

L.N. 396 of 2002

THE METROLOGY ACT
ACT NO. XXV OF 2002

Non-Automatic Weighing Instruments Regulations, 2002

IN exercise of the powers conferred by article 19 of the Metrology Act, the Malta Standards Authority has made the following regulations:—

1. (1) The title of these regulations is the Non-Automatic Weighing Instruments regulations of 2002. Citation and commencement.

(2) These regulations shall become operative on the 1st January, 2004, which date shall be notified by the Authority in the Gazette;

Provided that the requirement of regulation 6 of these regulations and the CE marking shall not be obligatory prior to the 1st January, 2003 in respect of non-automatic weighing instruments already placed on the market prior to this date.

2. For the purposes of these regulations, all the definitions in the Malta Standards Authority Act shall apply and, in addition, in these regulations, unless the context otherwise requires: Definitions.
Cap. 419.

“approved body” refers to a body approved to carry out EC type examination as laid down in the Directive. The names of such approved bodies are published in the Official Journal of the European Communities.

“CE marking” refers to marking as set out in Schedule 5 of these regulations.

“Community” refers to the European Community.

“importer” refers to any person who places instruments from a foreign country on to the Maltese market so that he supplies such instruments on the first occasion that they are supplied in Malta;

“local authorised representative” refers to any person (or organisation) who has been appointed by the manufacturer to act on his behalf in carrying out certain tasks required by these regulations.

“manufacturer” refers to the person, who is primarily responsible for designing and manufacturing the instruments so that they comply with the requirements of these regulations.

“National Standard transposing the Harmonised Standard” refers to a Standard issued by one of the members of CEN/CENELEC/ETSI which is declared and noted to be technically equivalent to the Harmonised Standard originally issued by CEN/CENELEC/ETSI;

“non-automatic weighing instrument” refers to a weighing instrument requiring the intervention of an operator during weighing;

“OJ” refers to the Official Journal of the European Communities;

“person who supplies instruments” refers to wholesalers, distributors, retailers etc.

“placing on the market” refers to the importation, wholesale, retail sale and distribution free of charge.

“responsible person” in relation to instruments refers to:

(a) the manufacturer thereof;

(b) the manufacturer's local authorised representative; or where the manufacturer is not established in Malta and he has not appointed a local authorised representative, the person who places the instruments on the local market.

“weighing instrument” refers to a measuring instrument serving to determine the mass of a body by using the action of gravity on that body. Weighing instrument may also serve to determine other mass-related magnitudes, quantities, parameters or characteristics.

Scope

3. (1) These regulations shall apply to all non-automatic weighing instruments, hereinafter referred to as ‘instruments’.

(2) A distinction shall be made in these regulations between two categories of instrument use:

- (a) i. determination of mass for commercial transactions,
- ii. determination of mass for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment,
- iii. determination of mass for the application of laws or regulations; expert opinion given in court proceedings,
- iv. determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment,
- v. 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,
- vi. determination of price on the basis of mass for the purposes of direct sales to the public and the making-up of pre-packages;

(b) all applications other than those listed in regulation 2.1. of these regulations.

4. (1) The provisions of these regulations are applicable to all Applicability. imported instruments, as well as to those manufactured for the local market.

(2) Subject to regulation 4(3) below, the provisions of these regulations shall not apply to instruments intended exclusively for export.

(3) Subject to regulation 9 below, regulation 4(2) above shall not apply if the CE marking or any inscription liable to be confused therewith is affixed to the instruments.

5. (1) (a) Instruments used for the applications listed in Conformity. regulation 3 (2) above must satisfy the essential requirements set out in Schedule 1 to these regulations.

(b) In cases where the instrument includes or is connected to devices which are not used for the applications listed in regulation 3 (2), such devices shall not be subject to the essential requirements.

(2) Conformity with the essential requirements referred to in regulation 5(1) shall be presumed by the Authority in respect of instruments which comply with the relevant national standards implementing the harmonized standards that meet the essential requirements referred to in regulation 5(1).

CE marking and
certificates of
conformity.

6. (1) All measures shall be taken to ensure that instruments may not be brought into service for the uses set out in regulation 3 (2) unless they meet the requirements of these regulations which apply to them, including the conformity assessment procedures referred to in regulation 8, and accordingly bear the CE marking provided for in regulation 9 of these regulations.

