BUSINESS IN EUROPE

Product standards

Non-automatic weighing instruments

Guidance notes on UK Regulations (Third Edition)

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Contents

This guide is intended to assist manufacturers and suppliers of non-automatic weighing instruments to understand the effect of the Regulations. It is not an authoritative interpretation of the Regulations which is a matter for the Courts.

The guide seeks to explain the requirements of the Regulations in general terms and does not attempt to address detailed issues. You should refer to the Regulations themselves for a full statement of the requirements.

Non-automatic weighing instruments - the new law in brief

The Non-automatic Weighing Instruments (EEC Requirements) Regulations 1995 [the 1995 Regulations] are a consolidation of the Non-automatic Weighing Instruments (EEC Requirements) Regulations 1992 [the 1992 Regulations], the Non-automatic Weighing Machines and Non-automatic Weighing Instruments (Amendment) Regulations 1995 [the Amendment Regulations] plus the transposition of the Council Directive 93/68/EEC.

Since **1 January 1993**, under the 1992 Regulations:

- new designs of non-automatic weighing instruments made or sold in the United Kingdom, including imports, for a Schedule 3 application (subject to transitional arrangements) have been required to:
  - satisfy various requirements, for example on accuracy, design and construction;
  - undergo type-examination (where appropriate) and verification, and for self-verifying organisations quality system approval by an approved body; and
  - carry the CE marking and specified information, mainly about the instrument.

Failure to comply with these requirements is a criminal offence.

- The same rules will apply everywhere in the Community, so instruments complying with these requirements may be sold anywhere in the Community.
- This booklet describes the 1995 Regulations and where necessary refers to the 1992 Regulations, but you should consult the Regulations themselves, the primary legislation under which they are made and other applicable legislation for all the provisions that may be relevant.

Free movement of goods

Achieving the free movement of goods lies at the heart of achieving an open market for business in Europe.

In May 1985, European Community Ministers agreed on a ‘New Approach to Technical Harmonisation and Standards’ in order to fulfil this objective.

‘New Approach’ Directives (that is Community laws) set out ‘essential requirements’ (for safety or protection, for example), written in general terms, which must be met before products may be sold in the UK or anywhere else in the Community. European Standards fill in the detail and are the main way for businesses to meet the ‘essential requirements’. The Directives also states how manufacturers are to show that products meet the ‘essential requirements’. Products meeting the requirements are to carry the CE marking, which indicates that they can be sold anywhere in the Community.

Under the European Economic Area (EEA) Agreement the provision of the Directives now additionally applies in three of the Member States of the European Free Trade Association (EFTA): Norway, Iceland and Liechtenstein.

For the wider background and to find out more about what this means for your business, get your copy of *Keeping your product on the market* by telephoning DTI’s Business in Europe Hotline on 0117 944 4888.

The Non-automatic Weighing Instruments (NAWI) Directive 90/384/EEC was transposed into UK law by the Non-automatic Weighing Instruments (EEC Requirements) Regulations 1992, which came into force on 1 January 1993 (SI 1992/1579), and provided transitional arrangements for a period of 10 years (up to 1 January 2003) to allow new instruments to continue to be subject to the rules previously in force.

The Amending Directive 93/68/EEC which amended the CE Marking provisions of a number of Directives including the NAWI Directive provided a 2 year transition for those changes from 1 January 1995 to 1 January 1997 after which the changes will be mandatory.

Non-automatic Weighing Instruments (EEC Requirements) Regulations 1995 (S.I. 1995/1907)

Consolidation of the 1992 Regulations (SI 1992/1579) and 1995 Amendment Regulations (SI 1995/428) plus provisions of the Amending Directive 93/68/EEC.

Entry into force: 1 January 1993 (1992 Regulations) and 1 September 1995 (1995 Regulations).

Primary legislation: the European Communities Act 1972 and the Weights and Measures Act 1985.

Supplementary legislation: the Non-automatic Weighing Instruments (EEC Requirements) (Use for Trade) Regulations (Northern Ireland) 1992 (SR 1992/484).

Transitional period: the sale and use of non-automatic weighing instruments which comply with the rules in force immediately before 1 January 1993 is permitted for a further period of 10 years from that date. The Amending Directive provisions are not mandatory until 1 January 1997.

Coverage: non-automatic weighing instruments; that is measuring instruments which determine the mass of a body or other mass related magnitudes, quantities, parameters or characteristics by using the action of gravity, and which require the intervention of an operator.

