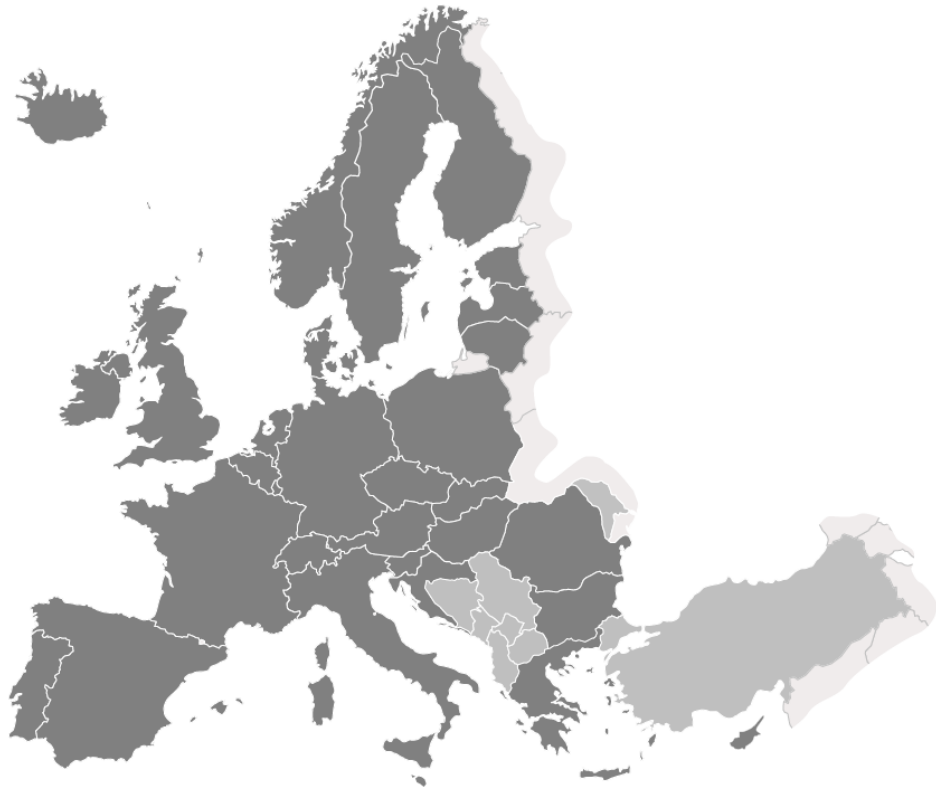


WELMEC

European Cooperation in Legal Metrology

Guide on the General and Administrative Aspects of the Voluntary System of Modular Evaluation of Measuring instruments



WELMEC

European Cooperation in Legal Metrology

WELMEC is a cooperation between the legal metrology authorities 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 EU 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 guide deals with the general and administrative aspects of the voluntary system of modular evaluation of measuring instruments under the Non-Automatic Weighing Instruments Directive (NAWID) and the Measuring Instruments Directive (MID).

This guide is only intended for the evaluation of parts that can be subject to the voluntary system of modular evaluation of the measuring instrument and should not be abused as a guide for modular certification of the whole measuring instrument.

Although the system of modular approach for measuring instruments is voluntary, it is intended that the procedures as described in this guide shall be followed if Certificates are issued under the scope of this guide.

- *It is reminded that the issuing of an EC, PC, PER, ER for a part by another notified body doesn't prejudge full responsibility of the notified body responsible for the conformity assessment of the complete measuring instrument.*
- *It is also reminded that it is the manufacturer of the complete instrument who is responsible for designing and manufacturing the measuring instrument in conformity with the requirements.*
- *Even if modular evaluation is used, the manufacturer shall apply for a conformity assessment procedure for the complete measuring instrument.*
- *The part may bear the applicable CE marking according to Directives other than the MID or NAWID and after evaluation the EC or PC number, but it cannot bear the supplementary metrology marking and notified body number relating to the MID or the NAWID.*

The original guide dates from December 2008.

The revision to version 2 of the guide in 2011 has been made to include non-automatic weighing instruments under the voluntary evaluation of parts and to extend the scope of the voluntary evaluation of parts to module D, F and G of the MID and the NAWID.