(1) (a) Where an instrument which is used for any of the applications referred to in regulation 3 (2) includes or is connected to devices that have not been subject to conformity assessment as referred to in regulation 8 of these regulations, each of these devices shall bear the symbol restricting its use as defined by regulation 3 of Schedule 4 of these regulations. This symbol shall be affixed to the devices in a clearly visible and indelible form.

(2) Where the instruments are subject to other regulations covering other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the instruments in question are also presumed to conform to the provisions of those other regulations.

(3) However, where one or more of the regulations which apply to the instruments allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only to the regulations applied by the manufacturer. In this case, particulars of the regulations applied, as published in the Government Gazette, must be given in the documents, notices or instructions required by the Directives and accompanying such instruments.

Withdrawal and
prohibition from
market.

7. (1) Where it is considered that instruments bearing the CE conformity marking referred to in regulations 2, 3 and 4 of Schedule 2 to these regulations, do not meet the requirements of these regulations when properly installed and used for the purposes for which they are intended, all appropriate measures shall be taken to withdraw those instruments from the market or to prohibit or restrict their being put into service and/or placed on the market.

(2) Where an instrument which does not comply bears the CE conformity marking, the Malta Standards Authority shall take appropriate action against whomsoever has affixed the marking.

8. (1) The conformity of instruments to the essential requirements set out in Schedule 1 to these regulations may be certified by either of the following procedures as selected by the applicant:

Conformity
Assessment.

(i) EC type examination as referred to in item 1 of Schedule 1 to these regulations, followed either by the EC declaration of type conformity (guarantee of production quality) as referred to in item 2 of Schedule 2 to these regulations, or by the EC verification as referred to in item 3 of Schedule 2 to these regulations.

(ii) 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;

(iii) EC unit verification as referred to in item 4 of Schedule 2 to these regulations.

(2) The documents and correspondence relating to the procedures referred to in Regulation 8(1) hereof shall be drafted in English, or in a language accepted by the Authority.

(3) The Authority shall take all steps to ensure that instruments bearing the CE marking attesting conformity with the requirements of these regulations continue to conform to those requirements.

9. (1) The CE conformity marking shall consist of the initials "CE" in the form shown in the specimen in Schedule 5 to these regulations.

CE Conformity
Marking and
Inscriptions.

(2) (a) The CE conformity marking and the required supplementary data as described in item 1 of Schedule 4 to these regulations shall be affixed in a clearly visible, easily legible and indelible form to instruments for which EC conformity has been established.

(b) The inscriptions referred to in item 2 of Schedule 4 to these regulations shall be affixed in a clearly visible, easily legible and indelible form to all other instruments.

(3) The affixing of markings on the instruments which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the instruments provided that the visibility and legibility of the CE markings is not thereby reduced.

(4) Without prejudice to regulation 7 of these regulations, where it is established that the CE marking has been affixed unduly, the responsible person shall be obliged to make the instrument conform as regards the provisions concerning the CE marking and to end the infringement, under the conditions imposed by the Malta Standards Authority. Where non-conformity continues, all appropriate measures shall be taken to restrict or prohibit the placing on the market of the instrument in question or to ensure that it is withdrawn from the market in accordance with the procedures as laid down in regulation 7

Designation of
bodies.

10. (1) The Authority 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 subregulations (1), (2), and (3) of this regulation, the specific tasks for which each body has been designated, and the identification codes of the designated bodies.

(2) To determine whether to designate or otherwise a body, the Authority shall apply the minimum criteria set out in Schedule V to these regulations. Bodies which satisfy the criteria fixed by the relevant harmonized standards shall be presumed to satisfy the criteria set out in Schedule V.

(3) The Authority, after having designated a body, shall cancel the designation if the body no longer meets the criteria for designation referred to in regulation 10 (2) above. It shall immediately inform the other Member States and the Commission thereof and withdraw the notification.

Notification of
decisions.

11. Any decision pursuant to these regulations 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 Malta and of the time limits to which such remedies are subject.

Schedule 1

The essential requirements that must be met by the instruments referred to in regulation 2. are set out below. The terminology used is that of the Organisation Internationale de Métrologie Légale.

