

# WELMEC

European Cooperation in Legal Metrology

## **Application of module B: EU-type examination**

Under directive 2014/32/EU (MID) or  
directive 2014/31/EU (NAWID)



# 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 is one of those which complete the general guide on the assessment and operation of notified bodies performing conformity assessment in application of the Measuring Instrument Directive (MID) and the Non-Automatic weighing instruments Directive (NAWID).

Several guides have been established for the detailed application of some modules of MID and the NAWID, see the WELMEC website. These guides should not be read without taking into consideration all relevant aspects in all the guides related to a module.

This guide is intended to provide guidance to all those concerned with the application of module B, EU-type examination, of the Directive 2014/32/EU and Directive 2014/31/EU.

This Guide covers both directives, the MID and the NAWID, although small differences exist in the text of Module B of the MID compared with the text in the NAWID. Also, the numbering of the articles is not the same.

For this guide the text and numbering of the articles of the MID is used. In Annex 3 of this guide a table is given with the correct text and numbering of Module B of the MID and the NAWID which also highlights the differences between these two texts.

If the documents mention measuring instruments than both NAWI and MI under the MID is meant.

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## Guidance on Module B: EU-type examination

[The guidance notes are indicated in *italics*.]

1. 'EU-type examination' is the part of a conformity assessment procedure in which a notified body examines the technical design of an instrument and verifies and attests that the technical design of the instrument meets the requirements of this Directive that apply to it.

*In the case where the validation of the technical design of an instrument has never been subject of a previous examination, the entirety of essential requirements is required to be checked by the notified body.*

*In the case of a modification of an instrument that may affect the conformity to specific essential requirements or conditions of validity of the certificate, a partial evaluation is possible. The NB shall clearly establish the technical reasons which justify this partial evaluation.*

*The renewal of a former certificate to extend its period of validity is also covered by the directives MID and NAWID.*

*Renewal is the privileged moment for the notified body to consider*

- *the changes in the generally acknowledged state of the art, see article 7 of Module B of the MID or article 1.7 of Module B of the NAWID,*
- *any change in harmonised standards, if harmonised standards have been used to declare conformity to the essential requirements,*
- *information coming from past manufactured measuring instruments (MI),*
- *if available information coming from the market surveillance and or*
- *information on instruments in use.*

*That information can be considered to confirm or not the conformity of MI to the essential requirements.*

*When the denomination of the manufacturer or its authorised representative changes, the notified body should change the existing EU-type examination certificate. This modification requires additional approval in the form of an addition to or a revision of the original EU-type examination certificate. In this procedure, the design features of the type remain unchanged therefore evaluation of the measuring instrument is not necessary.*

*The recipient of the EU-type examination certificate is the manufacturer in any case.*

## 2. EU-type examination may be carried out in either of the following manners:

- a) examination of a specimen, representative of the production envisaged, of the complete measuring instrument (production type),
- b) assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the instrument (combination of production type and design type);
- c) assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

*The notified body should decide, in each case, the appropriate method of examination (a, b or c) and if a specimen of the MI is required or not in the procedure.*

*Because these three methods are intended to procure confidence in the conformity to the essential requirements, NBs could use the criteria presented in table 1 that take into account the fact that the instrument is composed or not of parts that have already been validated by a test institute that can act as a notified body in the scope of a voluntary WELMEC system of modular evaluation (see WELMEC guide 8.8) or in the scope of other recognised systems such as the OIML Certificate System or in the case of previous approvals.*

| <b>Table 1</b>                                |                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                |                                                                                                        |
|-----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| <b>Method</b>                                 |                                                                                                                                                                                                                                                           | <b>Instrument composition</b>                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                |                                                                                                        |
| <b>Method available according to module B</b> | <b>Criteria of choice intended to use by notified body for an initial examination</b>                                                                                                                                                                     | <b>MI composed with unknown critical parts</b>                                                                                                                                                                                                                                                                                                                                                    | <b>MI composed with some critical parts already tested according to WELMEC guide 8.8 or equivalent</b>                                                                         | <b>MI only composed with critical parts already tested according to WELMEC guide 8.8 or equivalent</b> |
| <b>a)</b>                                     | <i>This method is most appropriate if the instrument does not have an OIML Certificate of Conformity or is not composed of parts with an OIML Certificate of Conformity or an EC or PC/TC under WELMEC guide 8.8 or testing of parts is not possible.</i> | <i>This method should be used for:</i> <ul style="list-style-type: none"> <li>• First evaluation</li> <li>• Modifications to type which can affect the conformity to the essential requirements</li> <li>• Renewal if conformity to the essential requirements of manufactured MI can't be demonstrated</li> <li>• If there are changes in the generally acknowledged state of the art</li> </ul> |                                                                                                                                                                                |                                                                                                        |
| <b>b.</b>                                     | <i>This method is most appropriate when testing of parts is the only possibility or if a part does not have an OIML Certificate of Conformity or an EC or PC/TC under WELMEC guide 8.8</i>                                                                | <i>This method should be used for:</i> <ul style="list-style-type: none"> <li>• First evaluation</li> <li>• Modifications which can affect the conformity to the essential requirements</li> </ul>                                                                                                                                                                                                | <i>The method should be used for:</i> <ul style="list-style-type: none"> <li>• First evaluation of parts that does not have an OIML Certificate of Conformity or an</li> </ul> |                                                                                                        |