The Regulations distinguish two categories of instruments:

Schedule 3 applications: instruments which determine mass:

- for commercial transactions;
- to calculate a toll, tariff, tax, bonus, penalty, remuneration indemnity or similar type of payment;
- when applying laws or regulations, or for expert's reports made by order of a court;
- to weigh patients for the purpose of monitoring, diagnosis and medical treatment in the practice of medicine;
- for making up medicines on prescription in a pharmacy, or in analyses in medical or pharmaceutical laboratories;
- to fix a price for direct sale to the public, or to make up pre-packages.

Other applications: instruments used for any other purpose, e.g. domestic and industrial control.

> Instruments used for other applications do not have to satisfy the essential requirements. Where they have not undergone any 'attestation' procedure, they must not bear the CE marking unless the CE marking is affixed as a result of compliance with another Directive.
>
> These instruments must, however, carry the manufacturer's name or mark, and indicate their maximum capacity in a clearly visible, easily legible and indelible form.

Essential requirements: instruments for Schedule 3 applications must satisfy the essential requirements set out in Annex A. These are based on Recommendation No 76 of the International Organisation of Legal Metrology (OIML) and include metrological requirements, such as accuracy and units of measurement; and design and construction requirements, such as resistance to environmental disturbances.

Devices embodied in, or attached to, instruments for Schedule 3 applications that are used for such purposes do not need to satisfy the essential requirements if they are used in accordance with the Preliminary Observation in Annex A, but must carry the restricted use symbol described in Annex F.

Methods of satisfying the essential requirements: manufacture in conformity with:

- ❑ specified European Standards, which are published in the UK as identically worded British Standards; or

- ❑ the essential requirements.

The reference number of the British Standard is BS EN 45501 + AC: 1994.

How to show the essential requirements are satisfied ('attestation'): the applicant can choose between:

- ❑ EC type-examination, followed by either the EC declaration of type conformity procedure or the EC verification procedure; and

- ❑ the EC unit verification procedure.

If the first route is chosen, the EC type-examination may be omitted for instruments which do not use electronic devices and whose load-measuring device does not use a spring to balance the load.

EC type-examination is a procedure carried out by a body approved by a Member State, to establish that a prototype instrument satisfies the relevant provisions of

the Directive. Details of the procedure are set out in Annex B. For instruments subject to EC type-examination, the design documentation described in Annex E is to be made available to the approved body.

EC type-examination will be more straightforward for instruments manufactured in conformity with the relevant specified standards.

Under the EC declaration of type conformity procedure, a manufacturer with an approved quality system may himself declare that instruments are in conformity with an approved prototype (where appropriate) and that they satisfy the relevant provisions of the Directive. The manufacturer affixes the CE marking, green metrology sticker and the number of the approved body responsible for EC surveillance. The manufacturer or his authorised representative may also issue a Declaration of Conformity for those instruments; mandatory from 1 January 1997. Details of what is required for a quality system to be approved are set out in Annex C. A quality system that has been certified as conforming to BS EN ISO 9001 or 9002 would meet those requirements provided that the system conforms to the provisions of the Directive in relation to the instruments for which an EC declaration of type conformity is to be made.

Under the EC verification procedure, an approved body, having received a declaration of conformity from the manufacturer or his authorised representative, checks that instruments conform with an approved prototype (where appropriate) and that they satisfy the relevant provisions of the Directive. To this end, the approved body examines each instrument and carries out or arranges for the carrying out of the appropriate tests as set out in the relevant specified standards, or equivalent tests and where satisfied affixes the approved body number and issues a certificate of conformity to the manufacturer or his authorised representative

As an alternative until 1 January 1997 the approved body may also attest the instrument conforms and in addition affix the CE Marking and green metrology sticker in which case the provision of the declaration of conformity and certificate of conformity are optional.

The EC unit verification procedure essentially combines the EC type-examination (without a type approval certificate being issued) and the EC verification procedure, and is intended for ‘one-off’ instruments designed for a specific application.

A number of common provisions and examples of conformity documents relating to these procedures are set out in Annex D.

The Department of Trade and Industry will inform the European Commission and the other Member States of the UK approved bodies and the tasks for which they have been designated. The Directive uses 'notified body' for the task referred to in the Regulations as approved body tasks. The Commission will allocate an identification number to each of these bodies. The Commission will also publish, and up-date, that information in the Official Journal of the European Communities.

Instruments for Schedule 3 applications that have been properly attested must carry the CE marking, as shown below, together with the information set out in Annex F. The CE marking also indicates that the instrument complies with any other relevant Directives.