Preliminary observation

METROLOGICAL REQUIREMENTS

1. Units of mass

The units of mass used shall be the legal units within the meaning of Schedule 1 of the Metrology Act, Act XXV of 2002

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 $n = \frac{Max}{e}$	
		Minimum Value	Minimum value	Maximum value
I	$0,001 \text{ g} \leq e$	100 e	50 000	-
II	$0,001 \text{ g} \leq e \leq 0,05 \text{ g}$	20 e	100	100 000
	$0,1 \text{ g} \leq e$	50 e	5000	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.

2.2. Scale intervals

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

$$1 \times 10^k, 2 \times 10^k, \text{ or } 5 \times 10^k \text{ mass units,}$$

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:

$$e = 1 \times 10^k \text{ g}$$

$$d < e \leq 10 d$$

except for instruments of class I with $d < 10^{-4} \text{ g}$, for which $e = 10^{-3} \text{ g}$.

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 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:

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

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	$0,001 \text{ g} \leq e_i$	$100 e_i$	50 000	-
II	$0,001 \text{ g} \leq e_i \leq 0,05 \text{ g}$ $0,1 \text{ g} \leq e_i$	$20 e_i$	5 000	100 000
		$50 e_i$	5 000	100 000
III	$0,1 \text{ g} \leq e_i$	$20 e_i$	500	10 000
III	$5 \text{ g} \leq e_i$	$10 e_i$	50	1 000

4. Accuracy

4.1. On implementation of the procedures laid down in regulation 8 of these regulations, 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	
$0 \leq m \leq 50\,000e$	$0 \leq m \leq 5\,000e$	$0 \leq m \leq 500e$	$0 \leq m \leq 50e$	$\pm 0,5 e$
$50\,000e < m \leq 200\,000e$	$5\,000e < m \leq 20\,000e$	$500e < m \leq 2\,000e$	$50e < m \leq 200e$	$\pm 1,0 e$
$200\,000e < m$	$20\,000e < m \leq 100\,000e$	$2\,000e < m \leq 10\,000e$	$200e < m \leq 1\,000e$	$\pm 1,5 e$

4.2. The maximum permissible errors in service are twice the maximum permissible errors fixed in regulation 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 $+40\text{ °C}$ 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 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 these regulations.

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 Schedule shall comply with the provisions of Schedule 1 of the Metrology Act, Act XXV of 2002, 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 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 regulation 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.

Schedule 2

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 these regulations that apply to it.

1.2. The application for type-examination shall be lodged by the responsible person with a single notified body.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the local authorised representative or the person who places the instruments on the local market, 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 Schedule 3 to these regulations.

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 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 these regulations 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. of this Schedule, 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 these regulations that apply to them.

The responsible person shall affix the CE marking to each instrument and the inscriptions provided for in Schedule 4 of these regulations and shall draw up a written declaration of conformity.

The CE marking shall be accompanied by the identification number of the notified body responsible for the EC surveillance referred to in Paragraph 2.4. of this Schedule.

2.2. The manufacturer shall have adequately implemented a quality system as specified in Paragraph 2.3. of this Schedule and shall be subject to EC surveillance as specified in Paragraph 2.4. of this Schedule.

2.3. *Quality system*

2.3.1. The manufacturer shall lodge an application for approval of the 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 these regulations 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. The 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 responsible person 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.

2.4 *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.

3. *EC verification*

3.1. EC verification is the procedure whereby the responsible person ensures and declares that the instruments which have been checked in accordance with Paragraph 3.3 of this Schedule are, where applicable, in conformity to the type described in the EC type-examination certificate and satisfy the requirements of these regulations which apply to them.

3.2. The manufacturer shall take all necessary measures in order that the manufacturing process ensures conformity of the instruments, where applicable, with the type as described in the EC type-examination certificate and with the requirements of these regulations which apply to them. The responsible person shall affix the CE marking to each instrument and draw up a written declaration of conformity.

3.3. For instruments not subject to EC type-approval, the documents relating to the design of the instruments, as set out in Schedule 3 to these regulations, must be accessible to the notified body should the latter so request.