The revision to version 3 in 2017 was made to implement the changes in the revised Non-Automatic Weighing Instruments Directive, 2014/31/EU (NAWID) and the revised Measuring Instruments Directive 2014/32/EU (MID) and to include a procedure with respect of a revision of an Evaluation or Part Certificate.

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1 DEFINITIONS AND ABBREVIATIONS

In this document, in addition to the definitions from the reference documents (see chapter 7), the following abbreviations and definitions are applied:

NAWID

Non-Automatic Weighing Instruments Directive, 2014/31/EU.

MID

Measuring Instruments Directive, 2014/32/EU.

NB

notified body.

Measuring instrument

Where ever this guide mentions measuring instruments it also covers non-automatic weighing instruments under the NAWID.

Part

A part of a measuring instrument or a sub-assembly which performs a specific function and can be evaluated separately. This includes devices, modules and peripherals, for example but not limited to: printers, data storage devices and (personal) computers.

(Under this guide software is not considered a part of a measuring instrument or a sub-assembly and can therefore not be evaluated separately. It should always be evaluated with a certain part, see chapter 4.)

Producer

The Original Equipment Manufacturer (OEM) that produces the part.

Testing

An activity during which the applicable performance tests are carried out and deviations / errors of the part under tests are determined, in comparison with reference values.

As a result of testing, a Test Report can be issued.

Examination

An activity during which:

- the technical documentation for the part, sub-assembly or measuring instrument is confirmed to be in accordance with the applicable requirements;
- the part, sub-assembly or measuring instrument is confirmed to be constructed in accordance with the documentation, and
- the part, sub-assembly or measuring instrument is confirmed to be in accordance with the applicable requirements, in particular when applicable, to be equipped with a clearly readable display, properly operating software, checking facilities, markings, etc.

Typically, a checklist is completed as part of the examination which shall form part of an evaluation report.

Evaluation

An activity where it is confirmed that the part, sub-assembly or measuring instrument submitted for evaluation meets the applicable requirements.

Evaluation includes the study of examination results and/or the study of test results.

Upon successful completion of an evaluation a "statement of conformity" (e.g. Certificate, EU type-approval or EU-type examination Certificate, OIML Certificate, Part Certificate, Evaluation Certificate) is issued.

Modular Evaluation

An activity which confirms that a part of a measuring instrument or a sub-assembly, if foreseen by the MID, meets the applicable requirements.

OIML Pattern Evaluation Report (PER)

A document presenting a record of an evaluation, performed in accordance with an OIML Recommendation.

Remarks:

- In OIML Recommendations, the word "Pattern" or "Type" can be used for both a complete measuring instrument and for a part of a complete measuring instrument.
- In OIML Recommendations the term Test Report is also used.

Evaluation Report (ER)

A document presenting a record of an evaluation, performed in accordance with a harmonised standard, normative document or WELMEC guide.

Compatibility sheets

Compatibility sheets are documents that indicate the relevant quantities and characteristics identified, which together establish the conformity of the complete instrument to the essential requirements, and the conditions for compatibility with other parts, interfaces and sub-assemblies.

Evaluation Certificate (EC)

A document that describes the relevant metrological characteristics of a part of a measuring instrument, including its compatibility with other parts, interfaces and / or sub-assemblies.

An EC under this guide can only be issued by a test institute that can also act as a notified body under the MID or NAWID for Conformity Assessment Module B for that particular measuring instrument.

An EC can only be issued if the part is evaluated and found to conform with an OIML Recommendation, harmonised standard, normative document and/or a WELMEC guide as a means of harmonised interpretation of examining parts, and a PER or ER is issued. Reference to the PER or ER must be included in the EC to identify that they belong together.

An EC can only be issued if the technical documentation conforms to the requirements of Article 18 of the MID even if the part is exclusively used for NAWI.

This technical documentation shall be kept by the notified body that has issued the EC. Following an individual permission of the owner of the EC that the technical documentation can be sent to other notified bodies in support of a conformity assessment procedure.