The CE marking is as illustrated in diagram 1 below. It may not be smaller than 5 mm in its vertical height, and the proportions in diagram 2 below must be maintained whatever its size. **The grid does not form part of the marking and is for information only.**

Diagram 1

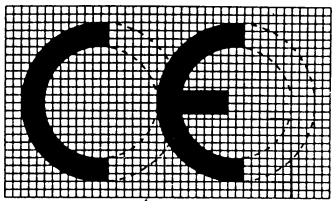

Diagram 2

- This mark looks the same as some previous marks, but there are subtle changes, and diagram 2 should be studied closely. It should be noted, for example, that the C and E are not formed by perfect semi-circles, i.e. the top and bottom arms extend one square beyond the semi-circles, and the middle arm of the E stops one square short.

Free circulation: Member States are required to ensure that instruments are placed on the market, and that instruments for Schedule 3 applications are put into service, only if they meet the relevant requirements of the Directive.

But Member States may not impede the placing on the market of instruments, or the putting into service of instruments for Schedule 3 applications, that do meet the relevant requirements of the Directive; and Member States are to presume that instruments manufactured in conformity with the relevant specified standards satisfy the essential requirements.

Safeguard procedure: a Member State is required to take all appropriate measures to remove from the market instruments bearing the CE marking that, when properly installed and used for their intended purpose, do not meet the requirements of the Directive. The Member State must immediately inform the European Commission of such actions, giving reasons. The Commission is to consult the parties concerned as soon as possible, and is immediately to inform the Member State of the result. If it finds the action justified, the Commission is immediately to inform the other Member States.

The Member State is also to notify the party concerned without delay, giving reasons, the judicial remedies available and any time limits to those remedies.

Other Directives: instruments that comply with the Directive must also comply with any other relevant legislation. For example, instruments with electrical components may also have to comply with Directive 73/23/EEC, implemented in

UK law as the Low Voltage Electrical Equipment (Safety) Regulations 1989, and Directive 89/336/EEC (as amended), implemented in UK law as the Electromagnetic Compatibility Regulations 1992 (as amended) in relation to electromagnetic emissions.

Implementation and enforcement: the Regulations were made after wide consultation. They include provisions on the control of instruments in service, which are not covered by the Directive in detail. The trading standards departments of local authorities in Great Britain and the trading standards branch of the Department of Economic Development in Northern Ireland are responsible for enforcement.

Standards: the European standard specified for the purposes of the Directive, i.e. EN 45501 - Metrological Aspects of Non-automatic Weighing Instruments, is based on Recommendation No 76 of the International Organisation of Legal Metrology (OIML).

Further information

Availability of text of Regulations: the 1995 Regulations SI 1995/1907, the 1992 Regulations SI 1992/1579, and the primary legislation under which they are made, and the Non-automatic Weighing Instruments (EEC Requirements) (Use for Trade) Regulations (Northern Ireland) 1992, SR 1992/484, are available from HMSO and their agents.

Availability of Notes for Guidance: the National Weights and Measures Laboratory has prepared notes for guidance on the 1992 Regulations which are being revised to take into account the 1995 Regulations. Information about the notes can be obtained from NWML, address as below.

Availability of text of standard: BS EN 45501 and BS EN ISO 9002:1994 can be obtained from BSI Sales at Linford Wood, Milton Keynes, MK14 6LE, (tel 01908 221166) and at any HMSO bookshop.

Availability of text of Directive: the complete text of the Directive has been published in the *Official Journal of the European Communities* (No. L189 of 20.07.90, pages 1-16 and No. L258 of 22.09.90, page 35). Copies of these texts are generally available from European Information Centres and European Documentation Centres located throughout the United Kingdom, who may provide them for a modest fee. To locate your nearest Centre, consult the DTI's Business in Europe booklet *Contacts,* available through the DTI's Business's in Europe Hotline on 0117 944 4888.

Other documents: the WELMEC organisation which provides a focus for European co-operation in legal metrology has produced a number of documents and guides relating to non-automatic weighing instruments. One of these documents *Directive 90/384/EEC: Explanation and Interpretation* provides further clarification on certain of the provisions and was prepared by the European Commission in collaboration with WELMEC. (For further information please contact the WELMEC secretariat at the NWML address below).

Queries on the Directive and Regulations: Department of Trade and Industry, Room F11, National Weights and Measures Laboratory, Stanton Avenue, Teddington, Middlesex TW11 0JZ. Tel: 0181 943 7264 (Technical - Peter Knowles), Tel: 0181 943 7266 (Legislation - Peter Badger), Tel: 0181 943 7298 (WELMEC secretariat - Peter Edwards) and Tel: 0181 943 7261 (Publications - Anne Mohan). Fax: 0181 943 7270.

Queries on Standards: Miss Margaret Ryan, BSI, 389 Chiswick High Road, Chiswick, London W4 4AL. Tel: 0181 996 9000.

Further copies of this booklet are available through the DTI's Business in Europe Hotline on 0117 944 4888.

Essential requirements

The essential requirements that must be met by instruments for Schedule 3 applications are set out below. 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 Schedule 3 applications, 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

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) (implemented in UK law as the Units of Measurement Regulations 1986) and 89/617/EEC(3).

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.

(1) Published in the *Official Journal of the European Communities* (No L39 of 15.2.1980, page 40.)
(2) Published in the *Official Journal of the European Communities* (No L2 of 3.1.1985, page 11.)
(3) Published in the *Official Journal of the European Communities* (No L357 of 7.12.1989, page 28.)

2 Accuracy classes

2.1 The following accuracy classes have been identified

I - special
II - high
III - medium
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 = Max/e	
		minimum value	minimum value	maximum value
I	0.001 g ≤ e	100e	50,000	-
II	0.001 g ≤ e ≤ 0.05g	20e	100	100,000
	0.1 g ≤ e	50e	5,000	100,000
III	0.1 g ≤ e ≤ 2g	20e	100	10,000
	5 g ≤ e	20e	500	10,000
IIII	5 g ≤ e	10e	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:

1×10^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 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 50,000e.

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 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, this class being the instrument's accuracy class.

TABLE 2: Multi-interval instruments

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

Class	Verification scale interval (e)	capacity (Min)	scale intervals	
		minimum value	minimum value (x) $n = Max_i/e_{(i+1)}$	maximum value $n = Max_i/e_i$
I	$0.001\ g \le e_i$	$100e_i$	50,000	-
II	$0.001\ g \le e_i \le 0.05g$	$20e_i$	5,000	100,000
	$0.1\ g \le e_i$	$50e_i$	5,000	100,000
III	$0.1\ g \le e_i$	$20e_i$	500	10,000
IIII	$5\ g \le e_i$	$10e_i$	50	1,000

(x) for i = r the corresponding column of Table 1 applies, with e replaced by e_r.

4 Accuracy

4.1 On implementation of the ‘attestation’ procedures, 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, excluding preset tare values.

TABLE 3: Maximum permissible errors

Load				Maximum permissible error
Class I	Class II	Class III	Class IIII	
0≤m≤50,000e	0≤m≤5,000e	0≤m≤500e	0≤m≤50e	±0.5e
50,000e<m≤200,000e	5,000e<m≤20,000e	500e<m≤2,000e	50e<m≤200e	±1.0e
200,000e<m	20,000e<m≤100,000e	2,000e<m≤10,000e	200e<m≤1,000e	±1.5e

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 ll, lll and llll, 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 ll,
30°C for an instrument in Class lll or llll.

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 ll 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 ll, lll or llll 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 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 with the addition of the symbol for the metric carat which shall be the symbol ‘ct’.

Indication shall be prevented 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 sales 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 straight forward.

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 sales to the public’.

15 Price labelling instruments

Price labelling instruments shall meet the requirements of price indicating instruments for direct sales 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.

EC type-examination

Applications for EC type-examination are to be made by the manufacturer or by his authorised representative established within the Community to a single approved body. They are to include: the name and address of the manufacturer; and, if the application is being lodged by the authorised representative, also his name and address; a written declaration that an application has not been lodged with any other approved body; and the design documentation described in Annex E.

The applicant must place at the disposal of the approved body a prototype instrument, representative of the production envisaged.

The approved body is to: examine the design documentation and verify that the prototype has been manufactured in accordance with that documentation; agree with the applicant where the examinations and/or tests are to be carried out; where the manufacturer has not used the relevant specified standards, perform, or have performed, the appropriate examinations and/or tests to check whether the solutions adopted by the manufacturer meet the essential requirements; and, where the manufacturer has used the relevant specified standards, perform, or have performed, the appropriate examinations and/or tests to check whether those standards have been applied effectively, thereby assuring conformity with the essential requirements.

If the prototype meets the provisions of the Directive, the approved body is to issue an EC type-approval certificate to the applicant. The certificate is to contain: the conclusions of the examination; the 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, are to be annexed to the EC type approval certificate. The certificate is to have a validity period of 10 years from the date of its issue, and may be renewed for subsequent periods each of 10 years. 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.