3.4. *Verification by checking and testing of each instrument.*

3.4.1. All instruments shall be individually examined and appropriate tests, as set out in the relevant standard(s) referred to in regulation 5.2. of these regulations, or equivalent tests, shall be carried out in order to verify their conformity, where applicable, to the type as described in the EC type-examination certificate and the requirements of these regulations that apply to them.

3.4.2. The responsible person shall ensure that he is able to supply the notified body's certificates of conformity on request.

4. EC unit verification

4.1. EC unit verification is the procedure whereby the responsible person ensures and declares that the instrument, generally designed for a specific application, which has been issued with the certificate referred to in Paragraph 4.2. of this Schedule, conforms to the requirements of these regulations that apply to it. The responsible person shall affix the CE marking to the instrument and shall draw up a written declaration of conformity.

4.2. The aim of the technical documentation relating to the design of the instrument, as referred to in Schedule 3 to these regulations, is to enable conformity to the requirements of these regulations to be assessed and the design, manufacture and operation of the instrument to be understood. It must be accessible to the notified body.

4.3. The responsible person shall ensure that he is able to supply the notified body's certificates of conformity on request.

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 Paragraph 5.1. of this Schedule may be carried out in two stages, where the second stage shall comprise all examinations and tests of which the outcome is gravity-dependant, and the first stage all other examinations and tests. The second stage shall be carried out at the place 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 Paragraph 5.1. of this Schedule, 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.

5.3.2 The responsible person shall ensure that he is able to supply the notified body's certificates of conformity on request.

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 CE 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.

Schedule 3

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 these regulations.

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 regulation 5(2) of these regulations, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where the standards referred to in regulation 5.2. of these regulations 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.

Schedule 4

1. Instruments subject to the EC conformity assessment procedure

1.1. These instruments must bear:

- (a) - the CE conformity marking comprising the CE symbol as described in Schedule 5 of these regulations, followed by the last two digits of the year in which it was affixed,
- the identification number(s) of the notified body/bodies that has/have carried out the EC surveillance or the EC verification.

The abovementioned marking 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 $e =$,
- the last two digits of the year in which the CE marking was affixed, 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 CE conformity marking 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 Paragraph 1.1 (b) of this Schedule.

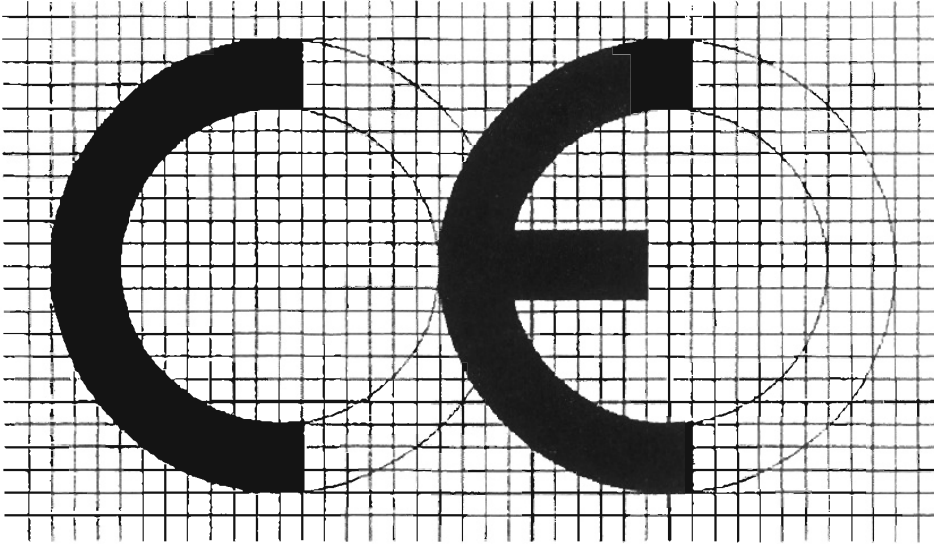
3. Restrictive use symbol specified in regulation 9 (1) of these regulations

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.

Schedule 5

CE Conformity Marking

The CE conformity marking shall consist of the initials "CE" taking the following form:



For the avoidance of doubt, it is hereby declared that the grid providing the background in the above graduated drawing is not part of the CE marking.

If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5mm.