|           |                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                  |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|           |                                                                                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>• <i>Renewal if conformity to the essential requirements of manufactured MI can't be demonstrated and if a critical part was identified to have a correlation with observed non-conformities</i></li> <li>• <i>If there are changes in the generally acknowledged state of the art</i></li> </ul> | <p><i>EC<sup>1</sup> or PC<sup>2</sup>/TC<sup>3</sup> under WELMEC guide 8.8</i></p> <ul style="list-style-type: none"> <li>• <i>Renewal if conformity to the essential requirements of manufactured MI can't be demonstrated and if a critical part was identified to have a correlation with observed non-conformities.</i></li> <li>• <i>If there are changes in the generally acknowledged state of the art</i></li> </ul> |                                                                                                                                                                                                                                                                                                                                  |
| <b>c.</b> | <p><i>This method is most appropriate when the complete MI has an OIML Certificate of Conformity or if all the critical parts of the MI have an OIML Certificate of Conformity or an EC or PC/TC under WELMEC guide 8.8 or in the case of minor modifications of the type.</i></p> | <p><i>This method should be used for:</i></p> <ul style="list-style-type: none"> <li>• <i>Minor modifications to type</i></li> <li>• <i>Renewal if conformity of manufactured MI is demonstrated</i></li> <li>• <i>There are no changes in the generally acknowledged state of the art</i></li> </ul>                                    | <p><i>This method should be used for:</i></p> <ul style="list-style-type: none"> <li>• <i>Minor modifications to type</i></li> <li>• <i>Renewal if conformity of manufactured MI is demonstrated</i></li> <li>• <i>There are no changes in the generally acknowledged state of the art</i></li> </ul>                                                                                                                          | <p><i>This method should be use for:</i></p> <ul style="list-style-type: none"> <li>• <i>First evaluation</i></li> <li>• <i>Modification of type</i></li> <li>• <i>Renewal if conformity of manufactured MI is demonstrated</i></li> <li>• <i>There are no changes in the generally acknowledged state of the art</i></li> </ul> |

<sup>1</sup> Evaluation Certificate (see WELMEC guide 8.8)

<sup>2</sup> Part Certificate (see WELMEC guide 8.8)

<sup>3</sup> Test Certificate (see WELMEC guide 8.8)

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

- a) the name and the address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- b) a written declaration that the same application has not been lodged with any other notified body;
- c) The technical documentation, (see *article 18 of MID or article 1.3 c) of Annex II of the NAWID*), shall make it possible to assess the instrument's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s).

*The technical documentation shall include an adequate analysis and assessment of the risk(s), in which the manufacturer identifies all risks, relevant to the measuring instrument, assesses them (quantitative, qualitative or combined) and classifies them (for example - major, marginal, negligible or minor) according to the assessment.*

*It is recognised that if a measuring instrument complies within the rated operating conditions with the essential requirements that this would cover most of the risks associated with the measuring instruments.*

*It is however expected that the following aspects should be assessed:*

- *Suitability of use in those cases where the use of the MI could influence conformity to the essential requirements. For example, the use of gas meters with bio gas or the use of measuring systems for the continuous and dynamic measurement of quantities of liquids other than water for cryogenic liquids or bio fuel, the use of automatic weighing instruments with heavy products.*
- *Durability, particularly for gas-, water-, thermal energy-meters as well as for liquids other than water for the cases mentioned above or if harmonised standards or normative documents<sup>4</sup> are not applied for durability.*
- *Software risk assessment to establish if the legally relevant software, parameters and data are adequately protected against accidental or unintentional changes and against intentional changes by unauthorised persons.*

*When the risks are classified the manufacturer produces and implements a plan with optimal measures for their limitation.*

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

*The technical documentation shall be sufficiently detailed to ensure compliance with the following requirements:*

- a) *the definition of the metrological characteristics;*
- b) *the reproducibility of the metrological performances of produced measuring instruments when properly adjusted using appropriate intended means;*
- c) *the integrity of the measuring instrument.*

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<sup>4</sup> *Generally, the durability tests are a part of harmonised standards or normative documents and therefore cover the risks associated with the measuring instruments on this point".*

*NB should establish a form or another equivalent document which clearly indicates the contents of the technical documentation requested to the manufacturer or its representative.*

*Table 2 gives guidelines to establish the technical documentation to fulfil requirements of article 18 of the MID.*

*The requirements for the technical document of a NAWI are not so detailed and is given in article 1.3 of module B of the NAWID. Nevertheless, table 2 below could be used for NAWI's as well.*

*When the instrument is composed of parts with a EC or a PC, 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, see WELMEC guide 8.8.*

| <b>Table 2</b>               |                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Article 18 of the MID</b> | <b>Text of the article</b>                                                                                                                                                                  | <b>Documentation that the NB should request</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>a</b>                     | a general description of the measuring instrument;                                                                                                                                          | <p><i>A commercial leaflet describing the instrument or a customised note explaining the measurement concept should be acceptable.</i></p> <p><i>This description could be completed by the definition of the metrological characteristics presented as a table taken into account all metrological parameters listed in the relevant specific annex.</i></p> <p><i>In case of modification of an already approved instrument, the note can be limited and focussed on the modification by itself.</i></p> <p><i>A table with the corresponding EC or PC/TC or OIML Certificate of Conformity corresponding to the part would also be helpful.</i></p> |
| <b>b</b>                     | conceptual design and manufacturing drawings and plans of components, sub-assemblies, circuits, etc.;                                                                                       | <p><i>Those documents could be those established by the company during the design phase.</i></p> <p><i>The NB could ask the manufacturer to limit document to those which are necessary for MID evaluation.</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>c</b>                     | manufacturing procedures to ensure consistent production;                                                                                                                                   | <p><i>When the manufacturer has a quality system certified by an accredited certification body, the copy of the ISO 9001:2015 certificate with the pertinent scope and / or the Module D certificate (see WELMEC guide 8.4) ensure that the production is consistent.</i></p> <p><i>Otherwise, a note explaining details of actions undertaken to ensure consistent production (final product verification procedure, surveillance of the manufacturing process...) is a solution to fulfil this item.</i></p>                                                                                                                                         |
| <b>d</b>                     | if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation; | <p><i>This items should be limited to useful information needed in the scope of this evaluation.</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>e</b>                     | descriptions and explanations necessary for the understanding of the information referred to in points (b), (c) and (d), including the operation of the measuring instrument;               | <p><i>This item could be limited to a note or a chart to explain links between the documents, drawings, diagrams corresponding to the paragraph b, c, d</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