However, the owner of the EC agrees a priori, with the application for an EC, that copies of the technical documentation, PER or ER and certificates shall always be sent to the market surveillance authorities of the Member States by the notified body that has issued the EC if that market surveillance authority request for it in respect to Article 19 of the EC Regulation 765/2008.

Parts that have been issued with an EC can only be used by manufacturers of complete measuring instruments after permission of the owner of the EC.

Parts that have been issued with an EC are not eligible for general acceptance in an EU type examination (or EU type-approval) certificate.

Parts Certificate (PC)

A document that describes the metrological relevant characteristics of a part of a measuring instrument, including its compatibility with other parts, interfaces and sub-assemblies.

A PC under this guide can only be issued by a test institute that can also act as a notified body under the MID or NAWID for Conformity Assessment Module B for that particular measuring instrument.

A PC can only be issued if the part is evaluated and found to conform with an OIML Recommendation, harmonised standard, normative document and/or a WELMEC guide as a means of harmonised interpretation of examining parts, and a PER or ER is issued. Reference to the PER or ER must be included in the PC to identify that they belong together.

A PC can only be issued if the technical documentation conforms to the requirements of Article 18 of the MID even if the part is exclusively used for NAWI. This technical documentation shall be kept by the notified body that has issued the PC.

Parts that have been issued with a PC can be freely used by manufacturers of a complete measuring instruments. The owner of the PC agrees a priori, with the application for a PC, with the free use of the PC, and that copies of the technical documentation, PER or ER and certificates shall be made available on request to other notified bodies in the cause of a conformity assessment procedure and that copies of the technical documentation, PER or ER and certificates shall always be sent to the market surveillance authorities of the Member States by the notified body that has issued the PC if that market surveillance authority request for it in respect to Article 19 of the EC Regulation 765/2008.

Parts that have been issued with a PC are eligible (under the responsibility of the notified body involved in the evaluation of the complete instrument) for general acceptance in an EU type examination or EU type-approval certificate, provided that the PC has been issued by a test institute that can also act as a notified body under the MID for Conformity Assessment module B for that particular measuring instrument or, in the case of parts exclusively used in NAWI, by a test institute that can act as a notified body under the NAWID for EU type examination.

And under the condition that the PC has not been withdrawn, see 4.1.3.

Test Certificate (TC)¹

TCs are tools to facilitate EU type examination of NAWI's. They deal with parts of, or peripherals to, a NAWI. In order to receive a TC, parts and peripherals must be in conformity not only with the essential requirements of Directive 2009/23/EC², but also with the specific requirements contained in the harmonised standard and/or the applicable WELMEC guides as a means of harmonised interpretation of existing regulations.

Originally TCs are tools to allow, under the wording of an EU type-approval certificate, to connect a peripheral to a NAWI or to include a part in a NAWI.

TEC

A TEC is an EU-type examination certificate under conformity assessment module B of the MID or the NAWID, whichever is applicable.

Market surveillance authority

Market surveillance authority shall mean an authority of a Member State responsible for carrying out market surveillance on its territory based on EC Regulation No. 765/2008 of the European Parliament and of the Council of 9 July 2008.

¹ WELMEC 2.5 (Issue 2), page 5, article 2.8 with the extension on the use of the technical documentation and conversion to the definitions used in this guide.

² Reference is made to the old Directive because only under this directive and the previous ones Test Certificates have been issued.

2 INTRODUCTION

The MID and the NAWID aim to harmonise the legal requirements for Measuring Instruments and non-automatic weighing instruments within the European Union.

Remarks

- *The MID includes provisions to deal with sub-assemblies, but only for the categories of measuring instruments specified in Annexes IV (MI-002) and VI (MI-004).*
- *There is no sub-assembly approach in the NAWID.*

In practice, measuring instruments often consist of an assembly of parts produced by different Original Equipment Manufacturers (OEMs), in this document referred to as “producers”. In that case, a manufacturer builds the several parts together into a complete measuring instrument, with the objective of placing such a measuring instrument on the market or putting it into use.

If such a part performs a specific/defined function inside the design of the measuring instrument, it can be evaluated separately with respect to its specific function as part of the complete design.

