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)

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[(1)].

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)[(2)]

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

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

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