| <b>Table 2</b>               |                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                             |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Article 18 of the MID</b> | <b>Text of the article</b>                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Documentation that the NB should request</b>                                                                                                                                                                                                                                             |
| <b>f</b>                     | a list of the harmonised standards and/or (in the case of MI under the MID) normative documents, applied in full or in part, the references of which have been published in the Official Journal of the European Union;                                                                                                                                                                                                                        | <i>This item could be presented as a table taken into account the relevant paragraphs of the standard.</i>                                                                                                                                                                                  |
| <b>g</b>                     | descriptions of the solutions adopted to meet the essential requirements where the harmonised standards and/or (in the case of MI under the MID) normative documents have not been applied, including a list of other relevant technical specifications applied;                                                                                                                                                                               | <i>a list of deviations from the harmonised standards and/or (in the case of MI under the MID) normative documents together with a cross reference to other relevant specifications if applicable should be acceptable.</i>                                                                 |
| <b>h</b>                     | results of design calculations, examinations, etc.;                                                                                                                                                                                                                                                                                                                                                                                            | <i>Those data are limited to evidence useful to NB for its evaluation.</i>                                                                                                                                                                                                                  |
| <b>i</b>                     | the appropriate test results, where necessary, to demonstrate that the type and/or the measuring instruments comply with the following: <ul style="list-style-type: none"> <li>the requirements of this Directive under declared rated operating conditions and under specified environmental disturbances,</li> <li>the durability specifications for gas-, water-, thermal energy-meters as well as for liquids other than water;</li> </ul> | <i>Test results may come from the manufacturers laboratory, third party test institutes or from producers of parts.</i><br><br><i>An OIML Certificate of Conformity with the related test report or an EC or PC/TC (and if requested with the related test report) is also appropriate.</i> |
| <b>J</b>                     | the EU-type examination certificates or EU design examination certificates in respect of measuring instruments containing parts identical to those in the design.                                                                                                                                                                                                                                                                              | <i>This item could be summarized in a table with the corresponding EU-type examination certificates or EC design examination certificates and technical conditions for compatibility with interfaces and sub-assemblies.</i>                                                                |

- d) the specimens, representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;

*The applicant should be able to supply the NB with a sufficient quantity of samples, prototypes or equipment to:*

- check that the samples, prototypes or equipment correspond to the specifications in the technical file and comply with the essential requirements,*

- *perform the EU-type examination tests.*

*If the applicant modifies the design of the instrument during the certification procedure without the written agreement of the NB, the entire examination procedure may be rendered invalid.*

*Modifications made to the equipment to correct any nonconformity identified by the NB should be made under conditions specified by the NB itself. These modifications shall be documented by the applicant and detailed in an addition to the technical documentation to be submitted to the NB.*

- e) the supporting evidence for the adequacy of the technical design solution.

This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards, and/or normative documents have not been applied in full.

The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

*The required elements concerns:*

- *the test report and the justification that standards used were correctly implemented by the manufacturer itself or its sub-contractor. In general, at this stage, there is no specific requirement for demonstrating the competence of the test laboratory.*
- *Evidence concerning the validation of the test methods if harmonised standards or normative documents have not been used. Those evidences may include: comparison of results corresponding to methods carried out and those described in the normative document or harmonised standards or validation of methods based on modelling or numeric simulations.*

*To help the manufacturer, the NB could organise technical visits focussed on specific evaluations to evaluate methods proposed by the manufacturer and to establish the corresponding evidences.*

4 The notified body shall:

*The procedure laid down in 4.1 to 4.5 concerns the method a and ~~the~~ method b for aspects on examination of specimens, representative of the production envisaged, of one or more critical parts of the measuring instrument.*

*As far as possible or practicable, the full set of tests should be performed on the same individual instrument. This is particularly important as far as influence factors (See OIML D 11, equivalent to rated operating conditions in MID) are concerned (that is as far as respect of maximum permissible errors is relevant for influence quantities).*

*However there are several cases where it may be envisaged not to perform all tests and examinations on the same instrument without adjustment or modification during type evaluation:*

- *the request concerns a family of MIs and it is not economically possible to make all tests on all instruments,*
- *some tests may be destructive,*
- *unfortunately the MI needs to be readjusted in the course of tests,*
- *unfortunately the MI needs modifications in the course of tests or examination,*
- *there is a need to share tests between two (or more) MIs in order to be able to issue quickly a type examination certificate,*
- *the normative test procedure gives specific provisions on the matter,*
- *the request concerns the modification of a type already approved and for economic and technical reasons it is not planned to submit the modified type to the full set of examinations and tests,*
- *...*

