A, is repealed with effect from 20 April 2016, without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and the dates of application of the Directives set out in Annex V, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VI.

Article 46

Entry into force and application

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 1, points (1) and (2) of Article 2, Articles 3, 4, 5 and 18 and Annexes I, V and VI shall apply from 20 April 2016.

Article 47

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 26 February 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS