

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 20 June 1990

on the harmonization of the laws of the Member States relating to non-automatic weighing instruments

(90/384/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

In cooperation with the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas Member States 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;

Whereas, in each Member State, mandatory provisions fix in particular the necessary performance requirements of non-automatic weighing instruments by specifying metrological and technical requirements, together with inspection procedures before and after going into service; whereas these mandatory provisions do not necessarily lead to different levels of protection from one Member State to another but do, by their disparity, impede trade within the Community;

Whereas the national provisions ensuring such protection must be harmonized in order to guarantee the free movement of non-automatic weighing instruments while ensuring a justified level of protection in the Community;

Whereas Community legislation as it stands at present provides that, notwithstanding one of the fundamental rules of the Community, namely the free movement of goods, barriers to intra-Community movement resulting from disparities in national laws on the use of products have to be accepted in so far as the provisions of those national laws are recognized as necessary to ensure that the products concerned meet essential requirements; whereas the harmonization of laws in the present case must therefore be confined to those provisions needed to ensure that non-automatic weighing instruments satisfy the essential metrological and performance requirements; whereas, because they are essential, these requirements must replace the corresponding national provisions;

Whereas this Directive therefore contains only mandatory and essential requirements; whereas, to facilitate proof of conformity with the essential requirements, it is necessary to have harmonized standards at European level, in particular as to the metrological, design and construction characteristics, so that instruments complying with those harmonized standards may be assumed to conform to the essential requirements; whereas these standards, harmonized at European level, are drawn up by private bodies and must remain non-mandatory texts; whereas for that purpose the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are recognized as the competent bodies for the adoption of harmonized standards in accordance with the general guidelines for cooperation between the Commission and those two bodies signed on 13 November 1984; whereas, within the meaning of this Directive, a harmonized standard is a technical specification (European standard or harmonized document) adopted by one or both of those bodies upon a remit from the Commission in accordance with Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in

⁽¹⁾ OJ No C 55, 4. 3. 1989, p. 6, and
OJ No C 297, 25. 11. 1989, p. 13.

⁽²⁾ OJ No C 158, 26. 6. 1989, p. 221, and
OJ No C 149, 18. 6. 1990.

⁽³⁾ OJ No C 194, 31. 7. 1989, p. 1.

the field of technical standards and regulations⁽¹⁾, as amended by Directive 88/182/EEC⁽²⁾, and the abovementioned general guidelines;

Whereas assessment of conformity with the relevant metrological and technical provisions is necessary to provide effective protection for users and third parties; whereas, the existing conformity assessment procedures differ from one Member State to another; whereas, to avoid multiple assessments of conformity, which are in effect barriers to the free movement of the instruments, arrangements should be made for the mutual recognition of conformity assessment procedures by the Member States; whereas, to facilitate the mutual recognition of conformity assessment procedures, harmonized Community procedures should be set up, together with harmonized criteria for the designation of the bodies responsible for carrying out tasks pertaining to the conformity assessment procedures;

Whereas it is therefore essential to ensure that such designated bodies ensure a high level of quality throughout the Community;

Whereas the presence on a non-automatic weighing instrument of the EC mark of conformity or of the sticker bearing the letter 'M' indicates that there is a presumption that it satisfies the provisions of this Directive and therefore makes it unnecessary to repeat the assessments of conformity already carried out;

Whereas the measures aimed at the gradual establishment of the internal market must be adopted by 31 December 1992; whereas the internal market consists of an area without internal frontiers within which the free movement of goods, persons, services and capital is guaranteed,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope, placing on the market, free movement

Article 1

1. A weighing instrument is defined as 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.

A non-automatic weighing instrument is defined as a weighing instrument requiring the intervention of an operator during weighing.

This Directive applies to all non-automatic weighing instruments, hereinafter referred to as 'instruments'.

⁽¹⁾ OJ No L 109, 26. 4. 1983, p. 8.

⁽²⁾ OJ No L 81, 26. 3. 1988, p. 75.

2. A distinction is made in this Directive between two categories of instrument use:

- (a)
 1. determination of mass for commercial transactions;
 2. determination of mass for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment;
 3. determination of mass for the application of laws or regulations; expert opinion given in court proceedings;
 4. determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment;
 5. 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;
 6. determination of price on the basis of mass for the purposes of direct sales to the public and the making-up of prepackages;
- (b) all applications other than those listed in point 2 (a) of this Article.

Article 2

1. Member States shall take all steps to ensure that instruments may not be placed on the market unless they meet the requirements of this Directive which apply to them.

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

Article 3

Instruments used for the applications listed in Article 1 (2) (a) must satisfy the essential requirements set out in Annex I.

In cases where the instrument includes or is connected to devices which are not used for the applications listed in Article 1 (2) (a), such devices shall not be subject to the essential requirements.

Article 4

1. Member States shall not impede the placing on the market of instruments which meet the requirements of this Directive which apply to them.

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

Article 5

1. Member States shall presume conformity with the essential requirements referred to in Article 3 in respect of instruments which comply with the relevant national standards implementing the harmonized standards that meet the essential requirements referred to in Article 3.

2. The Commission shall publish the references of the harmonized standards referred to in paragraph 1 in the *Official Journal of the European Communities*.

Member States shall publish the references of the national standards referred to in paragraph 1.

Article 6

Where a Member State or the Commission considers that the harmonized standards referred to in Article 5 (1) do not fully meet the essential requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the Standing Committee set up under Directive 83/189/EEC, hereinafter referred to as 'the Committee', giving its reasons for doing so. The Committee shall deliver an opinion without delay.

In the light of the Committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw those standards from the publications referred to in Article 5 (2).

Article 7

1. Where a Member State considers that instruments bearing the EC mark of conformity referred to in Annex 2, sections 2, 3 and 4, do not meet the requirements of this Directive when properly installed and used for the purposes for which they are intended, it shall take all appropriate measures to withdraw those instruments from the market or to prohibit or restrict their being put into service and/or placed on the market.

The Member State concerned shall immediately inform the Commission of any such measure, indicating the reasons for its decision, and in particular whether non-compliance is due to:

- (a) failure to meet the essential requirements referred to in Article 3, where instruments do not meet the standards referred to in Article 5 (1);
- (b) incorrect application of the standards referred to in Article 5 (1);

(c) shortcomings in the standards referred to in Article 5 (1) themselves.

2. The Commission shall enter into consultation with the parties concerned as soon as possible.

After such consultation the Commission shall immediately inform the Member State, which took the action, of the result. Should it find that the measure is justified it shall immediately inform the other Member States.

If the decision is attributed to shortcomings in the standards, the Commission, after consulting the parties concerned, shall bring the matter before the Committee within two months if the Member State which has taken the measures intends to maintain them, and shall subsequently initiate the procedures referred to in Article 6.

3. Where an instrument which does not comply bears the EC mark of conformity, the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall inform the Commission and the other Member States thereof.

4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

CHAPTER II

Conformity assessment

Article 8

1. The conformity of instruments to the essential requirements set out in Annex I may be certified by either of the following procedures as selected by the applicant:

- (a) EC type examination as referred to in Annex II.1, followed either by the EC declaration of type conformity (guarantee of production quality) as referred to in Annex II.2, or by the EC verification as referred to in Annex II.3.

However, EC type examination shall not be compulsory for instruments which do not use electronic devices and whose load-measuring device does not use a spring to balance the load;

- (b) EC unit verification as referred to in Annex II.4.

2. The documents and correspondence relating to the procedures referred to in paragraph 1 shall be drafted in an official language of the Member State where the said procedures are to be carried out, or in a language accepted by the competent body.

3. Where the instruments are subject to other Community Directives concerning other aspects, the EC mark referred to in Article 10 shall indicate in these cases that the instruments also fulfil the requirements of the other Directives.

Article 9

1. Member States shall notify to the other Member States and the Commission the bodies which they have designated for carrying out tasks pertaining to the procedure referred to in Article 8, the specific tasks for which each body has been designated, and the identification codes of the designated bodies.

The Commission shall publish the list of these notified bodies, together with the tasks for which they have been designated, in the *Official Journal of the European Communities* and shall ensure that the list is kept up to date.

2. Member States shall apply the minimum criteria set out in Annex V for the designation of bodies. Bodies which satisfy the criteria fixed by the relevant harmonized standards shall be presumed to satisfy the criteria set out in Annex V.

3. A Member State which has designated a body shall cancel the designation if the body no longer meets the criteria for designation referred to in paragraph 2. It shall immediately inform the other Member States and the Commission thereof and withdraw the notification.

CHAPTER III

EC mark of conformity and inscriptions

Article 10

1. The EC mark of conformity and the required supplementary data as described in Annex IV.1 shall be affixed in a clearly visible, easily legible and indelible form to instruments for which EC conformity has been established.