*Each time a body in charge of type examination does not perform (or does not require) the full set of examinations and tests on any concerned MI (in particular in the case of a family of MIs) and/or each time adjustments or modifications are performed in the course of type approval, this body must have established a clear policy in order to be sure that any MI covered by the application is able to fulfil all applicable provisions without any non-allowed adjustment and/or modification.*

#### 4.1 For the instrument:

*The examination corresponding to the description in 4.1 to 4.5 shall lead to the conclusion that each of the applicable requirements is respected.*

*Typically, the type examination of a new MI necessitates:*

- *examination of the technical documentation to check the conformity to the applicable requirements for aspects for which this checking is possible or necessary;*
- *checking that the MI is constructed in conformity with the technical documentation (this is an essential aspect);*
- *checking that the technical documentation is established with a sufficient level of detail, to ensure the adequate verification of conformity to type;*
- *testing and examining the instrument or its critical parts to check the conformity to the applicable requirements for aspects for which this checking is possible or necessary (see 4.2).*

*In case the measuring instrument or part of the measuring instrument has been tested before, the procedure may involve only some aspects of the here above described one, but it necessitates at least a review of the technical documentation with respect to the checking that the MI is constructed in conformity with the technical documentation, see 4.2.*

*As the result of identifying the elements which have been designed in accordance with the relevant provisions of the harmonised standards or in the case of a MI under the MID, the normative documents, all relevant requirements in the harmonised standards or in the case of a MI under the MID, the normative documents become applicable requirements. If the instrument does not respect these requirements, the procedure in 4.4 applies.*

*Examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the instrument;*

*Basically, checking the conformity to the applicable requirements using the technical documentation is appropriate in particular in the case of certain complex requirements such as on the integrity of the*

*software, management of error codes, methods of configuration of the instrument or compatibility of parts composing the instrument.*

#### 4.2 For the specimen(s):

verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or normative documents, as well as the elements which have been designed in accordance with other relevant technical specifications;

*This is particularly relevant for the application of 4.3 or 4.4.*

4.3 carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and normative documents, these have been applied correctly;

(Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal, see also article 6 of module B).

*General considerations in line with guidance in 4.1.*

*Basically, checking the conformity to the applicable requirements using the MI or its critical parts is appropriate to confirm the conclusion of the review of the technical documentation, for instance for sealing aspects or even for some simple aspects such as height of the figures of a display.*

*Tests may concern the determination of the metrological characteristics of the MI or functional aspects.*

- *Tests concerning the determination of the metrological characteristics are in general always resulting of explicit metrological requirements and, consequently, are directly foreseen in the appropriate harmonised standards or normative documents.*
- *Tests concerning functional aspects may be explicitly foreseen in the appropriate harmonised standards or normative documents or be considered necessary, at the appreciation of the NB, to establish the conformity to general aspects on suitability for use and/or non-susceptibility to fraudulent uses. In the latter case, the tests may consist, for example, of non-expected manipulations or operations.*

*If non-conformities appear, the applicant is informed with the corresponding explanations.*

*The notified body will take a decision whether he refuses to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal, see article 6 of module B, or propose to the manufacturer to modify the instrument.*

*In the latter case it is up to the manufacturer to decide to continue with the examination after a modification has been made to the instrument or ask for the final decision of the NB to refuse to issue an EU-type examination certificate, see also article 6 of module B.*

- *If the non-conformities result in minor modifications to the instrument, the process of certification could continue after analysis of the consequences and a new review of the application.*
- *If the non-conformities result in major modifications to the instrument, all or part of the examinations or tests already performed may necessitate to be repeated.*

*Where a NB sub-contracts specific tasks it should fulfil the requirements of the directive on sub-contracting. With regards to the tests the NB shall ensure that:*

- *The manufacturer agrees with his choice of test laboratory;*
- *The test program was correctly implemented by the laboratory chosen by the notified body;*
- *The test results reported in the test report are in conformity with each essential requirements of the directive and where applicable the relevant harmonised standard or normative document (in case of presumption of conformity), and not only rely on a general statement on the conformity.*

*The notified body should define in a note or in a contract, the particular requirements concerning subcontracting rules and recognition of the competence of the laboratories. These particular requirements should include:*

- *The laboratory should inform the notified body of any anomaly detected during realisation of the tests;*
- *No modification of the testing methods can be made by the laboratory without written agreement of the notified body;*
- *The heading "applicant" of the test report specifies the manufacturer's name;*
- *If during the execution of the tests, results highlight non-conformities, the laboratory informs immediately the notified body.*

*See also*

- *Guide 8.0 and*
- *Guide 8.5 and*
- *Guide 8.6.*

*If the NB decides to consider the test results provided by the manufacturer as the supporting evidence and not to repeat the tests, he shall have confidence in the competence and impartiality of the testing laboratory which performed them, and have sufficient information on the conditions in which the tests were performed.*

*In all the cases, when the NB accepts tests performed by an external testing laboratory, the tests shall be performed by a laboratory accredited for the specific task or by a laboratory having demonstrated its competence in an equivalent way.*

*The best way to provide evidence of the appropriate competence for testing is conformity to ISO/IEC 17025, but in any case, the evidence concerning compliance with the provisions in ISO/IEC 17025 shall exist and shall be sufficiently clear and established.*

*There shall be provisions to ensure that:*

- *the notified body shall ensure that the tested instrument was identical to the instrument subject to approval,*
- *the MI subjected to tests has not been adjusted or modified in a non-authorized way,*
- *the test conditions were those applicable to type evaluation,*
- *the communicated test report is in conformity with the original version.*

