

WELMEC 2.7 (Revision 3.1)
Issue 1

WELMEC

European cooperation in legal metrology

Directive 90/384/EEC Explanation and Interpretation



June 2006

WELMEC

European cooperation in legal metrology

WELMEC is a cooperation between the legal metrology services of the Member States of the European Union and EFTA. This document is one of a number of Guides published by WELMEC to provide guidance to manufacturers of measuring instruments and to notified bodies responsible for conformity assessment of their products. The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EC Directives. Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed.

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FOREWORD

This document provides explanation and interpretation in respect of the provisions contained in Council directive 90/384/EEC (amended by directive 93/68/EEC) on non-automatic weighing instruments.

It does not provide a systematic treatment of all provisions of the directive, but instead deals only with those of the directive's elements of which experience has shown that further clarification was needed.

The document will assist all interested parties in correctly interpreting and applying this piece of community legislation: Member States of the European Union and Signatories of the Agreement on the European Economic Area, who transposed the directive in their respective national legislations; manufacturers of non-automatic weighing instruments, whether established in the European Economic Area or in third countries; users of non-automatic weighing instruments; consumers.

This document revises WELMEC Guide 3.1 Issue 1, previously published as WELMEC guide 5.

The text of that document was prepared by the Directorate-General Industry of the European Commission, in collaboration with WELMEC Working Group 2. The text corresponded to the opinion of the services of the European Commission at the time of preparation. However, attention was drawn to the fact that a binding interpretation of Community legislation can only be given by the Court of Justice. With respect to that disclaimer it was decided to issue this revised document as a new WELMEC Guide under the full responsibility of WELMEC. The Commission together with the working group on NAWI directive may decide at a further stage to make reference to this WELMEC guide on the EU web-site.

Vienna, June 2006

DIRECTIVE 90/384/EEC: EXPLANATION AND INTERPRETATION

1. INTRODUCTION

Directive 90/384/EEC was adopted on 20 June 1990 and came into force on 1 January 1993. It was modified by directive 93/68/EEC of 22 July 1993, with effect from 1 January 1995.

The directive concerns all non-automatic weighing instruments and is total in application. This means that no national provisions dealing with the application field of the directive may exist any more, other than those transposing the directive.

The application areas listed in Article 1.2(a) became controlled areas or continue as controlled areas as and from 1 January 1993. All other areas of use were deregulated and fell under Article 1.2(b) from that date.

Without prejudice to the provisions of the transition arrangements (which ended on 31 December 2002), all new instruments being placed on the Community market from 1 January 1993 shall carry the manufacturer's mark or name and the maximum weighing capacity. They may have to carry the CE marking for conformity to another directive (without the green metrology sticker). In addition, instruments to be used for applications listed in Article 1.2(a) must bear the CE conformity marking accompanied by the green metrology sticker. In the latter case they shall satisfy the essential requirements that apply to them and their conformity with these essential requirements shall have been assessed in accordance with the provisions on conformity assessment.

An instrument in use on 1 January 1993 could continue in use according to the rules in force when the type/design was first placed on the market. It might be or might not be subject to metrological controls prior to 1 January 1993.

2. SCOPE

A **weighing instrument** is defined in Article 1.1 as a measuring instrument that uses the action of gravity on a body to determine the mass of the body. A characteristic that distinguishes a **non-automatic weighing instrument** from other weighing instruments is that an operator is required during the weighing operation to obtain the result, e.g. to place the load on the load receptor of the instrument. By this definition, the following types of weighing instrument among others are included: retail shop scales, laboratory balances, bathroom scales, baby scales and kitchen scales.

Only measuring instruments that meet the definition in Article 1.1 of a non-automatic weighing instrument are within the scope of the directive. Furthermore, legal weighing instruments must indicate the value of the mass (Essential requirement 8.1 of Annex I).

The definition of a non-automatic weighing instrument does not cover instruments which are used for qualitative analysis that do not indicate mass but the related characteristic only (e.g. geological or metallurgical analysis, hectolitre mass of grain, ...), and counting instruments that do not display mass (e.g. coin counters, pill counters, parts counters)

Concerning cases where doubt exists to determine whether an instrument is a NAWI or an AWI covered by an OIML recommendation the guidance provided in guide WELMEC 2 in paragraph 3.1.9 is to be used.

3. FREEDOM OF MOVEMENT

Placing on the market

The minimal control foreseen by the directive is that an instrument must bear the manufacturer's mark or name, and its maximum weighing capacity before being put on the market. An instrument marked in this way, with the CE marking because of other directives but without the green metrology sticker is entitled to free movement on the Community market, that is to say, it can be marketed in any of the EC Member States without having to comply with any other requirements concerning metrology. However, for bringing into service the directive identifies certain applications that require the mandatory use of instruments that bear the CE conformity marking and the green metrology sticker.

The CE conformity marking and the green metrology sticker

(Note : black M on green square background could also be "painted" on the instrument, however in the rest of the text the word sticker is nevertheless used but to be understood as covering all situations)

The CE conformity marking, if accompanied by the green metrology sticker, signifies that the instrument carrying these two markings satisfies the essential requirements of directive 90/384/EEC and has been subjected to conformity assessment in accordance with it. Additionally, the CE marking signifies conformity with the provisions of all other directives applying to the instrument that require the affixing of the CE conformity marking.¹

The green metrology sticker is a supplementary metrology marking, *mandatory* under directive 90/384/EEC as is the CE marking itself, which indicates that the CE marking includes a declaration of compliance to essential requirements of directive 90/384/EEC.

The green metrology sticker is not to be regarded as what used to be known in the past as an initial verification mark. Such an initial verification mark does not exist any more for non-automatic weighing instruments.

¹ Of particular relevance is directive 89/336/EEC on electromagnetic compatibility, amended by directive 92/31/EEC. Instruments that are used for Article 1.2(a) applications are covered, for their immunity against electromagnetic disturbances, by directive 90/384/EEC. For their emission of electromagnetic disturbances, however, they are covered by directive 89/336/EEC. Instruments used for Article 1.2(b) purposes are covered by directive 89/336/EEC for emission and immunity.

Consequently, like the CE marking, the green metrology sticker may not be removed from an instrument that is used for Article 1.2(a) purposes. The CE marking and the green metrology sticker belong indissolubly together to signify conformity with the essential requirements of directive 90/384/EEC at the time the instrument was placed on the market and brought into service.

When the instrument consists of a set of modules and peripherals, operating together, the CE-marking, accompanied by the green metrology sticker, shall be affixed on the instrument's main module . However, both markings together concern the complete instrument, including modules and peripheral devices, as far as applicable (see chapter 5, paragraph 2).² Unfortunately, this system does not indicate what devices were subject to the conformity assessment procedure. This might be a problem for market surveillance authorities, in particular where devices have been connected after the instrument is in use, without involvement of the original manufacturer. However, in case of doubt, market surveillance authorities may require all necessary information from the original manufacturer especially by the way of the declaration of conformity which could identify the modules and peripherals composing the complete instrument covered by the declaration.

To leave no doubt, a module or a peripheral cannot be subject on its own to a conformity assessment procedure and a declaration of conformity with reference to the NAWI directive. This is only possible for complete instruments. A module or a peripheral can bear the CE marking according to other directives but it cannot bear the green metrology sticker. This is also true for POS (Point of Sale) devices. Conformity assessment procedures should be applied to the complete instrument, including the eventually connected POS device. Modules having a test certificate are not indemnified against the procedure described before. A test certificate can only serve to be accepted by a notified body responsible for EC type-examination of the complete instrument to avoid duplication of tests and in the case of application of WELMEC guide 2.5 on modular approach.

Note : Concerning module, peripheral and modular approach of NAWIs refer to Guide 2.5 on modular approach

Affixing the CE marking and the green metrology sticker to the instrument is the responsibility of the manufacturer of the complete instrument. This does not imply that the affixation must necessarily be carried out by the manufacturer himself. It can be carried out under the manufacturer's responsibility by his authorised representative established within the Community. Notified bodies involved in EC verification or EC unit verification cannot take responsibility for affixing the CE marking and/or the green metrology sticker.

Since the CE conformity marking and the green metrology sticker necessarily go together under the directive, for reasons of simplicity 'CE marking', 'CE marked

² This paragraph replaces the former paragraph of Guide 3.1 because it was not the intention to apply the green metrology sticker to each of the devices. Due to the former interpretation there could be instruments put into service prior to this new version of the guide which may bear a green M on the main part of the instrument and also on peripherals .

instrument', etc, refers hereafter to CE marking plus green metrology sticker, unless specified otherwise.

Inscriptions accompanying the CE marking

As a general rule where a notified body is involved in the conformity assessment procedure, its identification number must follow the CE marking. This general rule has been adopted in directive 90/384/EEC, Annex IV. This does not apply to the notified body for type examination.

According to Annex IV, section 1.1, (c), of the directive, the identification number(s) of the notified body/bodies that has/have carried out the EC surveillance or the EC verification or the EC unit verification shall be affixed to the instrument distinctly grouped together with the CE marking and the year.

According to Annex IV, section 1.1, (c), of the directive instruments subject to the EC conformity assessment procedure must bear the last two digits of the year in which the CE marking was affixed.

Arrangement of CE marking, green metrology sticker, last two digits of the year and notified body number

Although directive 90/384/EEC specifies that :

- the CE marking,
- the identification number(s) of the notified body/bodies that has/have carried out the EC surveillance or the EC verification,
- the green sticker with the capital letter M
- and the last two digits of the year

shall be affixed in a clearly visible, easily legible and indelible form to instruments for which EC conformity has been established, it does not require a mandatory arrangement especially for the green M.

For reasons of uniformity on non-automatic weighing instruments and taking into consideration what is applicable to other measuring instruments submitted to the MID (Measuring Instruments Directive) it is considered preferable to arrange the markings and inscriptions referred to before in the same order as prescribed by the MID (e.g. CE, green M , last two digits of the year of affixing, identification number (s) of notified body(ies)).

“Clearly visible” means visible to an enforcement officer when the instrument is in its normal operating position.

Putting into service

The special areas of use requiring CE marked instruments are listed in Article 1.2(a) of the Directive. All other applications do not require instruments CE marked

according to the NAWI directive to be used,; these are covered by Article 1.2(b) and may be required to bear the CE marking according to other directives.

The shape, design, construction or configuration of the instrument (e.g. bench scale, platform scale, weighbridge, ...) do not identify its use as an Article 1.2(a) or Article 1.2(b) use. Although the potential use of an instrument can sometimes be readily identified by its shape, design, etc, (e.g. price computing retail scale, kitchen scale, postal scale, ...), nevertheless the final decision can only be made when the instrument is put into service. Taking a postal scale as an example, post office (or other carrying companies) use would be an Article 1.2.(a) application, whereas use in the mail room of a company when it is not by this way that the tariff of transport is legally determined would be an Article 1.2.(b) application.

