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)

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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the ordinary legislative procedure[(2)],

Whereas:

(1) Directive 2009/23/EC of the European Parliament and of the Council of 23 April 2009 on non-automatic weighing instruments[(3)] has been substantially amended[(4)]. Since further amendments are to be made, that Directive should be recast in the interests of clarity.

(2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products[(5)] lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

(3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products[(6)] lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 2009/23/EC should therefore be adapted to that Decision.

(4) This Directive covers non-automatic weighing instruments which are new to the Union market when they are placed on the market; that is to say they are either new non-automatic weighing instruments made by a manufacturer established in the Union or non-automatic weighing instruments, whether new or second-hand, imported from a third country.

(5) Member States should have the responsibility of protecting the public against incorrect results of weighing operations by means of non-automatic weighing instruments when used for certain categories of applications.

(6) This Directive should apply to all forms of supply, including distance selling.

(7) Economic operators should be responsible for the compliance of non-automatic weighing instruments with this Directive in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests covered by this Directive, and to guarantee fair competition on the Union market.

(8) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market non-automatic weighing instruments which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.

(9) In order to facilitate communication between economic operators, market surveillance authorities and end-users, Member States should encourage economic operators to include a website address in addition to the postal address.

(10) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.

(11) It is necessary to ensure that non-automatic weighing instruments from third countries entering the Union market comply with this Directive, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to those non-automatic weighing instruments. Provision should therefore be made for importers to make sure that the non-automatic weighing instruments they place on the market comply with the requirements of this Directive and that they do not place on the market non-automatic weighing instruments which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that marking of non-automatic weighing instruments and documentation drawn up by manufacturers are available for inspection by the competent national authorities.

(12) When placing a non-automatic weighing instrument on the market, every importer should indicate on the non-automatic weighing instrument his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided, including for cases where the importer should have to open the packaging only for the purpose of putting his name and address on the instrument.

(13) The distributor makes a non-automatic weighing instrument available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the non-automatic weighing instrument does not adversely affect the compliance of that instrument.

(14) Any economic operator that either places a non-automatic weighing instrument on the market under his own name or trade mark or modifies a non-automatic weighing instrument in such a way that compliance with this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.

(15) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the non-automatic weighing instrument concerned.

(16) Ensuring traceability of a non-automatic weighing instrument throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant non-automatic weighing instruments available on the market. When keeping the information required under this Directive for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with a non-automatic weighing instrument or to whom they have supplied a non-automatic weighing instrument.

(17) This Directive should be limited to the expression of the essential requirements as regards metrology and performance in relation to non-automatic weighing instruments. In order to facilitate conformity assessment with those essential requirements as regards metrology and performance, it is necessary to provide for a presumption of conformity for non-automatic weighing instruments which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation[(7)] for the purpose of expressing detailed technical specifications of those requirements, in particular as to the metrological, design and construction characteristics.

(18) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive.

(19) Assessment of conformity with the relevant metrological and technical provisions is necessary to provide effective protection for users and third parties.

(20) In order to enable economic operators to demonstrate and the competent authorities to ensure that non-automatic weighing instruments made available on the market conform to the essential requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion

to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.

(21) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of a non-automatic weighing instrument with the requirements of this Directive and of other relevant Union harmonisation legislation.

(22) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.

(23) The CE marking and the supplementary metrology marking, indicating the conformity of a non-automatic weighing instrument, are the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking and its relationship to other markings are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking and the supplementary metrology marking should be laid down in this Directive.

(24) The conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.

(25) Experience has shown that the criteria set out in Directive 2009/23/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.

(26) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Directive.

(27) In order to ensure a consistent level of conformity assessment quality, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.

(28) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.

(29) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of

demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

(30) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the non-automatic weighing instruments to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.

(31) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.

(32) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.

(33) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.

(34) Member States should take all appropriate measures to ensure that non-automatic weighing instruments may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons. Non-automatic weighing instruments should be considered as non-compliant with the essential requirements laid down in this Directive only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.

(35) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to non-automatic weighing instruments covered by this Directive. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.

(36) Directive 2009/23/EC already provides for a safeguard procedure allowing the Commission to examine the justification for a measure taken by a Member State against non-automatic weighing instruments it considers being non-compliant. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on expertise available in Member States.

(37) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to non-automatic weighing instruments presenting a risk to aspects of public interest protection covered by this Directive. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such non-automatic weighing instruments.