*To established confidence in the test results repeated tests in the laboratory of the NB or in the subcontracted laboratory may be carried out to verify the test results.*

4.4 carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards, and/or normative documents have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Directive;

*Where the manufacturer has chosen not to apply the solutions in these relevant documents, what is laid down under 4.1 and 4.2 is applicable. In addition, the following applies.*

*It is the manufacturer's responsibility, and not the one of the NB, to prove the MI fulfils the applicable essential requirements. This demonstration shall be accompanied with the necessary information such as:*

- *what requirements in the harmonised standards and or normative documents are not necessary for a specific application,*
- *what additional requirements or tests are necessary in the case of a new technology,*
- *demonstration of equivalence of the technical solutions.*

*To facilitate the evaluation, it is advisable that the manufacturer indicates to the NB the reason(s) why he does not refer to the harmonised standards and or normative documents.*

4.5 agree with the manufacturer on the location where the examinations and tests will be carried out.

*In the case of a NB that subcontracts the tests it is recommended that the applicant is informed.*

4.6 For the other parts of the measuring instrument:

*This procedure concerns the method c and the method b for aspects only based on examination of the technical documentation.*

*examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the other parts of the measuring instrument.*

*What is laid down under 4.1 to 4.5 is applicable with the exception there is no MI or part of it.*

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes.

Without prejudice to its obligations vis-à-vis, the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

*The evaluation of the conformity, as the result of the here above described examination, shall result in an evaluation report. The evaluation report shall permit to conclude that all applicable requirements are met. To this aim, it shall include the appropriate tests results and it is appropriate that a check-list demonstrating the whole conformity is attached to the report. When the examination is based on previous available information, appropriate information shall be provided.*

*Any important issue (testing conditions, sharing tests on two or more instruments...) or problem encountered in the process of evaluation shall be included in the report. In particular, if non-conformities appeared during the evaluation process of the instrument, they are related in the evaluation report in conjunction with the solutions applied, for instance adjustments or modifications performed. If the solutions do not result in the restart of the whole evaluation process, reasons are given.*

*The evaluation acts shall be recorded during each evaluation step to ensure the traceability of actions carried out.*

*The evaluation report should clearly indicate in a separate chapter when the evaluation process demonstrates the necessity of providing appropriate information in the certificate or its annexes on aspects such as:*

- *particular conditions of installation,*

- *restrictions of use,*
- *particular conditions of use,*
- *indications or specific provisions,*
- *specific conditions of verification.*

*An example of an evaluation report is given in annex 1.*

6. Where the type meets the requirements of this Directive, the notified body shall issue an EU-type examination certificate to the manufacturer.

That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured measuring instruments with the examined type to be evaluated and to allow for in-service control.

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, content shall include:

- the metrological characteristics of the type of instrument;
- measures required for ensuring the integrity of the instruments (sealing, identification of software, etc.);
- information on other elements necessary for the identification of the instruments and to check their visual external conformity to type;
- if appropriate, any specific information necessary to verify the characteristics of manufactured instruments;
- in the case of a sub-assembly, all necessary information to ensure the compatibility with other sub-assemblies or measuring instruments.

The EU-type examination certificate shall have a validity of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each.

For NAWI the following is also applicable: in the event of fundamental changes to the design of the instrument, e.g. because of the application of new techniques, the validity of EU-type examination certificate may be limited to two years and extended by three years.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

*An example of an EU-type examination certificate is given in annex 2.*

*Note that the visual external conformity should be distinguished of the necessary conformity to type that must be ensured by the technical documentation.*

*The visual external conformity to the type is limited to a visual checking, without disassembling instruments (as available when there are placed on the market and/or put into use) but should include the identification of software.*

- *The metrological characteristics of the type of instrument and its parts;*

- *Procedures to check the integrity of the instruments should be included, i.e. how to check the mechanical sealing, checksum, event logger, event counter, etc., accompanied by clear drawings that facilitate the inspection;*

*Concerning the software aspects, the certificate or its annex should include the relevant information described in WELMEC Guide 7.2 or in case of a NAWI in the EN45501, edition 2015, with clear instructions to allow the market surveillance or in use inspection of the software aspects (identification of the legally relevant software and detailed instructions of how to check it, with a procedure on how to check the integrity of the legal relevant software such as an instruction for the inspection of the event counter / event logger, etc ). When relevant they should be related to the specific software version in the EU-type examination certificate.*

- *Information on other elements necessary for the identification of the instruments and its parts, for example but not limited to software identification, 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;*
- *If appropriate, all necessary information to ensure the compatibility with other parts, parts or sub-assemblies of measuring instruments.*

*The certificate should include or reference to a list of the technical documentation which is relevant for the certified type. The certificate together with the technical documentation should define the certified part and any variant of instruments covered by the certificate.*

7. 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.

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

*Typically, harmonised standards and or normative documents reflects the state of the art with respect to the requirements for measuring instruments. Changes, revisions and or withdrawals of harmonised standards and or normative documents should lead to the investigation if already approved measuring instruments may no longer comply with the applicable requirements of the directive. This also applies to the revision, update or withdrawal of documents relevant to the evaluation of the parts or to the withdrawal of EC or PC for the part.*

*However, information from the market could also lead to an investigation, for example if the application of new technology leads to new kinds of disturbances or developments in software leads to new vulnerabilities.*

8. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the instrument with the essential requirements of this Directive or the conditions for validity of that certificate.

Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

*In the case of a modification of an already approved instrument, the application could be limited and focussed on the modification itself. (Modification to the approved type does not result in the extension of the validity of the certificate).*

*The NB shall establish if the modification is minor or not, if the previous entire examination procedure is or not rendered invalid and if the conformity examinations or tests already performed may have to be repeated or not and note this in the evaluation report.*

*A revision of the certificate or an amendment to the certificate is necessary as soon as the instrument does no longer meet at least one aspect of the description of the MI made in the certificate and/or its annexes.*

9. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

For NAWI's the following is also applicable: Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto.

On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer until the expiry of the validity of that certificate.

*This information could also be provided to member States using a web access database weekly updated with new issued certificates. Nevertheless, in case of withdrawal of an EU-type examination certificate, a quick information procedure should be used by the NB to make its member State aware of this as soon as possible.*

10. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market.
11. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 8 and 10, provided that they are specified in the mandate.

*When the application is established by an authorized representative, the NB should inform this representative of its obligations especially those corresponding to paragraphs 8 and 10 of the annex B.*

*The representative needs to be authorized by the manufacturer to apply. To ensure that this is in the mandate, it is recommended that the NBs ask for a copy of this mandate or a written confirmation of the manufacturer.*

# Annex 1: Example of an evaluation report

(Informative)

NB Logo

## A: General information

|                                                                                                              |                                                                                                                                       |
|--------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| Reference number:                                                                                            |                                                                                                                                       |
| Type of certificate:                                                                                         | EU-type examination certificate (MID annex II module B)                                                                               |
| Number of certificate                                                                                        |                                                                                                                                       |
| <input type="checkbox"/> Initial certificate                                                                 | <input type="checkbox"/> prolongation                                                                                                 |
| <input type="checkbox"/> Manufacturer information on modification of certified type                          | <input type="checkbox"/> re-evaluation due to change of state of the art or other reasons (e.g. information from market surveillance) |
| <input type="checkbox"/> Parallel certificate<br>Original certificate no.:<br>Owner of original certificate: |                                                                                                                                       |
| Kind of measuring instrument:                                                                                |                                                                                                                                       |
| Manufacturer:                                                                                                |                                                                                                                                       |
| Measuring instrument-type designation:                                                                       |                                                                                                                                       |
| Measuring instrument specific annex:                                                                         | MI-                                                                                                                                   |

\* NA: not applicable

## B: Order background

|                                                                                         | yes                      | no                       | NA*                      | note (s.b.)                  |
|-----------------------------------------------------------------------------------------|--------------------------|--------------------------|--------------------------|------------------------------|
| <b>1. In case of initial certificate respectively prolongation:</b>                     |                          |                          |                          |                              |
| Written order with mandatory signature.....                                             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> no. |
| Mandatory approval of certification conditions.....                                     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> no. |
| Declaration that the same application was not lodged with any other notified body ..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> no. |
| Technical documentation (MID art. 18).....                                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> no. |
| Specimens.....                                                                          | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> no. |
| Supporting evidence .....                                                               | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> no. |
| Order confirmation issued on .....                                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> no. |
| <b>2. In case of a different manufacturer and same type:</b>                            |                          |                          |                          |                              |
| Approval of the owner of the original certificate.....                                  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> no. |
| If necessary technical documentation that have to be adapted .....                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> no. |
| <b>3. In case of a modification of the certified type:</b>                              |                          |                          |                          |                              |
| Relevant technical documentation for the modification .....                             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> no. |
| If necessary relevant types for the modification .....                                  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> no. |
| If necessary additional documents (e.g. test reports) .....                             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> no. |

\* NA: not applicable

## Note

No. Text of note

|     |              |
|-----|--------------|
| No. | Text of note |
|     |              |