Article 1.2(a) uses

The applications that require the mandatory use of CE marked instruments cover the areas of commerce, health and public administration. They are specified in Article 1.2(a) and are:

1. **determination of mass for commercial transactions**, which deals with trading transactions where the goods are bought or sold by mass. The cost therefore is directly proportional to the mass of the product.
2. **determination of mass for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment**. This type of use not only includes situations where the payment is directly proportional to the mass, e.g remuneration, tax etc, but also situations where the mass value determines the cost of the service, e.g. post office use, laundry or airport baggage tariff, charge for transporting goods, disposal of waste.
3. **determination of mass for the application of laws or regulations; expert opinion given in court proceedings**, which covers the activities where an instrument is used by a person who is not an expert in metrology but is giving evidence based on weighing results. Instruments used for the same purposes by experts from metrological laboratories, government or public authority laboratories and forensic laboratories are therefore excluded on the condition that such laboratories keep their instruments properly maintained, calibrated and adjusted.
4. **determination of mass in the practice of medicine for the weighing of patients for the purposes of monitoring, diagnosis and medical treatment**, which covers those activities where medical staff are responsible for the weighing of patients. Examples are the use of weighing instruments in hospitals, health centres or taken into the community for medical purposes including diets. "Medical staff" includes all persons that lawfully carry out the medical weighing tasks concerned in their Member State.
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**, where medical laboratories are

laboratories that carry out analyses at the request of medical practitioners and pharmaceutical laboratories are quality control laboratories of manufacturers of medicinal products for human use (control of the final weight of a product, control of the composition of the product, gravimetric and quantitative analysis). Pharmaceutical laboratories do not include the research and development laboratories of manufacturers of these medicinal products.

6. **the determination of price on the basis of mass for the purposes of direct sales to the public and the making-up of pre-packages.** The former case covers the use of instruments with price calculation, in particular price-calculating retail sales, and the latter refers to scales used to make up pre-weighed non-predetermined quantities. Direct sales to the public is explained in Chapter 14.

Article 1.2 (b) uses

All uses other than Article 1.2(a) uses are Article 1.2(b) uses and do not require instruments CE marked under Directive 90/384/EEC.

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Uses for the following purposes are considered Article 1.2(b) uses.

- Sports and sporting records;
- Domestic use (kitchen, bathroom, ...);
- Geological surveys;
- Veterinary medicine; *Note: It should be noted that in some member states according to national regulation some uses like preparation of drugs for animals including certain products is however considered as regulated*
- Medical practice, except for the weighing of live patients;
- Goods inwards inspection, etc (checking scales);
- Weighing of goods for customer information only and not for the final determination of mass (not to be confused with self-service scales that are used for the final determination of mass) *Note: It should be noted that in some member states according to national regulation this type of “information use for the customer” is however still considered as regulated;*
- Weighing for any non-Article 1.2(a) purpose against payment. The payment represents a situation of commercial transaction for the determination of mass, which does not convert the use into an Article 1.2(a) use. (e.g.: coin operated person weighers).
- The use in quality systems. The metrological requirements that a measuring instrument, used in the operation of a quality system, needs to fulfil are, among other things, that it has appropriate accuracy and is properly calibrated and periodically recalibrated against traceable metrological standards by a metrological laboratory. These requirements apply regardless of the status of the system (private agreement between two parties, mandatory certification procedure, ...). Although they do not exclude the use of legal measuring instruments, they do not render them mandatory either.

Special case :

Although the use of instruments by

- Metrological enforcement agents;
- Metrological experts (eg national metrology laboratories, ...);
- Government or public authority laboratories, forensic laboratories, ...

had been initially considered as possible 1.2(b) uses due to the expertise of the user , it shall be recognised that it cannot be legally accepted in several countries and has brought doubts on the opinion of these experts in court proceedings. These uses that are clearly identified in 1.2(a) cannot be considered 1.2(b) on the basis that the weighing is made by an expert of the government (who in addition could possibly not be an expert in weighing).

Relationship with directive 76/211/EEC

Council directive 76/211/EEC on the making up by weight or by volume of certain pre-packed products provides in its Annex I, point 4 that legally controlled instruments must be used for the making up or the checking of pre-packages. The use of a non-automatic weighing instrument for any of these two alternatives is therefore an Article 1.2(a) use. The right to choose between the two alternatives offered by directive 76/211/EEC is not affected, however, by directive 90/384/EEC.

4. TRANSITION ARRANGEMENTS

Article 1.2(a) applications in certain Member States did not require CE marked instruments (in the sense of NAWI directive) until 1 January 2003, if on 31 December 1992, the particular Member State has not had requirements to use a controlled instrument for that application. Therefore, these Member States should have allowed the introduction onto their markets of instruments not carrying the CE marking plus green metrology sticker, for use in these areas for the full transition period (i.e. 10 years). However, the Member States were requested to encourage all manufacturers interested in these application areas to manufacture instruments capable of meeting the essential requirements, sufficiently in advance of the cut-off date of 1 January 2003.

In relation to type approvals, a distinction is made between EEC type approvals (granted under Council directive 73/360/EEC) and national type approvals (those granted under national legislation other than that which transposes directive 73/360/EEC).

An EEC type approval (with respect to Council directive 73/360/EEC) could not be granted after 31 December 1992. Those approvals that had an expiry date later than 31 December 1992 could not be renewed.