(38) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.

(39) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[8].

(40) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.

(41) The examination procedure should be used for the adoption of implementing acts with respect to compliant non-automatic weighing instruments which present a risk to the health or safety of persons or to other aspects of public interest protection.

(42) In line with established practice, the committee set up by this Directive can play a useful role in examining matters 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.

(43) When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.

(44) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant non-automatic weighing instruments are justified or not.

(45) Member States should lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and ensure that those

rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.

(46) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market and/or putting into service, without the need to comply with further product requirements, of non-automatic weighing instruments that have already been placed on the market in accordance with Directive 2009/23/EC before the date of application of national measures transposing this Directive. Distributors should therefore be able to supply non-automatic weighing instruments that have been placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.

(47) Since the objective of this Directive, namely to ensure that non-automatic weighing instruments on the market fulfil the requirements providing for a high level of protection of public interests covered by this Directive while guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

(48) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive amendment as compared to the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.

(49) This Directive should be 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,

HAVE ADOPTED THIS DIRECTIVE:

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

ANNEX I

ESSENTIAL REQUIREMENTS

The terminology used is that of the International Organisation of Legal Metrology.

Preliminary observation

Where an instrument includes, or is connected to, more than one indicating or printing device used for the applications listed in points (a) to (f) of Article 1(2), those devices which repeat the results of the weighing operation and which cannot influence the correct functioning of the instrument shall not be subject to the essential requirements if the weighing results are printed or recorded correctly and indelibly by a part of the instrument which meets the essential requirements and the results are accessible to both parties concerned by the measurement. However, in the case of instruments used for direct sales to the public, display and printing devices for the vendor and the customer must fulfil the essential requirements.

Metrological requirements

1. *Units of mass*

The units of mass used shall be the legal units within the meaning of Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement[9].

Subject to compliance with this condition, the following units are permitted:

(a) SI units: kilogram, microgram, milligram, gram, tonne;

(b) imperial unit: troy ounce, if weighing precious metals;

(c) other non-SI unit: metric carat, if weighing precious stones.

For instruments that make use of the imperial unit of mass referred to above, the relevant essential requirements specified below shall be converted to that unit, using simple interpolation.

2. *Accuracy classes*

2.1. The following accuracy classes have been defined:

(a) I special

(b) II high

(c) III medium

(d) IIII ordinary

The specifications of these classes are given in Table 1.

TABLE 1

Accuracy classes				
Class	**Verification scale interval (e)**	**Minimum capacity (Min)**	**Number of verification scale intervals** $n = ((\mathrm{Max}) / (e))$	
		minimum value	**minimum value**	**maximum value**
I	0,001 g ≤ e	100 e	50 000	—

II	0,001 g ≤ e ≤ 0,05 g	20 e	100	100 000
	0,1 g ≤ e	50 e	5 000	100 000
III	0,1 g ≤ e ≤ 2 g	20 e	100	10 000
	5 g ≤ e	20 e	500	10 000
IIII	5 g ≤ e	10 e	100	1 000

The minimum capacity is reduced to 5 e for instruments in classes II and III for determining a conveying tariff.

2.2. *Scale intervals*

2.2.1. The actual scale interval (d) and the verification scale interval (e) shall be in the form:

1×10^k, 2×10^k, or 5×10^k mass units,

k being any integer or zero.

2.2.2. For all instruments other than those with auxiliary indicating devices:

d = e.

2.2.3. For instruments with auxiliary indicating devices the following conditions apply:

$$e = 1 \times 10^k g$$

;

d < e ≤ 10 d.

Those conditions do not apply for instruments of class I with $d < 10^{-4}$ g, for which $e = 10^{-3}$ g.

3. *Classification*

3.1. *Instruments with one weighing range*

Instruments equipped with an auxiliary indicating device shall belong to class I or class II. For these instruments the minimum capacity lower limits for these two classes are obtained from Table 1 by replacement in column 3 of the verification scale interval (e) by the actual scale interval (d).

If $d < 10^{-4}$ g, the maximum capacity of class I may be less than 50 000 e.

3.2. *Instruments with multiple weighing ranges*

Multiple weighing ranges are permitted, provided they are clearly indicated on the instrument. Each individual weighing range is classified according to point 3.1. If the weighing ranges fall into different accuracy classes the instrument shall comply with the severest of the requirements that apply for the accuracy classes in which the weighing ranges fall.

