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WELMEC

European cooperation in legal metrology

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



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WELMEC

European cooperation in legal metrology

WELMEC is a co-operation 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 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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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:

Part

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

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 equipment 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 documentation relating to the part, sub-assembly or instrument is confirmed to be in accordance with the applicable requirements;
- the part, sub-assembly or instrument is confirmed to be constructed in accordance with the documentation, and
- the part, sub-assembly or 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 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, EC type-approval or EC type examination Certificate, OIML Certificate, Part Certificate, Evaluation Certificate) is issued.

Modular Evaluation

An activity which confirms that a part of a measuring instrument meets the applicable requirements.

OIML Pattern Evaluation Report (PER)

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

N.B. 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.

Evaluation Report (ER)

A document presenting a record of a (modular) 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 for Conformity Assessment Annex B for that particular measuring instrument or, in the case of parts exclusively used in a NAWI, by a test institute that can act as a Notified Body under the NAWI Directive for EC type examination.

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 10 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 individual permission of the owner of the EC, 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 holder of the EC.

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

Parts Certificate (PC)

A document that describes the metrologically 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 for Conformity Assessment Annex B for that particular measuring instrument or, in the case of parts exclusively used in a NAWI, by a test institute that can act as a Notified Body under the NAWI Directive for EC type examination.

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 10 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 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 765/208.

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 EC type examination or EC 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 Annex 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 NAWI Directive for EC type examination.

Test Certificate (TC)¹

TCs are tools to facilitate EC 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

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.

not only with the essential requirements of Directive 2009/23/EC, but also with the specific requirements contained in EN 45501 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 EC type-approval certificate, to connect a peripheral to a NAWI or to include a part in a NAWI.

TEC

A TEC is an EC type examination certificate under conformity assessment annex B of the MID or an EC type-approval certificate (TAC) under the EC type examination procedure under the NAWI-directive, 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.

2 INTRODUCTION

The Measuring Instruments and the Non-Automatic Weighing Instruments (NAWI) Directives aim to harmonise the legal requirements for Measuring Instruments and non-automatic weighing instruments within the European Union.

Remarks

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

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, the 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 NAWI Directive 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 NAWI directive, the following procedure of modular evaluation is considered to be appropriate by WELMEC.

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

The original guide dates from December 2008. This revision of the WELMEC guide is 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 annex D, F and G of the MID.

3 SCOPE AND BORDERS

This document describes for notified bodies, manufacturers and producers, and all other interested parties (e.g. notified bodies under annex B, D, F and G of the MID, notified bodies for EC type examination, EC verification, EC declaration of type conformity and EC unit verification under the NAWI Directive, notifying authorities and market surveillance authorities) the conditions for a harmonised procedure for a voluntary system of modular evaluation for non-automatic weighing instruments covered by the NAWI Directive and measuring instruments under conformity assessment:

- annex B, Type Examination,
- annex D, Declaration of Conformity to type based on Quality Assurance of the production process,
- annex F, Declaration of Conformity to type based on product verification and
- annex G, Declaration of Conformity based on unit verification

of the MID.

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 the NAWI Directive, 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 10 of the MID or, in the case of a NAWI, as described in Annex III, Design Technical documentation, of the NAWI Directive, 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 765/208, including the documentation relating to the parts which have been evaluated in accordance with the modular evaluation.

The part may bear the CE marking according to Directives other than the MID or NAWI Directive and the EC or PC number, but it cannot bear the supplementary metrology marking and Notified Body number relating to the MID or NAWI Directive. 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 NAWI Directive.

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 NAWI directive is not possible.

Where ever this guides mentions measuring instruments it also covers non-automatic weighing instruments under the NAWI-directive.

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

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.

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

Together with the application the producer shall provide the technical documentation in line with article 10 of the MID even if the part is exclusively used for NAWI.

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 may need to provide the manufacturer of measuring instruments, to whom he has given permission to use its part, with 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/pattern that was evaluated and certified;
- he shall inform the Notified Body, which has issued the EC or PC, 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. The producer shall inform the manufacturers using the part of the modification;
- he cannot affix the supplementary metrology marking and Notified Body number according to MID or NAWI Directive on the part, and he cannot provide or make any general statement of conformity to the MID or NAWI Directive 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 10 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 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.

The Notified Body that issues the EC or PC shall keep the technical documentation based on article 10 of the MID.

4.1.1 Revision

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 modifications 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.

4.2 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 annex 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 NAWI Directive, 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 has to comply with the relevant requirements of the MID or the NAWI Directive.

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 type examination or unit verification under the MID and EC type-examination and EC unit verification under the NAWI directive 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 10 of the MID or, in the case of

- EC type-examination,
- EC declaration of type conformity or
- EC unit verification

of non-automatic weighing instruments, as described in Annex III, Design Technical documentation, of the NAWI-directive. For instruments not subject to EC type-approval under the NAWI-directive, the documents relating to the design of the instrument, as set out in Annex III, must be accessible to the notified body should the latter so request.

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 Type examination²

When the Notified Body has determined that the 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 annex 3: "Example for a model of certificate " of WELMEC guide 8.3 and include in particular:

- the metrological characteristics of the type of instrument and its parts;
- measures required for ensuring the integrity of the instruments and its parts (sealing, identification of software, etc.);
- information on other elements necessary for the identification of the instruments and its parts and to check their visual external conformity to type;
- if appropriate, any specific information necessary to verify the characteristics of manufactured instruments and its parts;

² Conformity Assessment Procedures, Annex B of the MID: Type examination or Annex II Conformity Assessment Parts of the NAWI-directive: 1. EC type-examination.

- all necessary information to ensure the compatibility with other parts, parts or sub-assemblies of measuring instruments.

4.2.3 Unit Verification³

When the Notified Body has determined that the 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 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 process⁴

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 recommended.

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 Annex 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.

³ Conformity Assessment Procedures, Annex G of the MID: Declaration of Conformity based on unit verification or Annex II Conformity Assessment Parts of the NAWI-directive: 4. EC unit verification.

⁴ Conformity Assessment Procedures, Annex D of the MID: Declaration of Conformity to type based on quality assurance of the production process or Annex II Conformity Assessment Parts of the NAWI-directive: 2. EC declaration of type conformity (guarantee of production quality).

4.2.5 Product verification⁵

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 recommended.

5 Transitional arrangements for Test Certificates

Under the NAWI Directive many Test Certificates 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 Evaluation or Part Certificates 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 have to 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 with regard to 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.
- 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

⁵ Conformity Assessment Procedures, Annex F of the MID: Declaration of Conformity to type based on product verification or Annex II Conformity Assessment Parts of the NAWI-directive: 3. EC verification.

new EC or PC with a new number, has to be issued. The old TC will still 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 for which parts of the measuring instrument modular evaluation is possible, 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.

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 relevant WELMEC Working Groups are also to define under which conditions parts are included in the TEC⁶.

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.

7 REFERENCE DOCUMENTS

- DIRECTIVE 2004/22/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on measuring instruments (Measuring Instruments Directive MID).
- DIRECTIVE 2009/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2009 non-automatic weighing instruments (2009/23/EG).
- OIML International Vocabulary of Terms in Legal Metrology, edition 2000.
- 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.

⁶ For example: some critical parts may not be eligible for general acceptance in an EC type examination or type-approval certificate.