2. The inscriptions referred to in Annex IV.2 shall be affixed in a clearly visible, easily legible and indelible form to all other instruments.

3. The affixing to instruments of marks which are likely to be confused with the EC mark of conformity shall be prohibited.

Article 11

Where it is established that the EC mark of conformity has been wrongly affixed to instruments:

- not conforming to the standards referred to in Article 5 (1), where the manufacturer has chosen to manufacture instruments that conform to those standards,
- not conforming to an approved type,
- conforming to an approved type which does not meet the essential requirements applicable to it,

— in respect of which the manufacturer has failed to fulfil his obligations under the EC declaration of type conformity (guarantee of production quality),

the competent notified body shall, where necessary, withdraw the EC type-approval and/or the approval of the quality system. Withdrawal of EC type-approval shall have the effect of prohibiting submission for EC verification and the EC declaration of type conformity (guarantee of production quality).

Article 12

Where an instrument which is used for any of the applications referred to in Article 1 (2) (a) includes or is connected to devices that have not been subject to conformity assessment as referred to in Article 8, each of these devices shall bear the symbol restricting its use as defined by Annex IV.3. This symbol shall be affixed to the devices in a clearly visible and indelible form.

CHAPTER IV

Final provisions

Article 13

Member States shall take all steps to ensure that instruments bearing the EC mark attesting conformity with the requirements of this Directive continue to conform to those requirements.

Article 14

Any decision taken pursuant to this Directive and resulting in restrictions on the putting into service of an instrument shall state the exact grounds on which it is based. Such a decision shall be notified without delay to the party concerned, who shall at the same time be informed of the judicial remedies available to him under the laws in force in the Member State in question and of the time limits to which such remedies are subject.

Article 15

1. Member States shall, before 1 July 1992, adopt and publish the laws, regulations and administrative provisions necessary in order to comply with this Directive. They shall forthwith inform the Commission thereof.

2. Member States shall apply such provisions from 1 January 1993.

3. However, by way of derogation from paragraph 2, Member States shall permit during a period of 10 years from the date on which they apply the provisions referred to in

paragraph 1 the placing on the market and/or putting into service of instruments which conform to the rules in force before that date.

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

5. Directive 73/360/EEC shall be repealed as from 1 January 1993, except as regards the application of paragraph 3.

Article 16

This Directive is addressed to the Member States.

Done at Luxembourg, 20 June 1990.

For the Council

The President

D. J. O'MALLEY

ANNEX I

The essential requirements that must be met by the instruments referred to in Article 1 (2) (a) are set out below. The terminology used is that of the Organisation internationale de Métrologie Légale.

Preliminary observation

Where an instrument includes or is connected to more than one indicating or printing device used for the applications listed in Article 1 (2) (a), 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 Directive 80/181/EEC ⁽¹⁾, as last amended by Directive 85/1/EEC ⁽²⁾.

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

- SI units: kilogram, microgram, milligram, gram, tonne,
- Imperial units: pound, ounce (avoirdupois), Troy ounce,
- other non-SI units: metric carat, if weighing precious stones.

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

2. Accuracy classes

2.1. The following accuracy classes have been defined:

- I special
- II high
- III medium
- III 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 $n = \frac{\text{Max}}{e}$	
		minimum value	minimum value	maximum value
I	$0,001 \text{ g} \leq e$	100 e	50 000	—
II	$0,001 \text{ g} \leq e \leq 0,005 \text{ g}$	20 e	100	100 000
	$0,1 \text{ g} \leq e$	50 e	5 000	100 000
III	$0,1 \text{ g} \leq e \leq 2 \text{ g}$	20 e	100	10 000
	$5 \text{ g} \leq e$	20 e	500	10 000
III	$5 \text{ g} \leq e$	10 e	100	1 000

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

⁽¹⁾ OJ No L 39, 15. 12. 1980, p. 39.

⁽²⁾ OJ No L 2, 3. 1. 1985, p. 11.

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
 $d < e \leq 10 d$

except for instruments of class 1 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 1 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 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 1 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 $Max_i = Max$
- its minimum capacity Min_i with $Min_i = Max_{(i-1)}$
and $Min_1 = Min$

where:

$i = 1, 2, \dots, r$,

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, this class being the instrument's accuracy class.