3.3. *Multi-interval instruments*

3.3.1. Instruments with one weighing range may have several partial weighing ranges (multi-interval instruments).

Multi-interval instruments shall not be equipped with an auxiliary indicating device.

3.3.2. Each partial weighing range i of multi-interval instruments is defined by:

—	its verification scale interval e_i	with $e_{(i+1)} > e_i$
—	its maximum capacity Max_i	with $Max_r = Max$
—	its minimum capacity Min_i	with $Min_i = Max_{(i-1)}$ and $Min_1 = Min$

where:

i = 1, 2, … r,
i = partial weighing range number,
r = the total number of partial weighing ranges.

All capacities are capacities of net load, irrespective of the value of any tare used.

3.3.3. The partial weighing ranges are classified according to Table 2. All partial weighing ranges shall fall into the same accuracy class, that class being the instrument's accuracy class.

TABLE 2

Multi-interval instruments				
i1, 2, … ripartial weighing range numberrtotal number of partial weighing ranges				
Class	**Verification scale interval (e)**	**Minimum capacity (Min)**	**Number of verification scale intervals**	
		Minimum value	**Minimum value**[a] $n = ((Max_i) / (e_{(i+1)}))$	**Maximum value** $n = ((Max_i) / (e_i))$
I	0,001 g ≤ e_i	100 e_1	50 000	—
II	0,001 g ≤ e_i ≤ 0,05 g	20 e_1	5 000	100 000
	0,1 g ≤ e_i	50 e_1	5 000	100 000
III	0,1 g ≤ e_i	20 e_1	500	10 000
IIII	5g ≤ e_i	10 e_1	50	1 000

a For i = r, the corresponding column of Table 1 applies, with e replaced by e_r.

4. *Accuracy*

4.1. On implementation of the procedures laid down in Article 13, the error of indication shall not exceed the maximum permissible error of indication as shown in Table 3. In the case of digital indication the error of indication shall be corrected for the rounding error.

The maximum permissible errors apply to the net value and tare value for all possible loads, excluding preset tare values.

TABLE 3

Maximum permissible errors				
Load				**Maximum permissible error**
Class I	**Class II**	**Class III**	**Class IIII**	
0 ≤ m ≤ 50 000 e	0 ≤ m ≤ 5 000 e	0 ≤ m ≤ 500 e	0 ≤ m ≤ 50 e	± 0,5 e
50 000 e < m ≤ 200 000 e	5 000 e < m ≤ 20 000 e	500 e < m ≤ 2 000 e	50 e < m ≤ 200 e	± 1,0 e
200 000 e < m	20 000 e < m ≤ 100 000 e	2 000 e < m ≤ 10 000 e	200 e < m ≤ 1 000 e	± 1,5 e

4.2. The maximum permissible errors in service are twice the maximum permissible errors fixed in Section 4.1.

5. Weighing results of an instrument shall be repeatable, and shall be reproducible by the other indicating devices used and in accordance with other methods of balancing used.

The weighing results shall be sufficiently insensitive to changes in the position of the load on the load receptor.

6. The instrument shall react to small variations in the load.

7. *Influence quantities and time*

7.1. Instruments of classes II, III and IIII, liable to be used in a tilted position, shall be sufficiently insensitive to the degree of tilting that can occur in normal use.

7.2. The instruments shall meet the metrological requirements within the temperature range specified by the manufacturer. The value of this range shall be at least equal to:

(a) 5 °C for an instrument in class I;

(b) 15 °C for an instrument in class II;

(c) 30 °C for an instrument in class III or IIII.

In the absence of a manufacturer's specification, the temperature range of – 10 °C to + 40 °C applies.

7.3. Instruments operated from a mains power supply shall meet the metrological requirements under conditions of power supply within the limits of normal fluctuation.

Instruments operated from battery power shall indicate whenever the voltage drops below the minimum required value and shall under those circumstances either continue to function correctly or be automatically put out of service.

7.4. Electronic instruments, except those in class I and in class II if e is less than 1 g, shall meet the metrological requirements under conditions of high relative humidity at the upper limit of their temperature range.

7.5. Loading an instrument in class II, III or IIII for a prolonged period of time shall have a negligible influence on the indication at load or on the zero indication immediately after removal of the load.

7.6. Under other conditions the instruments shall either continue to function correctly or be automatically put out of service.