Approved bodies are periodically to make available to all Member States: lists of applications received for type-examination; EC type approval certificates issued; applications for EC type-approval certificates refused; and additions and amendments relating to documents already issued. They are also to inform all Member States forthwith of withdrawals of EC type-approval certificates. Each Member State is to make this information available to the bodies which it has approved. The other approved bodies may receive a copy of the certificates together with the Annexes to them.

The applicant is to keep the approved body that has issued the EC type-approval certificate informed of any modifications to the approved prototype. Modifications to the approved prototype must receive additional approval from the body that issued the EC type approval certificate where such changes influence conformity with the essential requirements or the prescribed conditions for use of the instrument. This additional approval is to be given in the form of an addition to the original EC type-approval certificate.

Approval of quality systems

The manufacturer is to lodge an application for approval of the quality system with an approved body. The application must include an undertaking to carry out the obligations arising from the approved quality system, and an undertaking to maintain the approved quality system to ensure its continuing suitability and effectiveness. The manufacturer is to make available to the approved body all relevant information, in particular the quality system's documentation and the design documentation of the instrument described in Annex E.

The quality system is to ensure conformity of the instruments with the prototype as described in the EC type-approval certificate and with the relevant requirement(s) of the Directive. All the elements, requirements and provisions adopted by the manufacturer are to be documented in a systematic and orderly manner in the form of written rules, procedures and instructions. The quality system documentation is to ensure a proper understanding of the quality programmes, plans, manuals and records. It is to contain, in particular, an adequate description of: the quality objectives and the organisational 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 to be used; the examinations and tests to be carried out before, during and after manufacture, and the frequency with which they are to be carried out; and the means to monitor the achievement of the required product quality and the effective operation of the quality system.

The approved body is to examine and evaluate the quality system to determine whether it satisfies those requirements. It is to presume that quality systems which implement the corresponding harmonised standard conform with those requirements. The approved body is to notify the manufacturer of its decision and inform the other approved bodies thereof. The notification to the manufacturer is to contain the conclusions of the examination and, in the event of refusal, the justification for the decision.

The manufacturer or his authorised representative is to keep the approved body that approved the quality system informed of any updating of the quality system in relation to any changes brought about by e.g. new technologies and new quality concepts. Any approved body that withdraws approval of a quality system is so to inform the other approved bodies through the Member State.

Thereafter the manufacturer is to grant the approved body access for inspection purposes to the manufacture, inspection, testing and storage premises, and is to provide it with all necessary information, in particular, the quality system documentation; the design documentation; and the quality records (e.g. the inspection reports and test and calibration data, reports on the qualifications of the personnel concerned, etc.).

The approved body is periodically to carry out audits in order to ensure that the manufacturer is maintaining and applying the quality system; it is to provide the manufacturer with an audit report. They may also carry out unscheduled visits to the manufacturer. During such visits, the approved body may carry out full or partial audits. It is to provide the manufacturer with a report on the visit and, where appropriate, an audit report. The approved body shall ensure that the manufacturer maintains and applies the approved quality system.

Common Provisions and Conformity Documentation

COMMON PROVISIONS

The documents and correspondence relating to any of the procedures are to be drafted in an official language of the Member State where the procedure is to be carried out, or in a language accepted by the approved body.

The EC declaration of type conformity, the EC verification and the EC unit verification procedures may be carried out at the manufacturer's works or at 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.

If the instrument's performance is sensitive to gravity variations, those procedures may be carried out in two stages. The second stage is to comprise all examinations and tests the outcome of which is gravity-dependent; and the first stage is to comprise all other examinations and tests. The second stage is to 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'.[1]

If a manufacturer has opted to have a procedure carried out in two stages, and if those two stages are to be carried out by different parties, an instrument which has undergone the first stage of the procedure concerned is to carry the identification symbol of the approved body involved in that stage. The party which has carried out the first stage of the procedure is to issue for each of the instruments a certificate (see C and D on page 24) 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 stage two of the procedure is to carry out those examinations and tests that have not yet been carried out.

The manufacturer who has opted for the EC declaration of type conformity in stage one may either use this same procedure in stage two or decide to continue in stage two with EC verification.

1 The UK has not established gravity zones in its territory.

CONFORMITY DOCUMENTATION

This section sets out examples of conformity documents required to be presented with an instrument at various stages in the verification procedure.

A Declaration of Conformity - For completion by the manufacturer or his authorised representative prior to verification.