TABLE 2

Multi-interval instruments

$i = 1, 2, \dots, r$

i = partial weighing range number

r = total number of partial weighing ranges

Class	Verification scale interval (e)	Minimum capacity (Min)	Number of verification scale intervals	
		Minimum value	Minimum value ⁽¹⁾ $n = \frac{\text{Max}_i}{e_{(i+1)}}$	Maximum value $n = \frac{\text{Max}_i}{e_i}$
I	$0,001 \text{ g} \leq e_i$	$100 e_1$	50 000	—
II	$0,001 \text{ g} \leq e_i \leq 0,05 \text{ g}$	$20 e_1$	5 000	100 000
	$0,1 \text{ g} \leq e_i$	$50 e_1$	5 000	100 000
III	$0,1 \text{ g} \leq e_i$	$20 e_1$	500	10 000
IIII	$5 \text{ g} \leq e_i$	$10 e_1$	50	1 000

(¹) 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 8, the error of indication shall not exceed the maximum permissible error of indication as shown in Table 3. In case of digital indication the error of indication shall be corrected for the rounding error.

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

TABLE 3

Maximum permissible errors

Load				Maximum permissible error
Class I	Class II	Class III	Class IIII	
$0 \leq m \leq 50\,000 e$	$0 \leq m \leq 5\,000 e$	$0 \leq m \leq 500 e$	$0 \leq m \leq 50 e$	$\pm 0,5 e$
$50\,000 e < m \leq 200\,000 e$	$5\,000 e < m \leq 20\,000 e$	$500 e < m \leq 2\,000 e$	$50 e < m \leq 200 e$	$\pm 1,0 e$
$200\,000 e < m$	$20\,000 e < m \leq 100\,000 e$	$2\,000 e < m \leq 10\,000 e$	$200 e < m \leq 1\,000 e$	$\pm 1,5 e$

- 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 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 exist in a normal installed condition.

- 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:
- 5 °C for an instrument in class I,
 - 15 °C for an instrument in class II,
 - 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 ⁽¹⁾.

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 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 facility, 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 paragraph 1 of this Annex shall comply with the provisions of Directive 80/181/EEC ⁽¹⁾ with the addition of the symbol for the metric carat which shall be the symbol 'ct'.

⁽¹⁾ OJ No L 33, 15. 2. 1980, p. 39.

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

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, unambiguously and conveniently arranged on a ticket or label for the customer.

Instruments shall bear no characteristics that can cause, directly or indirectly, indications whose interpretation 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

1. EC type-examination

- 1.1. EC type-examination is the procedure whereby a notified body verifies and certifies that an instrument, representative of the production envisaged, meets the requirements of this Directive that apply to it.
- 1.2. The application for type-examination shall be lodged by the manufacturer or his authorized representative established within the Community with a single notified body.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address in addition,
- a written declaration that the application has not been lodged with any other notified body,
- the design documentation, as described in Annex III.

The applicant shall place at the disposal of the notified body an instrument, representative of the production envisaged, hereinafter called the 'type'.

1.3. The notified body shall:

- 1.3.1. examine the design documentation and verify that the type has been manufactured in accordance with that documentation;
- 1.3.2. agree with the applicant on the location where the examinations and/or tests shall be carried out;
- 1.3.3. perform or have performed the appropriate examinations and/or tests to check whether the solutions adopted by the manufacturer meet the essential requirements where the standards referred to in Article 5 have not been applied;
- 1.3.4. perform or have performed the appropriate examinations and/or tests to check whether, where the manufacturer has chosen to apply the relevant standards, these have been applied effectively, thereby assuring conformity with the essential requirements.

- 1.4. Where the type meets the provisions of this Directive, the notified body shall issue an EC type-approval certificate to the applicant. The certificate shall contain the conclusions of the examination, conditions (if any) for its validity, the necessary data for identification of the approved instrument and, if relevant, a description of its functioning. All the relevant technical elements such as drawings and layouts shall be annexed to the EC type-approval certificate.

The 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 the certificate may be limited to two years and extended by three years.

1.5. Each notified body shall periodically make available to all Member States the list of:

- applications received for EC type-examination,
- EC type-approval certificates issued,
- applications for type-certificates refused,
- additions and amendments relating to documents already issued.

Each notified body shall moreover inform all the Member States forthwith of withdrawals of EC type-approval certificates.

Each Member State shall make this information available to the bodies which it has notified

- 1.6. The other notified bodies may receive a copy of the certificates together with the Annexes to them.
- 1.7. The applicant shall keep the notified body that has issued the EC type-approval certificate informed of any modification to the approved type.