Design and construction

8. *General requirements*

8.1. Design and construction of the instruments shall be such that the instruments will preserve their metrological qualities when properly used and installed and when used in an environment for which they are intended. The value of the mass must be indicated.

8.2. When exposed to disturbances, electronic instruments shall not display the effects of significant faults, or shall automatically detect and indicate them.

Upon automatic detection of a significant fault, electronic instruments shall provide a visual or audible alarm that shall continue until the user takes corrective action or the fault disappears.

8.3. The requirements of points 8.1 and 8.2 shall be met on a lasting basis during a period of time that is normal in view of the intended use of such instruments.

Digital electronic devices shall always exercise adequate control of the correct operation of the measuring process, of the indicating device, and of all data storage and data transfer.

Upon automatic detection of a significant durability error, electronic instruments shall provide a visual or audible alarm that shall continue until the user takes corrective action or the error disappears.

8.4. When external equipment is connected to an electronic instrument through an appropriate interface the metrological qualities of the instrument shall not be adversely influenced.

8.5. The instruments shall have no characteristics likely to facilitate fraudulent use, whereas possibilities for unintentional misuse shall be minimal. Components that may not be dismantled or adjusted by the user shall be secured against such actions.

8.6. Instruments shall be designed to permit ready execution of the statutory controls laid down by this Directive.

9. *Indication of weighing results and other weight values*

The indication of the weighing results and other weight values shall be accurate, unambiguous and non-misleading and the indicating device shall permit easy reading of the indication under normal conditions of use.

The names and symbols of the units referred to in point 1 of this Annex shall comply with the provisions of Directive 80/181/EEC with the addition of the symbol for the metric carat which shall be the symbol ‘ct’.

Indication shall be impossible above the maximum capacity (Max), increased by 9 e.

An auxiliary indicating device is permitted only to the right of the decimal mark. An extended indicating device may be used only temporarily, and printing shall be inhibited during its functioning.

Secondary indications may be shown, provided that they cannot be mistaken for primary indications.

10. *Printing of weighing results and other weight values*

Printed results shall be correct, suitably identified and unambiguous. The printing shall be clear, legible, non-erasable and durable.

11. *Levelling*

When appropriate, instruments shall be fitted with a levelling device and a level indicator, sufficiently sensitive to allow proper installation.

12. *Zeroing*

Instruments may be equipped with zeroing devices. The operation of these devices shall result in accurate zeroing and shall not cause incorrect measuring results.

13. *Tare devices and preset tare devices*

The instruments may have one or more tare devices and a preset tare device. The operation of the tare devices shall result in accurate zeroing and shall ensure correct net weighing. The operation of the preset tare device shall ensure correct determination of the calculated net value.

14. *Instruments for direct sales to the public, with a maximum capacity not greater than 100 kg: additional requirements*

Instruments for direct sale to the public shall show all essential information about the weighing operation and, in the case of price-indicating instruments, shall clearly show the customer the price calculation of the product to be purchased.

The price to pay, if indicated, shall be accurate.

Price-computing instruments shall display the essential indications long enough for the customer to read them properly.

Price-computing instruments may perform functions other than per-article weighing and price computation only if all indications related to all transactions are printed clearly and unambiguously and are conveniently arranged on a ticket or label for the customer.

Instruments shall bear no characteristics that can cause, directly or indirectly, indications the interpretation of which is not easy or straightforward.

Instruments shall safeguard customers against incorrect sales transactions due to their malfunctioning.

Auxiliary indicating devices and extended indicating devices are not permitted.

Supplementary devices are permitted only if they cannot lead to fraudulent use.

Instruments similar to those normally used for direct sales to the public which do not satisfy the requirements of this Section must carry near to the display the indelible marking ‘Not to be used for direct sale to the public’.

15. *Price labelling instruments*

Price labelling instruments shall meet the requirements of price indicating instruments for direct sale to the public, as far as applicable to the instrument in question. The printing of a price label shall be impossible below a minimum capacity.

ANNEX II

CONFORMITY ASSESSMENT PROCEDURES

1. Module B: EU-type examination

1.1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an instrument and verifies and attests that the technical design of the instrument meets the requirements of this Directive that apply to it.

1.2. EU-type examination may be carried out in any of the following manners:

— examination of a specimen, representative of the production envisaged, of the complete instrument (production type);

— assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 1.3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the instrument (combination of production type and design type);

— assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 1.3, without examination of a specimen (design type).