A national type approval could not be granted after 31 December 1992. Those valid on 1 January 1993 could be renewed or modified provided their validity after renewal or modification did not extend beyond 31 December 2002.

Even if there was no limit of validity in the national system of type approval system, none of the national approval certificates is valid after 31 December 2002.

From 1 January 2003 only non-automatic weighing instruments that meet the requirements of the Directive 90/384/EEC shall be placed on the market and in addition only NAWI that meet the essential requirements and have been subject to the conformity assessment procedures shall be put into service for 1.2(a) uses.

5. ESSENTIAL REQUIREMENTS

Annex I of the Directive contains the essential requirements that must be met by a non-automatic weighing instrument that is used in Article 1.2(a) applications. These are the technical and metrological performance requirements for the instrument and include the maximum permissible error (including mpe in service).

The essential requirements apply also to devices, included in or connected to a non-automatic weighing instrument that is used for an Article 1.2(a) application, if these devices are themselves also used for that application.

According to the preliminary observation of Annex 1, the only exception to this rule is the case of supplementary indicating or printing devices that are included in or connected to a non-automatic weighing instrument that is not used for direct sales to the public, if :

- they repeat the result of the weighing operation and cannot influence the correct functioning of the instrument, and
- the result of the weighing operation is printed or recorded correctly and indelibly by a part of the instrument that meets the essential requirements, and
- this result is accessible to both parties concerned by the measurement.

Under the above conditions and even though those supplementary indicating or printing devices have not gone through a procedure of conformity assessment and shall bear the red symbol referred to in article 12 of the directive, they may be used for Article 1.2(a) applications.

6. EUROPEAN STANDARD EN45501

A harmonised European standard for non-automatic weighing instruments, EN45501:1992/AC:1993, has been adopted by CEN/CENELEC. This standard not only sets down technical solutions to the essential requirements but also the tests that can be used to establish conformity with the performance requirements.

The references of this harmonised standard were published, in accordance with Article 5.2, in the Official Journal of the European Communities, nr. C 153 of 04.06.1994, page 17. Application of this standard, in whole or in part, provides presumption of conformity with the corresponding essential requirements.

It should be fully clear that presumption of conformity with the essential requirements of the Directive can only be valid for provisions in the standard related to the essential

requirements. This means that as long as the Directive does not specify essential requirements for modules (as example), aspects from the standard concerning modules cannot be used to presume conformity of the module with the Directive. Article 5(1) of the Directive justifies this opinion because “instruments” is not the same as “modules”.

7. NOTIFIED BODIES

Member States notify to the Commission and the other Member States the bodies they designate to carry out conformity assessment tasks, together with the specific tasks for which each body is designated. Designation and notification is carried out in accordance with the provisions of Article 9.

These bodies must fulfil a set of minimum criteria listed in Annex V of the directive.

The primary task of a notified body is to provide services for conformity assessment on the conditions set out in the directive.

Notified bodies may carry out the tasks of conformity assessment, within their scope of notification, also on the territory of any Member States or of third countries.

The member state responsible for their notification shall verify periodically that they fulfil the conditions wherever they work (minimum criteria in Annex V of the NAWI directive plus other designation criteria if any, and requirements resulting from the description of conformity assessment procedures or other articles of the directive).

Manufacturers are free to choose any notified body that has been designated to carry out the conformity assessment procedure in question according to the directive (with the exception of the case of a modification of an existing certificate according to 1.7 of annex II chapter 1).

The different conformity assessment procedures and the relevant tasks of notified bodies are explained in Chapter 8 of this Guide.

An actual list of notified bodies under the New Approach Directives is available on:

http://europa.eu.int/comm/enterprise/newapproach/legislation/nb/notified_bodies.htm

8. CONFORMITY ASSESSMENT

General

The procedures used to establish conformity with the essential requirements are laid down in Annex II of the Directive.

A non-automatic weighing instrument must undergo type examination followed by either EC declaration of type conformity (guarantee of production quality) or EC verification.

The exception to this general rule is the case of a NAWI which does not contain electronic devices and for which the load measuring device does not use a spring to balance the load. These instruments are considered sufficiently simple so that type examination is unnecessary and only the EC declaration of conformity or the EC verification is necessary).

Instruments that are custom-designed and custom-made for a specific application need only undergo EC unit verification. This procedure is also open to very small production series of instruments.

The conformity assessment procedures (see Annex I)

EC type examination

A notified body, chosen by the manufacturer or his authorised representative established within the Community among the bodies notified to the Commission for carrying out the task of type examination, tests and certifies that an instrument, representative of the production envisaged, meets the essential requirements of the Directive. The notified body issues an EC type-approval certificate that, among other things, contains enough information for the identification of the instrument. The certificate has a validity of 10 years but may be subsequently renewed. In special circumstances, such as the application of new technologies, the validity of the certificate may be reduced to 2 years with the allowance for an extension of 3 years.

An example for the layout of an EC type-approval certificate is given in WELMEC Guide 2 *Directive 90/384/EEC: Common application non-automatic weighing instruments*.

According to Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives, the manufacturer or his authorised representative established within the Community must keep with the technical documentation copies of EC type-approval certificates and their additions for a period ending at least 10 years after the last product has been manufactured.