Modifications to the approved type must receive additional approval from the notified body that issued the EC type-approval certificate where such changes influence conformity with the essential requirements of this Directive or the prescribed conditions for use of the instrument. This additional approval is given in the form of an addition to the original EC type-approval certificate.

2. EC declaration of type conformity (guarantee of production quality)

- 2.1. The EC declaration of type conformity (guarantee of production quality) is the procedure whereby the manufacturer who satisfies the obligations of paragraph 2.2 declares that the instruments concerned are, where applicable, in conformity with the type as described in the EC type-approval certificate and satisfy the requirements of this Directive that apply to them.

The manufacturer shall affix the EC mark to each instrument as well as the inscriptions provided for in Annex IV.

The EC mark shall be accompanied by the identification symbol of the notified body responsible for the EC surveillance referred to in paragraph 2.4.

- 2.2. The manufacturer shall have adequately implemented a quality system as specified in paragraph 2.3 and shall be subject to EC surveillance as specified in paragraph 2.4.

2.3. *Quality system*

- 2.3.1. The manufacturer shall lodge an application for approval of this quality system with a notified body.

The application shall include:

- an undertaking to carry out the obligations arising from the approved quality system,
- an undertaking to maintain the approved quality system to ensure its continuing suitability and effectiveness.

The manufacturer shall make available to the notified body all relevant information, in particular the quality system's documentation and the design documentation of the instrument.

- 2.3.2. The quality system shall ensure conformity of the instruments with the type as described in the EC type-approval certificate and 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 rules, procedures and instructions. This quality system documentation shall ensure a proper understanding of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,
- the manufacturing process, the quality control and assurance techniques and the systematic measures that will be used,
- the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out,
- the means to monitor the achievement of the required product quality and the effective operation of the quality system.

- 2.3.3. The notified body shall examine and evaluate the quality system to determine whether it satisfies the requirements referred to in paragraph 2.3.2. It shall presume conformity with these requirements in respect of quality systems that implement the corresponding harmonized standard.

It shall notify its decision to the manufacturer and inform the other notified bodies thereof. The notification to the manufacturer shall contain the conclusions of the examination and, in the event of refusal, the justification for the decision.

- 2.3.4. The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any updating of the quality assurance system in relation to changes brought about by, e.g. new technologies and new quality concepts.

2.3.5. Any notified body that withdraws approval of a quality system shall so inform the other notified bodies.

2.4. *EC surveillance*

2.4.1. The purpose of EC 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 grant the notified body access for inspection purposes to the manufacture, inspection, testing and storage premises and shall provide it with all necessary information, in particular:

- the quality system documentation,
- the design documentation,
- the quality records, e.g. the inspection reports and tests and calibration data, reports on the qualifications of the personnel concerned, etc.

The notified body shall periodically carry out audits in order to ensure that the manufacturer is maintaining and applying the quality system; it shall provide the manufacturer with an audit report.

In addition, the notified body may carry out unscheduled visits to the manufacturer. During such visits, the notified body may carry out full or partial audits. It shall provide the manufacturer with a report on the visit, and, where appropriate, an audit report.

2.4.3. The notified body shall ensure that the manufacturer maintains and applies the approved quality system.

3. **EC verification**

3.1. The EC verification is the procedure whereby a notified body checks and attest that instruments concerned are, where appropriate, in conformity with the type as described in the EC type-approval certificate and satisfy the requirements of this Directive that apply to them. The notified body shall affix the EC mark to each instrument.

3.2. Each instrument shall be examined and appropriate tests as set out in the relevant standards referred to in Article 5, or equivalent tests, shall be carried out to ensure its conformity with the essential requirements of this Directive.

3.3. The EC mark referred to in 3.1 above shall be accompanied by the identification symbol of the notified body.

3.4. For instruments not subject to EC-type approval, the design documentation referred to in Annex III must be accessible to the notified body to the extent that the latter so requests.

4. **EC unit verification**

4.1. EC unit verification is the procedure whereby a notified body checks and attests that an instrument, generally designed for a specific application, satisfies the requirements of this Directive which apply to it. The notified body shall affix the EC mark to the instrument.

4.2. The instrument shall be examined and appropriate tests as set out in the relevant standards referred to in Article 5, or equivalent tests, shall be carried out to ensure its conformity with the relevant requirements of this Directive.