1.3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) the technical documentation. The technical documentation shall make it possible to assess the instrument's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall contain, wherever applicable, at least the following elements:

(i) a general description of the instrument;

(ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

(iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;

(iv) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event

of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(v) results of design calculations made, examinations carried out, etc.;

(vi) test reports;

(d) the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;

(e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer or by another testing laboratory on his behalf and under his responsibility.

1.4. The notified body shall:

For the instrument:

1.4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the instrument;

For the specimen(s):

1.4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements which have been designed in accordance with other relevant technical specifications;

1.4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly;

1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Directive;

1.4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

1.5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 1.4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

1.6. Where the type meets the requirements of this Directive, that apply to the instrument concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured instruments with the examined type to be evaluated and to allow for in-service control.

The EU-type examination certificate shall have a validity period of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each. In the event of fundamental changes to the design of the instrument, e.g. as a result of the application of new techniques, the validity of EU-type examination certificate may be limited to two years and extended by three years.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

1.7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the instrument with the essential requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

1.8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

1.9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

1.10. The manufacturer's authorised representative may lodge the application referred to in point 1.3 and fulfil the obligations set out in points 1.7 and 1.9, provided that they are specified in the mandate.

2. **Module D: Conformity to type based on quality assurance of the production process**

2.1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations

laid down in points 2.2 and 2.5, and ensures and declares on his sole responsibility that the instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2.2. *Manufacturing*

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the instruments concerned as specified in point 2.3, and shall be subject to surveillance as specified in point 2.4.

2.3. *Quality system*

2.3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the instruments concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) all relevant information for the instrument category envisaged;

(d) the documentation concerning the quality system; and

(e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

2.3.2. The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

2.3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 2.3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2.3.1(e) to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

2.3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

2.3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 2.3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

2.4. *Surveillance under the responsibility of the notified body*

2.4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

2.4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

2.4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

2.4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

2.5. *Conformity marking and EU declaration of conformity*

2.5.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 2.3.1, the latter's identification number to each individual instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

2.5.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

2.6. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 2.3.1;

(b) the information relating to the change referred to in point 2.3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 2.3.5, 2.4.3 and 2.4.4.

2.7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

2.8. *Authorised representative*

The manufacturer's obligations set out in points 2.3.1, 2.3.5, 2.5 and 2.6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

3. **Module D1: Quality assurance of the production process**

3.1. Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 3.2, 3.4 and 3.7, and ensures and declares on his sole responsibility that the instruments concerned satisfy the requirements of this Directive that apply to them.

3.2. *Technical documentation*

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall, wherever applicable, contain at least the following elements:

(a) a general description of the instrument;

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

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;

(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant

technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(e) results of design calculations made, examinations carried out, etc.;

(f) test reports.

3.3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

3.4. *Manufacturing*

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the instruments concerned as specified in point 3.5, and shall be subject to surveillance as specified in point 3.6.

3.5. *Quality system*

3.5.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the instruments concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) all relevant information for the instrument category envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation referred to in point 3.2.

3.5.2. The quality system shall ensure compliance of the instruments with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.5.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.2 in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.5.2 or whether reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.6. *Surveillance under the responsibility of the notified body*

3.6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

3.6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the technical documentation referred to in point 3.2;

(c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

3.6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

3.6.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

3.7. *Conformity marking and EU declaration of conformity*

3.7.1. The manufacturer shall affix the CE marking and the supplementary metrology marking, set out in this Directive, and, under the responsibility of the notified body referred to in point 3.5.1, the latter's identification number to each individual instrument that satisfies the applicable requirements of this Directive.

3.7.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

3.8. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.5.1;

(b) the information relating to the change referred to in point 3.5.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5.5, 3.6.3 and 3.6.4.

3.9. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

3.10. *Authorised representative*

The manufacturer's obligations set out in points 3.3, 3.5.1, 3.5.5, 3.7 and 3.8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

4. Module F: Conformity to type based on product verification

4.1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 4.2 and 4.5 and ensures and declares on his sole responsibility that the instruments concerned, which have been subject to the provisions of point 4.3, are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

4.2. *Manufacturing*

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instruments with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

4.3. *Verification*

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the instruments with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

The examinations and tests to check the conformity of the instruments with the appropriate requirements shall be carried out by examination and testing of every instrument as specified in point 4.4.