If such a part fulfils prescribed functional aspects of a measuring instrument and conforms to the applicable OIML recommendations, harmonised standards, normative documents and/or WELMEC guides, a document illustrating such compliance can be issued.

Although this is not a procedure which stems from the NAWID or the MID, it is common practice in legal metrology. In order to accommodate this (cost efficient) practice, and without prejudice of the possibility for the manufacturer to use other means possible under the MID and NAWID, the following procedure of modular evaluation is considered to be appropriate by WELMEC because this guide secures the requirements within MID or NAWID that the Member State has access to the technical documentation.

It is reminded that in any case the application concerning the complete instrument (or sub-assembly if foreseen by the MID) should still be delivered to a notified body.

3 SCOPE AND BORDERS

This document describes for notified bodies, manufacturers and producers, and all other interested parties (e.g. notified bodies under modules B, D, F and G of the MID, or the NAWID, notifying authorities and market surveillance authorities) the conditions for a harmonised procedure for a voluntary system of modular evaluation of measuring instruments covered by the NAWID and measuring instruments covered by the MID under conformity assessment:

- Module B, EU-Type Examination,
- Module D, Conformity to type based on quality assurance of the production process,
- Module F, Conformity to type based on product verification and
- Module G, Conformity based on unit verification.

This document is limited to the general and administrative aspects of such an approach, leaving the instrument specific and technical aspects to be specified by the applicable WELMEC Working Groups.

It should be noted that it is the responsibility of the manufacturer of the complete instrument to be able to demonstrate the conformity to all applicable requirements of the MID or NAWID, as appropriate, even in case the modular evaluation is used.

The manufacturer should therefore ensure that the producer(s) of the part(s) used in the measuring instrument take(s) responsibility with respect to compliance to type and to compliance to the requirements against which the part(s) have (has) been evaluated.

Even if modular evaluation is used, the manufacturer shall apply for a conformity assessment procedure for the complete measuring instrument or, in some categories of measuring instruments under the MID, for sub-assemblies.

The manufacturer of the measuring instrument or the sub-assembly shall make available the technical documentation, as described in Article 18 of the MID or, in the case of a NAWI, as described in Annex II, article 1.3 of the NAWID, to the Notified Bodies in the cause of a Conformity Assessment Procedure or to the market surveillance authority of the Member States if they request for it in respect to Article 19 of the EC Regulation 765/2008, including the documentation relating to the parts which have been evaluated in accordance with the modular evaluation, including the certificates belonging to the measuring instrument, such as the TEC, EC and PC.

The part may bear the CE marking according to Directives other than the MID or NAWID and the EC or PC number, but it cannot bear the supplementary metrology marking and notified body number relating to the MID or NAWID.

Only a complete measuring instrument (or sub-assembly if foreseen by the MID) can bear the supplementary metrology marking and notified body number relating to conformity to the MID or NAWID.

If specific annexes exist in the MID, laying down the essential requirements for sub-assemblies, the provisions of this guide shall apply *mutatis mutandis* to such sub-assemblies as it does to complete measuring instruments under the MID.

Please note that a sub-assembly approach under the NAWID is not possible.

4 GENERAL PRINCIPLE

Below, in chronological order, the general (administrative) principle of the voluntary system of modular evaluation is described.

4.1 Evaluation of a part of a complete measuring instrument

Under this guide software is not considered a part of a measuring instrument or a sub-assembly and can therefore not be evaluated separately. It should always be evaluated with a certain part.

A producer of a part of a complete measuring instrument can make an application to a notified body requesting an evaluation (with reference to this guide) of that particular part of a measuring instrument against the relevant OIML recommendations, harmonised standards, normative documents and/or WELMEC guides.

Together with the application the producer shall provide the technical documentation in line with article 18 of the MID even if the part is exclusively used for NAWI.

It is the producer who has to specify whether a PC or EC is required.

The producer shall indicate that he is aware of the fact that:

- the technical documentation, the PER or ER shall be sent by the notified body to the market surveillance authorities of the member states if they request for it in respect to Article 19 of the EC Regulation 765/2008.
- he should provide the manufacturer of measuring instruments, to whom he has given permission to use its part, the necessary individual technical data for the compatibility with other parts, interfaces and sub-assemblies as foreseen in the relevant OIML recommendations, harmonised standards, normative documents, WELMEC guides and/or the compatibility sheets.
- he shall ensure that each individual part he provides with reference to the PC or EC is in conformity with the type that was evaluated and certified.
- he shall inform the notified body, which has issued the EC or PC, and the manufacturer using the part when he considers or has reason to believe that a part does not comply with the requirements. He shall also inform manufacturer that use his part if the EC or PC has been withdrawn.
- he shall inform the notified body, which has issued the EC or PC, and the manufacturer using the part of any modification that may affect the conformity of the part or the conditions of validity of the EC or PC, so that an evaluation of the modified part can be performed. This evaluation may result in a revision of the PC or EC being issued;
- he cannot affix the supplementary metrology marking and notified body number according to MID or NAWID on the part and he cannot provide or make any general statement of conformity to the MID or NAWID based on the PC or EC issued by the notified body. However, there is no objection to putting the EC or PC number on the part.

The notified body shall then

- examine if the technical documentation for the part fulfils the requirements of article 18 of the MID;
- examine the information provided to ensure that compatibility with other parts, interfaces or sub-assemblies can be established.

The notified body shall also conduct an evaluation of the part. When the evaluation is completed with a positive result, the notified body may issue a PC or an EC, depending on the request of the producer.

An EC or a PC can only be issued if the part is evaluated and found to conform with OIML recommendations, harmonised standards, normative documents and/or WELMEC guides, and a PER or ER is issued. Reference to the PER or ER must be included in the EC or PC to identify that they belong together.

The EC or PC shall include reference to the applied OIML recommendation, harmonised standard, normative document and / or WELMEC guide including the applied version of the used documents.

The EC or PC shall include all relevant information describing the parts appearance, applicability, functionality and the conditions which have to be satisfied in order to guarantee the compatibility with other parts, interfaces and sub-assemblies.

The EC, PC, PER, ER and any paper related to the part and issued by the notified body cannot bear the reference of the notified body as this is not a notified body activity and cannot contain any statement of conformity to the MID or NAWID.

The notified body that issues the EC or PC shall keep the technical documentation based on article 18 of the MID.

With the increasing use of modular approach, it is important for notified bodies and market surveillance authorities to have access to EC/PC certificates. It is therefore necessary that Member States make these certificates available through their national database.

4.1.1 Revision of an EC or PC

A revision of an EC or PC is possible if the conformity to type of measuring instruments that are already installed remains unchanged by the revision. This means that the latest revision should contain all of the information from the previous versions of the EC or PC, and that a reduction of the metrological characteristics of already certified parts is not possible.

The principles of the revision that can be allowed to an EC or PC will need to be defined in the specific WELMEC guides for that part, together with the conditions under which a new EC or PC is required.

4.1.2 Revision or update of evaluation documents

In the case of a revision, update or withdrawal of an OIML recommendation, harmonized standard, normative document and / or WELMEC guide the notified body shall determine whether such changes require further investigation of the part.

If so, the notified body shall inform the producer accordingly.

Such investigation may result in a new evaluation of the part and a revision of the EC or PC or in the case of non-compliance in the withdrawal of the EC or PC.

In case of a withdrawal of an EC or PC, 4.1.3 applies.

4.1.3 Withdrawal of an EC or PC

It is not allowed for a producer to withdraw an EC or PC.

Withdrawal of an EC or PC is only possible after an evaluation of a notified body or market surveillance authority that proves the non-compliance of the part.

In the latter case the notified body that has issued the EC or PC should withdraw the certificate and inform other notified bodies and Member States. The Member States are then recommended to make the status of the EC or PC available in their national database together with the date of obsolescence. After a withdrawal, it might be necessary to revise the EU-type examination certificates, see also 4.2.2.

Withdrawal of a part because of a non-compliance might necessitate corrective actions from the manufacturers with respect to instruments placed on the market or into use or already in use depending on the reason for the withdrawal.