4.3. The EC mark referred to in 4.1. shall be accompanied by the identification symbol of the notified body.

4.4. The design documentation of the instrument as specified in Annex III shall be made available to the notified body.

5. **Common provisions**

5.1. The EC declaration of type conformity (guarantee of production quality), the EC verification, and the EC unit verification 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 taking 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, they shall be carried out at the place of use of the instrument.

- 5.2. If the instrument's performance is sensitive to gravity variations the procedures referred to in 5.1 may be carried out in two stages, where the second stage shall comprise 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'.
- 5.3.1. Where a manufacturer has opted for execution in two stages of one of the procedures mentioned in 5.1, and where these two stages will be carried out by different parties, an instrument which has undergone the first stage of the procedure concerned shall carry the identification symbol of the notified body involved in that stage.
- 5.3.2. The party which has carried out the first stage of the procedure shall issue for each of the instruments a certificate, containing the necessary data 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.
- 5.3.3. The manufacturer who has opted for the EC declaration of type conformity (guarantee of production quality) in stage one may either use this same procedure in stage two or decide to continue in stage two with EC verification.
- 5.3.4. The EC mark shall be affixed to the instrument after completion of the second stage together with the identification symbol of the notified body involved in stage two.

ANNEX III

DESIGN DOCUMENTATION

The technical documentation must render the design, manufacture and operation of the product intelligible and enable an assessment to be made of its conformity with the requirements of the Directive.

The documentation shall include in so far as relevant for assessment:

- a general description of the type,
 - conceptual designs and manufacturing drawings and plans of components, sub-assemblies, circuits, etc.,
 - descriptions and explanations necessary for the understanding of the above, including the operation of the instrument,
 - a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where the standards referred to in Article 5 have not been applied,
 - results of design calculations made and of examinations, etc.,
 - test reports,
 - the EC type-approval certificates and the results of relevant tests on instruments containing parts identical to those in the design.
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ANNEX IV

1. Instruments subject to the EC conformity assessment procedure

1.1. These instruments must bear:

- (a) — the EC mark of conformity comprising the EC symbol as described in Annex VI, followed by the last two digits of the year in which it was affixed,
— the identification symbol(s) of the notified body/bodies that has/have carried out the EC surveillance or the EC verification.

The abovementioned mark and inscriptions shall be affixed to the instrument, distinctly grouped together;

- (b) a green sticker at least 12,5 mm × 12,5 mm square bearing a capital letter 'M' printed in black;

(c) the following inscriptions:

- the number of the EC type-approval certificate, where appropriate,
- the manufacturer's mark or name,
- the accuracy class, enclosed in an oval or in two horizontal lines joined by two half circles,
- maximum capacity in the form Max . . . ,
- minimum capacity in the form Min . . . ,
- verification scale interval in the form $e =$,

plus, when applicable:

- serial number,
- for instruments consisting of separate but associated units: identification mark on each unit,
- scale interval if it is different from e , in the form $d =$. . . ,
- maximum additive tare effect, in the form $T = +$. . . ,
- maximum subtractive tare effect if it is different from Max, in the form $T = -$. . . ,
- tare interval if it is different from d , in the form $d_T =$. . . ,
- maximum safe load if it is different from Max, in the form Lim . . . ,
- the special temperature limits, in the form . . . °C/. . . °C,
- ratio between load receptor and load.

- 1.2. The instruments shall have adequate facilities for the affixing of the EC mark of conformity and/or inscriptions. These shall be such that it shall be impossible to remove the mark and inscriptions without damaging them, and that the mark 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 , 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. Other instruments

The other instruments must bear:

- the manufacturer's mark or name,
- maximum capacity in the form Max . . .

These instruments may not bear the stickers provided for in 1.1 (b).

3. Restrictive use symbol specified in Article 12

This 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 V

Set out below are the minimum criteria to be applied by Member States when designating bodies for the carrying-out of tasks pertaining to the procedures referred to in Article 8.

1. The bodies shall dispose of the necessary personnel, means and equipment.
2. The personnel shall have technical competence and professional integrity.
3. The bodies shall work independently of all circles, groups or persons having direct or indirect interest in non-automatic weighing instruments regarding the carrying-out of the tests, the preparation of the reports, the issuing of the certificates and the surveillance requested by this Directive.
4. The personnel shall respect the professional secret.
5. The bodies shall have taken out a civil liability insurance if their civil liability is not covered by the State under national law.

The fulfilment of the conditions under points 1 and 2 shall be periodically verified by the Member States.

ANNEX VI