4.4. *Verification of conformity by examination and testing of every instrument*

4.4.1. All instruments shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

4.4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the instrument has been placed on the market.

4.5. *Conformity marking and EU declaration of conformity*

4.5.1. The manufacturer shall affix the CE marking and the supplementary metrology marking, set out in this Directive, and, under the responsibility of the notified body referred to in point 4.3, the latter's identification number to each individual instrument that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

4.5.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities, for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

If the notified body referred to in point 4.3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the instruments.

4.6. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the instruments during the manufacturing process.

4.7. *Authorised representative*

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in point 4.2.

5. **Module F1: Conformity based on product verification**

5.1. Conformity based on product verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 5.2, 5.3 and 5.6 and ensures and declares on his sole responsibility that the instruments concerned, which have been subject to the provisions of point 5.4, are in conformity with the requirements of this Directive that apply to them.

5.2. *Technical documentation*

5.2.1. The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall, wherever applicable, contain at least the following elements:

(a) a general description of the instrument;

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

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;

(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(e) results of design calculations made, examinations carried out, etc.;

(f) test reports.

5.2.2. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

5.3. *Manufacturing*

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instruments with the applicable requirements of this Directive.

5.4. *Verification*

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests to check the conformity of the instruments with the applicable requirements of this Directive.

The examinations and tests to check the conformity with those requirements shall be carried out by examination and testing of every instrument as specified in point 5.5.

5.5. *Verification of conformity by examination and testing of every instrument*

5.5.1. All instruments shall be individually examined and appropriate tests, set out in the relevant harmonised standards and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify conformity with the requirements that apply to them. In the absence of such a harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out.

5.5.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

5.6. *Conformity marking and EU declaration of conformity*

5.6.1. The manufacturer shall affix the CE marking and the supplementary metrology marking, set out in this Directive, and, under the responsibility of the notified body referred to in point 5.4, the latter's identification number to each individual instrument that satisfies the applicable requirements of this Directive.

5.6.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

If the notified body referred to in point 5.5 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the instruments.

5.7. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the instruments during the manufacturing process.

5.8. *Authorised representative*

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 5.2.1 and 5.3.

6. **Module G: Conformity based on unit verification**

6.1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 6.2, 6.3 and 6.5, and ensures and declares on his sole responsibility that the instrument concerned, which has been subject to the provisions of point 6.4, is in conformity with the requirements of this Directive that apply to it.

6.2. *Technical documentation*

6.2.1. The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 6.4. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall, wherever applicable, contain at least the following elements:

(a) a general description of the instrument;

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

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;

(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(e) results of design calculations made, examinations carried out, etc.;

(f) test reports.

6.2.2. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

6.3. *Manufacturing*

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instrument with the applicable requirements of this Directive.

6.4. *Verification*

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the instrument with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved instrument, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

6.5. *Conformity marking and EU declaration of conformity*

6.5.1. The manufacturer shall affix the CE marking and the supplementary metrology marking, set out in this Directive, and, under the responsibility of the notified body referred to in point 6.4, the latter's identification number to each instrument that satisfies the applicable requirements of this Directive.

6.5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6.6. *Authorised representative*

The manufacturer's obligations set out in points 6.2.2 and 6.5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

7. **Common provisions**

7.1. The conformity assessment according to Module D, D1, F, F1 or G may be carried out at the manufacturer's works or any other location if transport to the place of use does not require dismantling of the instrument, if the putting into service at the place of use does not require assembly of the instrument or other technical installation work likely to affect the instrument's performance, and if the gravity value at the place of putting into service is taken into consideration or if the instrument's performance is insensitive to gravity variations. In all other cases, it shall be carried out at the place of use of the instrument.

7.2. If the instrument's performance is sensitive to gravity variations the procedures referred to in point 7.1 may be carried out in two stages, with the second stage comprising all examinations and tests of which the outcome is gravity-dependent, and the first stage all other examinations and tests. The second stage shall be carried out at the place of use of the instrument. If a Member State has established gravity zones on its territory the expression 'at the place of use of the instrument' may be read as 'in the gravity zone of use of the instrument'.

7.2.1. Where a manufacturer has opted for execution in two stages of one of the procedures mentioned in point 7.1, and where these two stages will be carried out by different parties, an instrument which has undergone the first stage of the procedure shall bear the identification number of the notified body involved in that stage.