At the request of market surveillance authorities the manufacturer or his authorised representative established within the Community must make available the EC type approval certificates and the technical documentation. To be discussed with the Commission, normally the member state shall have the TAC available from the Notified Body on periodic basis

EC declaration of type conformity (guarantee of production quality)

To use the procedure of EC declaration of type conformity (guarantee of production quality) a manufacturer must make application for approval of his production quality system to one of the bodies notified to the Commission for carrying out such work. Furthermore, the correct application of the quality system must be surveyed by that notified body. The EC declaration of type conformity (guarantee of production

quality) allows that the CE marking and the green metrology sticker are affixed to the products by the manufacturer under its quality system and without the intervention of a notified body for EC verification on each product).

The manufacturer or his authorised representative established within the Community shall affix to each instrument the CE marking, the green metrology sticker, the last two digits of the year in which the CE marking was affixed and the identification number of the notified body responsible for the EC surveillance.

The manufacturer or his authorised representative established within the Community shall draw up a written declaration of conformity. An example for the layout of a Declaration of conformity is given in WELMEC Guide 2 *Directive 90/384/EEC: Common application non-automatic weighing instruments*.

According to Council Decision 93/465/EEC a declaration of conformity is drawn up for each instrument model and the manufacturer or his authorised representative established within the Community must keep a copy of it at the disposal of the relevant national authorities for inspection purposes for a period of at least 10 years after the last product has been manufactured.

In such a procedure the manufacturer cannot declare that "he is notified to do the EC verification himself". The term "Notification" is only to be used by bodies independent of manufacturers and designated by a member state to perform EC verification.

In such a procedure a manufacturer cannot entitle another company to do part of the job for him unless it is covered by the quality assurance system as approved by the notified body.

EC verification

EC verification is the procedure under which a notified body, chosen by the manufacturer or his authorised representative, carries out tests to assure itself that the individual instruments conform to the approved type and to those of the essential requirements that are to be checked upon completion of the manufacture. If no type examination is required, the tests will assure conformity with the essential requirements.

The responsibility for the conformity of the instrument remains even in this case with the manufacturer. The responsibility of the notified body is limited to what it has examined and tested.

The notified body shall affix, or cause to be affixed, its identification number on each instrument the conformity of which to requirements has been established and shall draw up a written certificate of conformity relating to the tests carried out. The certificate of conformity shall be presented to the manufacturer or his authorised representative established within the Community. An example for the layout of a certificate of conformity is given in WELMEC Guide 2 *Directive 90/384/EEC: Common application non-automatic weighing instruments*.

The manufacturer or his authorised representative shall ensure that he is able to supply the notified body's certificates of conformity on request of, in particular, market surveillance authorities

The manufacturer or his authorised representative established within the Community shall affix to each instrument the CE marking, the green metrology sticker and the last two digits of the year in which the CE marking was affixed and if applicable and known in advance the number of the Notified Body.

The manufacturer or his authorised representative established within the Community shall draw up a written declaration of conformity. Although the NAWI directive does not require that it shall accompany the instrument when placed on the market and put into use, it is common and good practice to do so for example by including a copy of it in the user manual. An example for the layout of a Declaration of conformity is given in WELMEC Guide 2 *Directive 90/384/EEC: Common application non-automatic weighing instruments*.

According to Council Decision 93/465/EEC a declaration of conformity is drawn up for each instrument and the manufacturer or his authorised representative established within the Community must keep a copy of it at the disposal of the relevant national authorities for inspection purposes for a period ending at least 10 years after the last product has been manufactured.

EC unit verification

When a single instrument or very limited number of instruments is/are manufactured, usually custom-designed, the manufacturer or his authorised representative in the Community may choose to have conformity established by unit verification. This is the procedure where a notified body, chosen by the manufacturer or his authorised representative, establishes conformity of the instrument with the essential requirements of the Directive, without the instrument first having received a type approval.

The notified body shall affix, (or cause to be affixed), its identification number on each instrument for which the conformity to essential requirements has been established, and shall draw up a written certificate of conformity relating to the tests carried out. The certificate of conformity shall be delivered to the manufacturer or his authorised representative established within the Community. An example for the layout of a certificate of conformity is given in WELMEC Guide 2 *Directive 90/384/EEC: Common application non-automatic weighing instruments*.

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

The manufacturer or his authorised representative established within the Community shall affix to each instrument the CE marking, the green metrology sticker and the last two digits of the year in which the CE marking was affixed.

The manufacturer or his authorised representative established within the Community shall draw up a written declaration of conformity. Although the NAWI directive does not require that it shall accompany the instrument when placed on the market and put into use, it is common and good practice to do so for example by including a copy of it in the user manual. An example for the layout of a Declaration of conformity is given in WELMEC Guide 2 *Directive 90/384/EEC: Common application non-automatic weighing instruments*.

The manufacturer or his authorised representative established within the Community must keep a copy of it at the disposal of the relevant national authorities for inspection purposes for a period ending at least 10 years after the last product has been manufactured.

Execution in two stages

The conformity assessment procedures of EC declaration of type conformity, EC verification and EC unit verification may be carried out in a single stage or in two separate stages, at the manufacturer's choice. In the case of EC declaration of type conformity we are referring to those tests of the final product which form part of the manufacturer's quality system. The provisions relating to the choice of one or two stages, the place of their performance and the responsibilities of the bodies involved are contained in point 5 of Annex II of the Directive.

Criteria for the choice of one or two stage procedure, and place of assessment

After type examination (unless the instrument is exempted from it), one of the procedures referred to above must be carried out. The procedure chosen is, in principle, carried out in one stage at the manufacturer's works, provided transport of the instrument to its place of use, after establishment of its conformity, does not require dismantling; the putting into service at the place of use does not require assembly or installation work that is likely to affect the instrument's performance; and the gravity value at the place of use is accounted for when adjusting the instrument, if the weighing results are sensitive to gravity. The manufacturer may, however, choose to have the procedure carried out in two stages.