For example, if the EC or PC was unjustifiably issued to a part that does not comply with the applied evaluation document with the consequence that the measuring instrument does not comply with the essential requirements, corrective actions of the manufacturer with respect to instruments placed on the market or into use or already in use is necessary.

4.1.4 Referencing within an EC or PC to another PC

Referencing within an EC or PC to another EC or PC should be avoided. Only under very specific circumstances, see below, is referencing within an EC or PC allowed.

- Reference in an EC or PC can only be made under the following conditions:
 - Reference in a PC to an EC is not allowed.
 - Reference in an EC to another EC is allowed provided that the producer of the EC, which is referenced to, gives his permission.
- The PC or EC of the part that is referenced in the EC or PC of another part should fulfil the conditions as defined under this guide.
- The part is a physical device, it is not possible to reference in an EC or PC to software with an EC or PC.
- The reference can only be made to an EC or PC that has no reference to another EC or PC. The level of certificates within an EC or PC should be limited to only one level.

The technical working groups should define in the appropriate technical guides which parts could contain reference to another part, see 6.

4.1.5 Transforming an EC into a PC

The transformation of an EC into a PC through a revision of the certificate is allowed if the conformity to type of measuring instruments that are already installed remains unchanged by the revision.

This means that the PC should contain all the information from the EC, and that a reduction of the metrological characteristics of already certified parts is not possible.

A note in the PC should describe that this revision was made because of the transformation of the EC into a PC. With that note a revision of the EU-type examination certification to include the certificate as a PC is then not necessary.

4.1.6 Transforming a PC into an EC is not allowed

The transformation of a PC into an EC is not allowed.

4.2 Conformity assessment of a complete measuring instrument

4.2.1 General

For conformity assessment of a complete instrument in accordance with the MID, an application shall be made to a notified body under the MID not necessarily the one who has evaluated the part(s). This guide covers the conformity assessment procedure under module B, D, F and G of the MID.

For conformity assessment of a NAWI, an application shall be made to a notified body under the NAWID, not necessarily the one who has evaluated the part(s).

Remarks

- *The issuing of an EC, PC, PER, ER for a part by another notified body doesn't prejudice full responsibility of the notified body responsible for the conformity assessment of the complete instrument.*
- *It is also reminded that it is the manufacturer of the complete instrument who is responsible for designing and manufacturing the instrument in conformity with the requirements.*

The application for conformity assessment of the complete measuring instrument should comply with the relevant requirements of the MID or the NAWID.

The guidance in this guide is specific for the use of parts with an EC, PC, PER, and/or ER.

4.2.1.1 Application

The application for conformity assessment procedure for EU-type examination, unit verification or quality assurance of the production process under the MID or the NAWID can (partly) be supported by EC(s) and/or PC(s), and the associated PER(s) and/or ER(s) of the part(s), indicating the conformity of those part(s) with the relevant requirements.

- If the application is supported by (a) PC(s) then the notified body can request the manufacturer to provide the PC(s) together with the PER or ER through the notified body that has issued the PC(s).
- If the application is supported by (an) EC(s) then the manufacturer should supply the notified body either with a copy of the EC(s) and the PER(s) and/or ER(s), or the notified body can request the manufacturer to provide the EC(s) together with the PER(s) or ER(s) through the notified body that has issued the EC(s). Without a copy of these documents, the EC(s) and PER(s) and/or ER(s) cannot be included in the application.

The application for the complete measuring instrument for

- type examination,
- unit verification or

- quality assurance of the production process

under the MID shall include the technical documentation as described in Article 18 of the MID or, in the case of a NAWI, as described in article 1.3 Application of Annex II, Module B or as set out in article 6.2 of Module G.

Remarks

- *In the case of a part with a PC or EC, the technical documentation of the used parts shall be made available. A notified body can require the manufacturer to provide these documents either directly or through the notified body that has issued the EC or PC.*

With the application, the notified body should remind the manufacturer that special attention should be given to the necessary compatibility sheets that need to be prepared. These compatibility sheets should be included in the application for all conformity assessment procedures.

4.2.1.2 Evaluation of the measuring instrument

The notified body, within its sole responsibility, determines if the application and the supporting documents are complete and satisfy all the relevant requirements for the measuring instrument specified in the application.

Additional tests and examinations may be required.

4.2.2 EU-type examination, module B

When the notified body has determined that the measuring instruments comply with the essential requirements, a TEC is issued in the name of the manufacturer of the instrument. In the TEC, the necessary information for the conformity of the parts is included.

All the relevant technical information as foreseen by the appropriate directive shall be annexed to the TEC; this may include the used EC(s) and PC(s).

In particular, to allow the conformity of manufactured instruments to be evaluated with the examined type regarding the reproducibility of their metrological performances, when they are properly adjusted using appropriate means, the content shall be compatible with WELMEC guide 8.3, point 6.

The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation, particularly in the case of a revision, update or withdrawal of an OIML recommendation, harmonized standard, normative document and / or WELMEC guide which might be relevant to the parts.

Or in case an EC or PC is withdrawn, see 4.1.3.

If so, the notified body shall inform the manufacturer accordingly.

In the case that there is no longer presumption of conformity for the measuring instrument with certain parts with an EC or PC a revision of the TEC is necessary. The revision of the TEC should indicate that Measuring Instruments with these parts can from a specific date no longer be put on the market or in to use with reference to the EC-number or in case of a PC with reference to the OIML recommendation, harmonised standard, normative document and / or WELMEC guide including the applied version of the used documents under which the part has been evaluated.

4.2.3 Unit Verification, module G

When the notified body has determined that the measuring instruments comply with the essential requirements, a Certificate of Conformity is issued in the name of the manufacturer of the instrument.

If applicable, evaluation of the compatibility sheets that indicate the relevant quantities and characteristics identified, which together establish the compatibility of the complete measuring instrument to the essential requirements and the conditions for compatibility with other parts, interfaces and sub-assemblies, is recommended.

4.2.4 Quality Assurance of the production process, module D

Special attention should be made to the conformity of the production of the part (s) delivered by a producer. The manufacturer of the measuring instrument may not transfer his responsibility regarding the conformity of the production of the part(s) to the producer.

If applicable, evaluation of the compatibility sheets that indicate the relevant quantities and characteristics identified, which together establish the conformity of the complete instrument to the essential requirements and the conditions for compatibility with other parts, interfaces and sub-assemblies, is needed.

4.2.4.1 Audit of a producer

Some producers provide parts to several different manufacturers and consequently it is possible that those producers will be audited several times a year by more than one NB in charge of Module D for each of the different manufacturers. To reduce the costs associated with these audits, a producer may decide to be audited by one of these NBs independently from the audits of manufacturers, following the provisions defined in WELMEC guide 8.4.

If this is the case, the NB in charge of the quality system (QS) approval of the manufacturer may take into consideration the audit reports issued by the NB that has evaluated the QS of the producer. To this aim, these audit reports are to be held available by the producer for the NB in charge of the QS approval of the manufacturer.

It is not foreseen in all cases that the quality system of the producer has to be certified. However, in the case of voluntary audits, the report and the procedure used shall be in conformity with the WELMEC guides 8.4 and 8.6 with the necessary adaptation.

4.2.5 Product verification

Special attention should be made to the conformity of the production of the part delivered by a producer. The manufacturer of the measuring instrument may not transfer its responsibility regarding the conformity of the production of the part to the producer.

If applicable, evaluation of the compatibility sheets that indicate the relevant quantities and characteristics identified, which together establish the conformity of the complete instrument to the essential requirements and the conditions for compatibility with other parts, interfaces and sub-assemblies, is needed.

5 TRANSITIONAL ARRANGEMENTS FOR TEST CERTIFICATES

Under the NAWID many TC have been issued in accordance with WELMEC guide 2.5: Guide for modular approach and testing of Personal Computers and other digital peripheral devices (Non-automatic Weighing Instruments). These TCs have been used for the evaluation of automatic weighing instruments under the MID and have been quoted in the TEC.

However, it was decided by WELMEC working group 2 during the 31st meeting to use this guide also in the field of non-automatic weighing instruments. The decision was also endorsed by the WELMEC Committee during the May 2010 meeting.

The consequence of that decision is that for new applications only EC or PC can be issued according to this guide.