7.2.2. The party which has carried out the first stage of the procedure shall issue for each of the instruments a certificate containing the data necessary for identification of the instrument and specifying the examinations and tests that have been carried out.

The party which carries out the second stage of the procedure shall carry out those examinations and tests that have not yet been carried out.

The manufacturer or his authorised representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

7.2.3. A manufacturer who has opted for Module D or D1 in the first stage may either use this same procedure in the second stage or decide to continue in the second stage with Module F or F1 as appropriate.

7.2.4. The CE marking and the supplementary metrology marking shall be affixed to the instrument on completion of the second stage, along with the identification number of the notified body which took part in the second stage.

ANNEX III

INSCRIPTIONS

1. **Instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2)**

1.1. Those instruments shall bear visibly, legibly and indelibly the following inscriptions:

(i) the number of the EU-type examination certificate, where appropriate;

(ii) the manufacturer's name, registered trade name or registered trade mark;

(iii) the accuracy class, enclosed in an oval or in two horizontal lines joined by two half circles;

(iv) maximum capacity, in the form Max …;

(v) minimum capacity, in the form Min …;

(vi) verification scale interval, in the form e = …;

(vii) type, batch or serial number;

and when applicable:

(viii) for instruments consisting of separate but associated units: identification mark on each unit;

(ix) scale interval if it is different from e, in the form d = …;

(x) maximum additive tare effect, in the form T = + …;

(xi) maximum subtractive tare effect if it is different from Max, in the form T = – …;

(xii) tare interval if it is different from d, in the form d_T = …;

(xiii) maximum safe load if it is different from Max, in the form Lim …;

(xiv) the special temperature limits, in the form … ^{o}C/… ^{o}C;

(xv) ratio between load receptor and load.

1.2. Those instruments shall have adequate facilities for the affixing of the conformity marking and inscriptions. These shall be such that it shall be impossible to remove the conformity marking and inscriptions without damaging them, and that the conformity marking and inscriptions shall be visible when the instrument is in its regular operating position.

1.3. Where a data plate is used it shall be possible to seal the plate unless it cannot be removed without being destroyed. If the data plate is sealable it shall be possible to apply a control mark to it.

1.4. The inscriptions Max, Min, e, and d, shall also be shown near the display of the result if they are not already located there.

1.5. Each load measuring device which is connected or can be connected to one or more load receptors shall bear the relevant inscriptions relating to the said load receptors.

2. Instruments not intended to be used for the applications listed in points (a) to (f) of Article 1(2) shall bear visibly, legibly and indelibly:

— the manufacturer’s name, registered trade name or registered trade mark;

— maximum capacity, in the form Max ….

Those instruments shall not bear the conformity marking as set out in this Directive.

3. **Restrictive use symbol referred to in Article 18**

The restrictive use symbol shall be constituted by a capital letter ‘M’ printed in black on a red background at least 25 mm × 25 mm square with two intersecting diagonals forming a cross.

ANNEX IV

EU DECLARATION OF CONFORMITY (No XXXX)[10]

1. Instrument model/Instrument (product, type, batch or serial number):

2. Name and address of the manufacturer and, where applicable, his authorised representative:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of the declaration (identification of instrument allowing traceability; it may, where necessary for the identification of the instrument, include an image):

5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:

7. The notified body … (name, number) performed … (description of intervention) and issued the certificate:

8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

ANNEX V

PART A

REPEALED DIRECTIVE WITH THE AMENDMENT THERETO

(referred to in Article 45)

Directive 2009/23/EC of the European Parliament and of the Council (OJ L 122, 16.5.2009, p. 6).	
Regulation (EU) No 1025/2012 of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).	Only point (i) of Article 26(1)

PART B

TIME-LIMITS FOR TRANSPOSITION INTO NATIONAL LAW AND DATES OF APPLICATION OF THE DIRECTIVES SET OUT IN PART B OF ANNEX VII TO DIRECTIVE 2009/23/EC

(referred to in Article 45)

Directive	Time-limit for transposition	Date of application
90/384/EEC	30 June 1992	1 January 1993[a]
93/68/EEC	30 June 1994	1 January 1995[b]

a In accordance with Article 15(3) of Directive 90/384/EEC Member States shall permit, during a period of 10 years from the date on which they apply the laws, regulations and administrative provisions adopted by the Member States in order to transpose that Directive into national law, the placing on the market and/or putting into service of instruments which conform to the rules in force before 1 January 1993.

b In accordance with Article 14(2) of Directive 93/68/EEC: 'Until 1 January 1997, Member States shall allow the placing on the market and the bringing into service of products which comply with the marking arrangements in force before 1 January 1995.