If the conditions referred to above are not satisfied, the procedure is carried out either in one stage at the place of use, or in two stages, where stage one is carried out at the manufacturer's works and stage two at the place of use. If the weighing results are gravity dependent, stage two must as a minimum comprise all examinations and tests whose outcome is gravity dependent. If the instrument has different modules, which have to be assembled at the place of use, the conformity assessment procedure has to include a part at the place of use (applicable in particular to scale + POS). In all cases (i.e. whether the weighing results are gravity dependent or not), stage two must comprise all examinations and tests not carried out in stage one.

Responsibilities of the bodies involved

When any of the relevant procedures above is carried out in two stages each instrument that passes from the first stage to the second must be accompanied by a certificate that details the examinations and tests carried out in the first stage and the necessary data for the identification of the instrument. The certificate is drawn up by the notified body in the case of EC verification or EC unit verification, or the manufacturer when he operates a quality system. Examples for the layout of certificates of tests are given in WELMEC Guide 2 *Directive 90/384/EEC: Common application non-automatic weighing instruments*.

An instrument which has undergone the first stage of the procedure shall bear the identification number of the notified body involved in that stage. In the case of EC declaration of type conformity (guarantee of production quality) this shall be the number of the notified body responsible for the approval and supervision of the manufacturer's quality system and shall be affixed by the manufacturer or its authorised representative within the Community. In the case of EC verification or EC unit verification this must be the number of the notified body involved in the first stage and shall be affixed, or caused to be affixed, by this notified body.

The tests and examinations that have not been carried out in the first stage must be carried out in the second stage. In the case of an instrument sensitive to gravity the second stage must comprise all examinations and tests where the results are gravity dependent.

A certificate of tests performed in the second stage shall be issued. The certificate is drawn up by the notified body in the case of EC verification or EC unit verification, or the manufacturer in case of declaration of conformity by quality assurance.³

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

The identification number of the body involved in the second stage must be affixed to the instrument too. This number shall be affixed, or caused to be affixed, by this notified body. Where two different bodies have been involved both their numbers are affixed.

If the same notified body is involved in the 2 stages even in 2 different types of assessment procedure (e.g. EC verification and surveillance of quality system) the number of this notified body need not be applied twice.

A manufacturer who operates a quality system may carry out the second stage himself if his quality system certification extends to the place of use of the instrument and to

³ This is not clearly stated in the directive but is a logical consequence in comparison with a one-stage procedure. *When the manufacturer has completely verified the instrument and so has issued only the declaration of conformity but then it is decided to put the instrument into service in another gravity zone than the one foreseen, there is a need for another adjustment and a second stage ; in this case the initial declaration of conformity has to be considered as a certificate of first stage with all tests done and only accuracy has to be checked at second stage.*

the technicians involved, otherwise he may opt for EC verification to finish the second stage.

On completion of the second stage the manufacturer or his authorised representative established within the Community shall affix to each instrument the CE marking, the green metrology sticker and the last two digits of the year in which the CE marking was affixed.

The manufacturer or his authorised representative established within the Community shall draw up a written declaration of conformity. An example for the layout of a Declaration of conformity is given in WELMEC Guide 2 *Directive 90/384/EEC: Common application non-automatic weighing instruments*.

According to Council Decision 93/465/EEC a declaration of conformity is drawn up for each instrument model and the manufacturer or his authorised representative established within the Community must keep it at the disposal of the relevant national authorities for inspection purposes for a period ending at least 10 years after the last product has been manufactured.

9. MOMENT OF AFFIXATION OF CONFORMITY MARKS AND IDENTIFICATION NUMBERS

On completion of the conformity assessment, the CE conformity marking, the green metrology sticker and the two last digits of the year must be affixed by the manufacturer or his authorised representative.

According to the “Guide to the implementation of directives based on the New Approach and the Global Approach”, the so-called Blue Guide, the CE marking may not, in principle, be affixed until the conformity assessment procedure has been completed to ensure that the product complies with all the provisions of the relevant directives. This is usually considered to be at the end of the production phase. However, in exceptional cases, the CE marking, the green metrology sticker and the two last digits of the year can be affixed at any other stage of the production phase, provided that the conformity of the product is verified as appropriate throughout the production phase and the conformity assessment procedure is successfully completed before the instrument is placed on the market.

Likewise, the affixation of their identification numbers is the responsibility of the notified bodies. Therefore, a notified body may affix its identification number itself, or have it affixed under its responsibility, e.g. by the manufacturer, if satisfactory (to the notified body) arrangements are made. Again, the physical affixation may be carried out in advance.

10. OTHER MARKINGS AND INSCRIPTIONS

A CE marked instrument shall also carry the additional markings and inscriptions, detailing the instrument’s specifications, according to the requirements of Annex IV of the directive.

An instrument CE marked according to the NAWI directive is presumed to be placed on the market for Article 1.2(a) uses and must therefore satisfy all provisions of the directive pertaining to this category of use, including the requirements on markings and inscriptions (identification number of the notified body involved, last two digits of the year of affixing of the CE marking,). An instrument placed on the market for Article 1.2(b) uses need not bear the green metrology sticker. It must at least carry the manufacturer's mark or name and the maximum weighing capacity. An instrument placed on the market for Article 1.2(b) uses may carry the CE marking (without the green metrology sticker). It indicates that this marking was affixed under another directive. A manufacturer may also decide to put on the market for 1.2(b) uses instruments which could also be used for 1.2(a) as they bear the CE and M and they have been submitted to the complete conformity assessment procedure.