## C: Result of survey of technical documentation and of supporting evidence

- |    |                                                                                                          |                                                            |                                |                                 |                                             |                               |                                        |                                 |                                             |
|----|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------|--------------------------------|---------------------------------|---------------------------------------------|-------------------------------|----------------------------------------|---------------------------------|---------------------------------------------|
| 1. | Appropriateness of the technical design of the measuring instrument<br>(MID module B 4.1)                | yes<br><input type="checkbox"/>                            | no<br><input type="checkbox"/> | NA*<br><input type="checkbox"/> | note (s.b.)<br><input type="checkbox"/> no. |                               |                                        |                                 |                                             |
| 2. | Conformity specimens – technical documentation<br>(MID module B 4.2)                                     | <input type="checkbox"/>                                   | <input type="checkbox"/>       | <input type="checkbox"/>        | <input type="checkbox"/> no.                |                               |                                        |                                 |                                             |
| 3. | Conformity of parts with harmonised standards respectively normative documents (MID module B 4.3)        | yes<br><input type="checkbox"/>                            | no<br><input type="checkbox"/> | NA*<br><input type="checkbox"/> | note (s.b.)<br><input type="checkbox"/> no. |                               |                                        |                                 |                                             |
|    | standard /document:                                                                                      | <input type="checkbox"/>                                   | <input type="checkbox"/>       | <input type="checkbox"/>        | <input type="checkbox"/> no.                |                               |                                        |                                 |                                             |
|    | standard /document:                                                                                      | <input type="checkbox"/>                                   | <input type="checkbox"/>       | <input type="checkbox"/>        | <input type="checkbox"/> no.                |                               |                                        |                                 |                                             |
|    | standard /document:                                                                                      | <input type="checkbox"/>                                   | <input type="checkbox"/>       | <input type="checkbox"/>        | <input type="checkbox"/> no.                |                               |                                        |                                 |                                             |
|    | standard /document:                                                                                      | <input type="checkbox"/>                                   | <input type="checkbox"/>       | <input type="checkbox"/>        | <input type="checkbox"/> no.                |                               |                                        |                                 |                                             |
| 4. | Software-classification according to WELMEC Guide 7.2:                                                   |                                                            |                                |                                 |                                             |                               |                                        |                                 |                                             |
|    | risk class [A-F] ____                                                                                    | P/U<br><input type="checkbox"/> / <input type="checkbox"/> | L<br><input type="checkbox"/>  | T<br><input type="checkbox"/>   | S<br><input type="checkbox"/>               | D<br><input type="checkbox"/> | I<br><input type="checkbox"/> no. ____ | NA*<br><input type="checkbox"/> | note (s.b.)<br><input type="checkbox"/> no. |
| 5. | Conformity of other parts of the measuring instrument with MID annex I<br>(MID module B 4.4)             | yes<br><input type="checkbox"/>                            | no<br><input type="checkbox"/> | NA*<br><input type="checkbox"/> | note (s.b.)<br><input type="checkbox"/> no. |                               |                                        |                                 |                                             |
| 6. | Conformity of other parts of the measuring instrument with MID annex MI-<br>(MID module B 4.5)           | <input type="checkbox"/>                                   | <input type="checkbox"/>       | <input type="checkbox"/>        | <input type="checkbox"/>                    | <input type="checkbox"/>      | <input type="checkbox"/>               | <input type="checkbox"/>        | <input type="checkbox"/> no.                |
| 7. | Appropriateness of the technical design of other parts of the measuring instrument<br>(MID module B 4.6) | <input type="checkbox"/>                                   | <input type="checkbox"/>       | <input type="checkbox"/>        | <input type="checkbox"/>                    | <input type="checkbox"/>      | <input type="checkbox"/>               | <input type="checkbox"/>        | <input type="checkbox"/> no.                |

\* NA: not applicable

**Note**

No. Text of note

|  |  |
|--|--|
|  |  |
|--|--|

**D) Test programme**

No. Description

agreed location of tests

|  |  |  |
|--|--|--|
|  |  |  |
|--|--|--|

## E) Test results

### 1. From manufacturer received or of previous procedures existing test results or partly evaluations

| Test report/no. | Body/Laboratory | Issue date | Report appr.             | Test passed              | Note (s.b.)                  |
|-----------------|-----------------|------------|--------------------------|--------------------------|------------------------------|
|                 |                 |            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> no. |
|                 |                 |            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> no. |
|                 |                 |            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> no. |
|                 |                 |            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> no. |

#### Note

No.      Text of note (e.g. basis for the approval of test results, details of failed tests, notes,...)

|  |  |
|--|--|
|  |  |
|--|--|

### 2. In own laboratories \_\_\_\_\_ performed tests

| Test report/no. | Person/Laboratory | Issue date | Test passed              | Note (s.b.)                  |
|-----------------|-------------------|------------|--------------------------|------------------------------|
|                 |                   |            | <input type="checkbox"/> | <input type="checkbox"/> no. |
|                 |                   |            | <input type="checkbox"/> | <input type="checkbox"/> no. |
|                 |                   |            | <input type="checkbox"/> | <input type="checkbox"/> no. |
|                 |                   |            | <input type="checkbox"/> | <input type="checkbox"/> no. |

#### Note

No.      Text of note (e.g. details of failed tests, notes,...)

|  |  |
|--|--|
|  |  |
|--|--|

### 3. In external laboratories performed tests (sub-contract)

| Test report/no. | Body/Laboratory | Issue date | Test passed              | Note (s.b.)                  |
|-----------------|-----------------|------------|--------------------------|------------------------------|
|                 |                 |            | <input type="checkbox"/> | <input type="checkbox"/> no. |
|                 |                 |            | <input type="checkbox"/> | <input type="checkbox"/> no. |
|                 |                 |            | <input type="checkbox"/> | <input type="checkbox"/> no. |
|                 |                 |            | <input type="checkbox"/> | <input type="checkbox"/> no. |

#### Note

No.      Text of note (e.g. details of failed tests, notes,...)

|  |  |
|--|--|
|  |  |
|--|--|

## F) Evaluation

|                                                                       |                                    |                                        |                              |
|-----------------------------------------------------------------------|------------------------------------|----------------------------------------|------------------------------|
| Requirements of MID                                                   | <input type="checkbox"/> fulfilled | <input type="checkbox"/> not fulfilled | Note (s.b.)                  |
| <input type="checkbox"/> Conditions/obligations/limitations necessary |                                    |                                        | <input type="checkbox"/> no. |
| <input type="checkbox"/> Evaluation documents compiled/updated        |                                    |                                        | <input type="checkbox"/> no. |
| <input type="checkbox"/> Certification documents compiled/updated     |                                    |                                        | <input type="checkbox"/> no. |
| <input type="checkbox"/> Draft of type examination certificate        |                                    |                                        | <input type="checkbox"/> no. |

Note

No. Text of note

|  |  |
|--|--|
|  |  |
|--|--|

☐ Further notes see annex

Evaluator: \_\_\_\_\_

Date: \_\_\_\_\_

\_\_\_\_\_

## G) Certification decision

- ☐ positive    ☐ with conditions/obligations/limitation (see note no.    )  
☐ negative (see note no.    )  
☐ Return to evaluator for clarification (see note no.    )