- However, to avoid that a large number of TECs have to be revised to include general acceptance in the TEC for parts with a PC it is allowed that a PC for a certain part can have two titles, namely Part Certificate and Test Certificate. The double title avoids that new reference must be made in the TEC to PCs for parts that are eligible for general acceptance in the TEC while still maintaining the conformity to type. The double title is however not allowed under this guide for ECs. The technical WELMEC workings groups should define for which parts with a PC a double title can be quoted. In any case, the PC with a double title cannot bear a reference to a notified body number.
- Because Test Certificates are widely implemented in the TEC it will still be possible to revise, modify or extend these Test Certificates. However, with any modification to the Test Certificate, the producer should be made aware that regarding the responsibilities and conditions of use of the Test Certificates, in particular regarding the availability of the technical documentation, the conditions apply as described in this guide.
- However, in the case of a revision, modification or extension of the TC, the part should comply with the latest version of the OIML recommendation, harmonized standard, normative document and / or WELMEC guide, whichever is applicable. The upgraded TC should have a reference to the version and applicable OIML recommendation, harmonized standard, normative document and / or WELMEC guide which has been applied for the evaluation of the part.
- Test Certificates cannot be transferred into a PC or an EC because in the TEC reference is made to the TC. If the TC is transferred into a PC or an EC, then the complete measuring instrument as described in the TEC is no longer in conformity to type. If the producer wants to convert his TC into an EC or PC a new EC or PC, with a new number, must be issued. The old TC will remain valid to avoid problems as described with conformity to type.
However, it is possible on a TC to additionally include a PC title. Under this guide, it is not allowed on a TC to additionally include an EC title.

6 TECHNICAL ASPECTS

The relevant WELMEC Working Groups are to identify which parts of the measuring instrument can be subject to the voluntary system of modular evaluation of the measuring instrument, under which conditions and what evaluation should be carried out.

Until then it is presumed that parts identified by OIML recommendations, harmonised standards, normative documents and/or WELMEC guides can be subject to the voluntary system of modular evaluation of the measuring instrument.

The principles of the revision that can be allowed to an EC or PC will need to be defined in the specific WELMEC guides for that part, together with the conditions under which a new EC or PC is required, see 4.1.1.

In the case of a revision of a WELMEC guide, OIML recommendation or (harmonised) standard, the relevant working group should indicate what the implications are for the existing certificates, i.e. the revision has no influence on the existing EC or PC, or additional evaluation is necessary with detail on what kind of evaluation is required, or existing EC or PC give no longer presumption of conformity to the revised WELMEC guide, OIML recommendation or (harmonised) standard, see 4.1.2.

The relevant WELMEC Working Groups should also define the relevant information that have to be in the EC or PC describing the parts appearance, applicability, functionality and the conditions which have to be satisfied in order to guarantee the compatibility with other parts, interfaces and sub-assemblies.

The EC or PC should in any case have a reference to the version and applicable OIML recommendation, harmonized standard, normative document and / or WELMEC guide which has been applied for the evaluation of the part.

The technical working groups should define in the appropriate technical guides which parts could contain reference to another part under the conditions stated in 4.1.4.

The relevant WELMEC Working Groups are also to define under which conditions parts are included in the TEC and for which parts general acceptance is allowed and under which conditions³.

In any case, the TEC should specify that only a PC can be used that has not been withdrawn, see 4.1.3.

The relevant WELMEC Working Groups are also to define the necessary compatibility sheets that indicate the relevant quantities and characteristics identified which together establish the conformity of the complete instrument to the essential requirements and the conditions for compatibility with other parts, interfaces and sub-assemblies.

³ For example: some critical parts may not be eligible for general acceptance in an EU-type examination certificate.

7 REFERENCE DOCUMENTS

- DIRECTIVE 2014/32/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast) (Measuring Instruments Directive MID).
- DIRECTIVE 2014/31/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (recast).
- OIML International Vocabulary of Terms in Legal Metrology, edition 2013.
- WELMEC Guide 8.1, edition 1 June 2006 Guide on Terms and definitions in MID and their relation to terms defined in other international metrologically relevant documents.