When an instrument does not bear the CE mark with green M according to Directive 90/384 it is considered misleading if other markings especially the reference to the type approval certificate are put on it.

The red symbol of restricted use

Devices that are connected to or included as part of a CE marked instrument and have not been subject to conformity assessment must bear the red symbol of restricted use with the capital letter M in black crossed by an X.

These devices may not be used for any of the Article 1.2(a) purposes unless it is a situation as foreseen in preliminary note of Annex 1 of the directive where this device repeats the value and there is a printer or data storage device (not applicable in direct sales to the public)

11. SUPERVISION OF INSTRUMENTS IN USE

All instruments used for Article 1.2(a) purposes must be supervised to see that they continue to comply with the requirements of the directive. The Member States are free to establish their own systems of inspection and control but they should ensure that these do not lead to barriers to trade.

This means among other things that the provisions for marking of the instruments under the national systems of inspection and control, to show their status to user and inspector, shall not lead to the obligation of having to satisfy additional requirements before they can be placed on the market or put into service.

12. NATIONAL RULES APPLYING TO THE USE

Member States are free to establish national rules on the *use* of legal measuring instruments, providing these do not lead to barriers to trade. This means e.g. requirements for the installation of an instrument such that customers can see the platform and the mass indication where a freight or postage is determined, or for additional labelling of the instrument in relation to its use to be put on by the user, or

to forbid weighing of the same body in two operations, or prescribing a class for some uses.

13. REPEALS

Directive 73/360/EEC has been repealed from the 1 January 1993.

14. MISCELLANEOUS

Manufacturer and authorised representative

“Manufacturer” means a natural or legal person responsible for the conformity of the measuring instrument with the Directive with a view to either placing it on the market under his own name and/or putting it into use for his own purposes;

“Authorised representative” means a natural or legal person who is established within the Community and authorised by a manufacturer, in writing, to act on his behalf for specified tasks within the meaning of this Directive

Note 1 : It does not mean an authorisation for a dealership, selling or repairing of NAWI.

Note 2 : An authorised representative is not allowed to further authorise others persons or companies. It is the responsibility of the manufacturer only.

Note 3 : The NAWI directive refers to “bringing into service” (article 2) and “putting into service” (article 4) with the same meaning as “putting into use” mentioned in the definition above which is used in the measuring instrument directive.

Direct sales

A situation of direct sales exists when all of the following conditions are satisfied:

1. The weighing operation is carried out for, and simultaneously with, a trading transaction where goods are bought or sold by mass;
2. The customer is present when the weighing operation is carried out;
3. All aspects of the trading transaction are concluded at that time and place.

Condition 1 excludes weighing operations for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity, or similar type of payment. Direct sales is strictly limited to the buying and selling of goods.

The customer in a trading transaction where goods are bought or sold by mass is the party that is not responsible for the instrument being used for the weighing. The customer is usually the buying party but can, in some cases, be the selling party. Where the weighing instrument used is a self service instrument, operated by the customer in the absence of the other party, this is direct sales.

Direct sales to the public

Direct sales to the public exists when direct sales as defined above is taking place in respect of goods being bought or sold by a private person being the ultimate consumer.

Field trials

Where a need to carry out trials in working conditions is established, this shall be dealt with by issuing a type approval certificate, limited in time according to point 1.4 of Annex II of the directive (two years, with possibility of extension by another three years), and, if necessary, limited in validity according to paragraph 1 of the same point. In the latter case, conditions for validity that one might think of could be, e.g. the number of instruments covered by the certificate, the location in which the instruments must be installed, and the like.

Changing the instrument after it has been put into use

According to the “Blue Guide” (Chapter 2), a product, which has been subject to important changes that aim to modify its original performance, purpose or type after it has been put into service, may be considered as a new product. This has to be assessed on a case-by-case basis and, in particular, in view of the objective of the directive and the type of products covered by the directive in question. Where a rebuilt or modified product is considered as a new product, it must comply with the provisions of the applicable directives when it is placed on the market and put into service. At least a manufacturer, with all his responsibilities, has to be defined for this new instrument. The person who carries out important changes to the product is responsible for verifying whether or not it should be considered as a new product.

In principle any extension or changing in a used instrument exceeding a repair or a service is considered a new product with all consequences concerning placing on the market and bringing into use.

For the judgement on whether a modification is important or not the following might be taken into account.

Article 3 (2nd paragraph) of Directive 90/384/EEC states: “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”.

From this it can be concluded that if devices, which are not used for the applications listed in article 1(2)(a), are connected to the instrument after it has been put into service, such a modification may be regarded as not important.

Another point to be taken into account is Annex I, preliminary observation, of Directive 90/384/EEC, that states : “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”.

From this it can be concluded that connecting , for example, a printer to an instrument that is not used for direct sales to the public after it has been put into service is regarded as not being an important modification.

However, Article 12 of Directive 90/384/EEC states : “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.”

From the last point it can be concluded that connection of a POS to a direct selling scale is an important modification. The complete instrument needs to be submitted to a conformity assessment procedure and a declaration of conformity.

From this, it is justifiable to conclude that devices that have not been subject to conformity assessment shall bear the “red M”, even if these devices are or have been connected to the instrument after it has been put into service. It is also justifiable to conclude that the person responsible for the modification shall affix the “red M”.