The form which may be included in the operator's manual of the instrument is required to be available at the site of installation.

This declaration should include a statement that it is only valid with a certificate of conformity issued by a notified body. The statement does not appear if the manufacturer operates a quality system and declares conformity in accordance with Annex II.2 of Directive 90/384/EEC.

In case of verification in two stages the validity of the declaration of conformity may depend on evidence (or proof) of the carrying out of the second stage of verification. (See page 25).

B Certificate of Conformity - For completion by the notified body at the time of verification (EC unit verification and EC verification) and presented to the manufacturer or his authorised representative.

One certificate of conformity may be used for many instruments of the same type by including all serial numbers. The certificate of conformity is to be made available by the manufacturer or his authorised representative. (See page 26).

C Certificate on tests of the 1st stage - For completion by the notified body at the time of 1st stage verification (EC unit verification and EC verification) and presented to the manufacturer or his authorised representative. This certificate must be presented with the instrument at the time of 2nd stage verification. (See page 27).

D Certificate on tests of the 1st stage - For completion by the manufacturer or his authorised representative at the time of 1st stage verification (EC declaration of type conformity). This certificate must be presented with the instrument at the time of 2nd stage verification. (See page 28).

Certificates of Conformity and Declarations of Conformity and Certificates of Tests of 1st stage verification may be combined on one document.

Specimen **A**

Name and address of manufacturer or his authorised representative

CE	***Declaration of Conformity***

The non-automatic weighing instrument 

Manufacturer:	
Type / Model:	
No of the EC type-approval certificate (where applicable):	

corresponds to the production model described in the EC type-approval certificate and to the requirements of the Council Directive 90/384/EEC as amended and to the requirements of the following EC directives:

Signature	*Date*

Specimen **B**

Name, address and identification number of the Notified Body

Certificate of Conformity

The conformity of the non-automatic weighing instrument ⊂⊃

Manufacturer:	
Type / Model:	
Serial number:	

with the requirements of the Council Directive 90/384/EEC as amended was established by tests referred to in EN 45 501 - 8.2.

The EC-verification is valid for the following place of installation/location/ area of use:

Signature	*Date* *Stamp*

Specimen **C**

Name, address and identification number of the Notified Body

Certificate on tests of the 1st stage

The conformity of the non-automatic weighing instrument 

Manufacturer:	
Type / Model:	
Serial number:	

with the requirements of the Council Directive 90/384/EEC as amended was established by examinations and tests referred to in EN 45 501 - 8.2, with the exception of the following tests:

Pending tests to ensure the conformity will be performed at the second stage.

Signature	*Date* *Stamp*

Specimen **D**

Name and address of the manufacturer or his authorised representative

Identification number of the Notified Body that has carried out the EC surveillance referred to the Council Directive 90/384/EEC

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Certificate on tests of the 1st stage

The conformity of the non-automatic weighing instrument ⊂⊃

Manufacturer:	
Type / Model:	
Serial number:	

with the requirements of the Council Directive 90/384/EEC as amended was established by examinations and tests referred to in EN 45 501 - 8.2, with the exception of the following tests:

Pending tests to ensure the conformity will be performed at the second stage.

Signature	*Date*	*Stamp*

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 is to include, insofar 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 product;
- a list of the specified standards that have been applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where such standards have not been applied;
- results of design calculations made and of examinations etc.;
- test reports; and
- the EC type approval certificates and the results of relevant tests on instruments containing parts identical to those in the design.

Accompanying information

(a) The CE marking and the identification symbol(s) of the approved body/bodies:

- responsible for EC surveillance under the EC declaration of type conformity procedure;
- that carried out the EC verification procedure;
- that carried out the EC unit verification procedure.

The CE marking and the identification symbol(s) are to be distinctly grouped together.

(b) A green sticker at least 12.5 mm x 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

and, **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: Li m ...;
- the special temperature limits, in the form: . . . °C/. . .°C;
- ratio between load receptor and load.

The CE marking and accompanying information must be clearly visible, easily legible and indelible.

Instruments are to have adequate facilities for affixing CE marking and accompanying information. These are to be such that it is impossible to remove them without damaging them, and that they are visible where the instrument is in its regular operating position.

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

The inscriptions Max, Min, e, d, are additionally to be shown near the display of the result if they are not already located there.

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

Restricted use symbol: a capital letter M printed in black on a red background at least 25 mm x 25 mm square with two intersecting diagonals forming a cross, to be affixed in a clearly visible and indelible form.