ANNEX VI

CORRELATION TABLE

Directive 2009/23/EC	This Directive
Article 1(1)	Article 1(1)
Article 1(2), introductory wording	Article 1(2), introductory wording
Article 1(2), point (a)(i)	Article 1(2), point (a)
Article 1(2), point (a)(ii)	Article 1(2), point (b)
Article 1(2), point (a)(iii)	Article 1(2), point (c)
Article 1(2), point (a)(iv)	Article 1(2), point (d)
Article 1(2), point (a)(v)	Article 1(2), point (e)
Article 1(2), point (a)(vi)	Article 1(2), point (f)
Article 1(2), point (b)	Article 1(2), point (g)
Article 2(1)	Article 2(1)
Article 2(2)	Article 2(2)
Article 2(3)	—
—	Article 2(3) to (19)
Article 3	Article 3(1) and (2)
Article 4	Article 4
Article 5	Article 5
Article 6	—

Article 7	—
Article 8	—
—	Article 6
—	Article 7
—	Article 8
—	Article 9
—	Article 10
—	Article 11
—	Article 12
Article 9(1), introductory wording	Article 13(1), introductory wording
Article 9(1), point (a)	Article 13(1), point (a)
Article 9(1), point (b)	Article 13(1), point (b)
Article 9(2)	Article 13(2)
Article 9(3)	—
Article 10	—
Article 11	—
Article 12	—
—	Article 14
—	Article 15
—	Article 16
—	Article 17(1) to (5)
—	Article 17(6)
Article 13, first sentence	Article 6(5), fourth subparagraph
Article 13, second sentence	Article 18
—	Article 19
—	Article 20
—	Article 21
—	Article 22
—	Article 23
—	Article 24
—	Article 25
—	Article 26
—	Article 27
—	Article 28

—	Article 29
—	Article 30
—	Article 31
—	Article 32
—	Article 33
—	Article 34
—	Article 35
—	Article 36
—	Article 37
—	Article 38
—	Article 39
—	Article 40
—	Article 41
—	Article 42
Article 14	Article 3(3)
Article 15	—
—	Article 43
—	Article 44(1)
Article 16	Article 44(2)
Article 17	Article 45
Article 18	Article 46, first paragraph
—	Article 46, second paragraph
Article 19	Article 47
Annex I	Annex I
Annex II, point 1	—
—	Annex II, point 1
Annex II, point 2	—
—	Annex II, point 2
—	Annex II, point 3
Annex II, point 3	—
—	Annex II, point 4
—	Annex II, point 5
Annex II, point 4	—
—	Annex II, point 6

Annex II, point 5	Annex II, point 7
Annex III	—
Annex IV	Annex III
—	Annex IV
Annex V	—
Annex VI	—
Annex VII	Annex V
Annex VIII	—
—	Annex VI

STATEMENT OF THE EUROPEAN PARLIAMENT

The European Parliament considers that only when and in so far as implementing acts in the sense of Regulation (EU) No 182/2011 are discussed in meetings of committees, can the latter be considered as ‘comitology committees’ within the meaning of Annex I to the Framework Agreement on the relations between the European Parliament and the European Commission. Meetings of committees thus fall within the scope of point 15 of the Framework Agreement when and insofar as other issues are discussed.

(**1**) OJ C 181, 21.6.2012, p. 105.

(**2**) Position of the European Parliament of 5 February 2014 (not yet published in the Official Journal) and decision of the Council of 20 February 2014.

(**3**) OJ L 122, 16.5.2009, p. 6. Directive 2009/23/EC is the codification of Council Directive 90/384/EEC of 20 June 1990 on the harmonization of the laws of the Member States relating to non-automatic weighing instruments (OJ L 189, 20.7.1990, p. 1).

(**4**) See Annex V, Part A.

(**5**) OJ L 218, 13.8.2008, p. 30.

(**6**) OJ L 218, 13.8.2008, p. 82.

(**7**) OJ L 316, 14.11.2012, p. 12.

(**8**) OJ L 55, 28.2.2011, p. 13.

(**9**) OJ L 39, 15.2.1980, p. 40.

(**10**) It is optional for the manufacturer to assign a number to the declaration of conformity.