Note: It should be clear that when these devices have been connected to the instrument during the EC declaration of type conformity (guarantee of production quality) as referred to in Annex II.2, or the EC verification as referred to in Annex II.3, or the EC unit verification as referred to in Annex II.4, the manufacturer or his authorised representative shall affix the “red M”.

Hybrid instruments

Hybrid instruments are instruments that perform more than one measurement function.

Where a measuring instrument has a non-automatic weighing mode of operation together with one or more other measurement modes, then the instrument must be the subject of conformity assessment under directive 90/384/EEC in so far as it relates to the non-automatic weighing mode of operation. The other measurement modes could relate to automatic weighing, volume or length measurement, pressure measurement, etc.

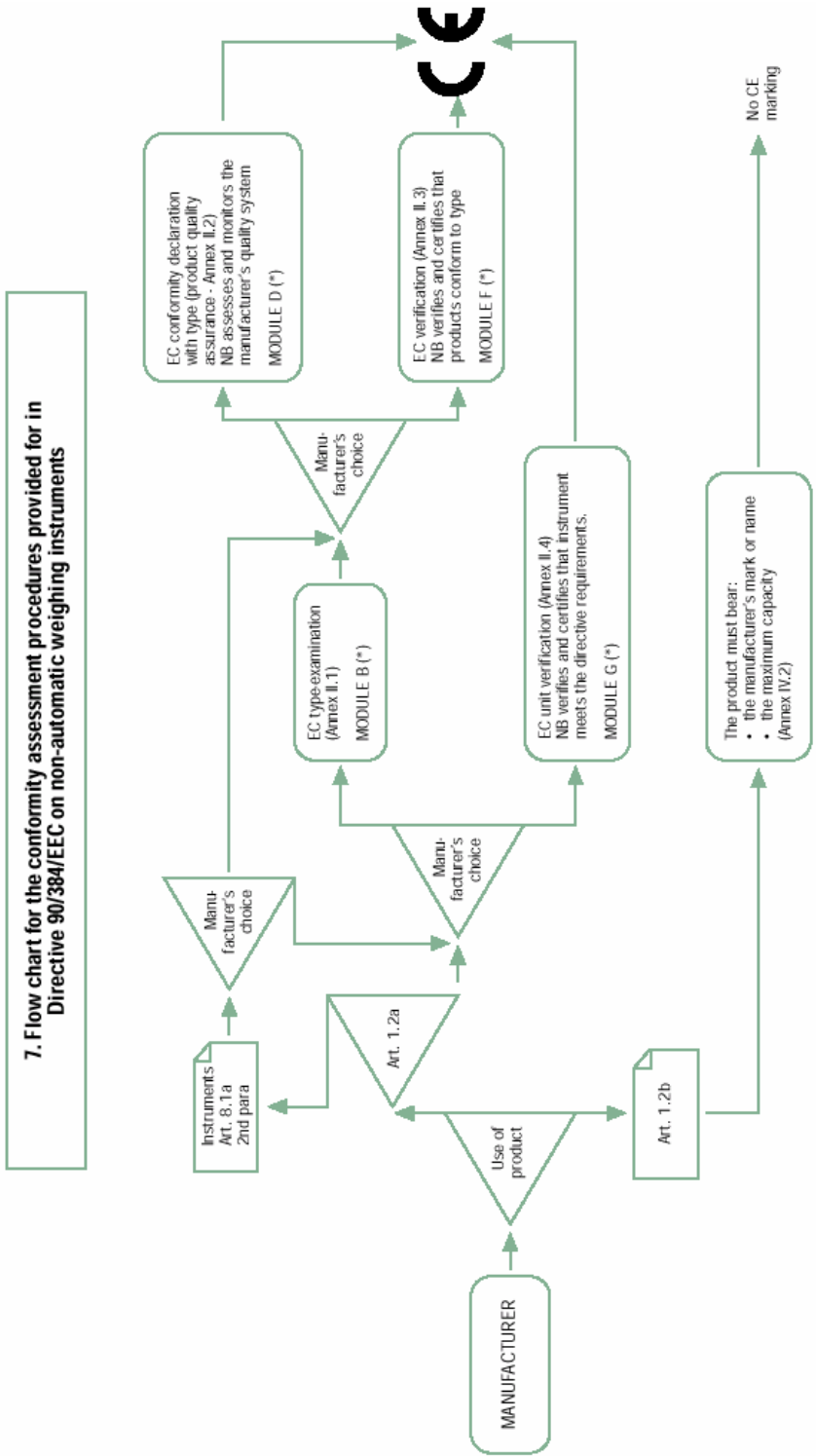
The EC type approval certificate issued must clearly state that the EC conformity marking and green metrology sticker cover only the non-automatic weighing mode of operation and that the other measurement modes are the subject of national controls. These other measurement modes may not be the subject of national prescriptions in all Member States.

A hybrid instrument having a non-automatic weighing mode of operation may therefore carry the CE conformity marking with green metrology sticker, as well as a national marking where appropriate.

Where an automatic weighing instrument has a non-automatic mode of operation for the purpose of calibration or setting up only, then the weighing instrument is only subject to national controls related to automatic weighing instruments, not to directive 90/384/EEC.

Note concerning the flow chart on next page :

In the drawing the “no CE marking” at the right end should be completed by “according to NAWI directive” so it means only “no green M” because the product could bear the CE marking for other directives.



(*) These procedures were approved before the adoption of Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.

ANNEX I