Note

No. Text of note

|  |  |
|--|--|
|  |  |
|--|--|

☐ Further notes see annex

Certifier: \_\_\_\_\_

Date: \_\_\_\_\_

\_\_\_\_\_

## Annex

## Annex 2: Example of an EU-type examination certificate

(informative)

NB-Logo, Address, NB-Number

### EU Type-examination Certificate

|                     |                                                                                                                                                                                                                                                              |
|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Issued to:          | <Manufacturer>                                                                                                                                                                                                                                               |
| In accordance with: | <for example: Annex II Module B of the 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> |
| Type of instrument: | <e.g. Heat Meter>                                                                                                                                                                                                                                            |
| Type designation:   | <Type designation of the instrument>                                                                                                                                                                                                                         |
| Certificate No.:    | <no. of the certificate and revision no, if applicable>                                                                                                                                                                                                      |
| Date of issue:      | <Date of the issue of this certificate or revision>                                                                                                                                                                                                          |
| Valid until:        | <Date of the end of the validity period (10 years after initial certification or prolongation)>                                                                                                                                                              |
| Number of pages:    | <total number of pages of this certificate>                                                                                                                                                                                                                  |

*(Signature of the authorized representative of the NB)*

Date, place and signature:

## History of the Certificate

| Issue of the Certificate | Date            | Modifications                        |
|--------------------------|-----------------|--------------------------------------|
| Cert. no                 | <date of issue> | Initial certificate                  |
| Revision 01              | <date of issue> | <brief description of modifications> |
| Revision 02              | <date of issue> | <...>                                |
| ....                     |                 |                                      |

## Conclusions of the examination

*For the instruments mentioned in this Certificate, the following essential requirements of Directive 2014/32/EU (or in the case of a NAWI Directive 2014/31/EU) apply:*

- Annex I "Essential Requirements"
- Annex ... (MI-...) "Title of MI specific annex" (In the case of a MI under the MID)

For the instruments, the following harmonized standards or normative documents will be applied:

- <harmonized standards, with number and version>
- <OIML recommendations, with number and version>

For the instruments, the following technical specifications will be applied additionally:

- <other relevant specifications, e.g. WELMEC guides, with number and version>

Conclusions of the examination: The measuring instrument's technical design which is described below complies with the above-mentioned essential requirements. With this Certificate, permission is given to attach the number of this Certificate to the instruments that have been manufactured in compliance with this Certificate.

## The instruments must meet the following provisions:

- 1 Design of the instrument
  - 1.1 Construction
  - 1.2 Sensor
  - 1.3 Measurement value processing
    - Hardware
    - Software *(With respect to the necessary information to be included in the EU-type examination certificate concerning the software, specific guidance is given in WELMEC guide 7.2)*
  - 1.4 Indication of the measurement results
  - 1.5 Optional equipment and functions
  - 1.6 Technical documents
  - 1.7 Integrated equipment and functions which do not fall into the validity range of this Type-examination Certificate

- 2 Technical data
  - 2.1 Rated operating conditions
    - Measurand
    - Measurement range
    - Accuracy class
    - Environmental conditions / influence quantities
    - Climatic
    - Mechanical
    - Electromagnetic
  - 2.2 Other operating conditions
- 3 Interfaces and compatibility conditions
- 4 Requirements on production, putting into use, and utilization
- 5 Checking of instruments which are in operation
  - 5.1 Documents required for the test
  - 5.2 Special test facilities or software
  - 5.3 Identification
    - Hardware
    - Software
  - 5.4 Calibration/adjustment procedure
- 6 Security measures
  - 6.1 Mechanical seals
  - 6.2 Electronic seals
  - 6.3 Software seals
- 7 Labelling and inscriptions
  - 7.1 Information to be enclosed with the instrument
  - 7.2 Markings and inscriptions
- 8 Figures

## Annex 3: Comparison between Module B of the MID and NAWID

| Number   | Module B MID                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Number | Module B NAWI                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Remarks |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|          | Module B: EU-type examination                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 1.     | Module B: EU-type examination                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |         |
| <b>1</b> | 'EU-type examination' is the part of a conformity assessment procedure in which a notified body examines the technical design of an instrument and verifies and attests that the technical design of the instrument meets the requirements of this Directive that apply to it.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 1.1    | EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an instrument and verifies and attests that the technical design of the instrument meets the requirements of this Directive that apply to it.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |         |
| <b>2</b> | <p>EU-type examination may be carried out in either of the following manners:</p> <ul style="list-style-type: none"> <li>a) examination of a specimen, representative of the production envisaged, of the complete measuring instrument (production type),</li> <li>b) assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the instrument (combination of production type and design type);</li> <li>c) assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).</li> </ul> <p>The notified body decides on the appropriate manner and the specimens required.</p> | 1.2    | <p>EU-type examination may be carried out in any of the following manners:</p> <ul style="list-style-type: none"> <li>— examination of a specimen, representative of the production envisaged, of the complete instrument (production type);</li> <li>— assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 1.3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the instrument (combination of production type and design type);</li> <li>— assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 1.3, without examination of a specimen (design type).</li> </ul> |         |
| <b>3</b> | <p>The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.</p> <p>The application shall include:</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 1.3    | <p>The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.</p> <p>The application shall include:</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |         |

| Number | Module B MID                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Number | Module B NAWI                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Remarks |
|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|        | <p>(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;</p> <p>(b) a written declaration that the same application has not been lodged with any other notified body;</p> <p>(c) The technical documentation shall make it possible to assess the instrument's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s).</p> <p>The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.</p> <p>The technical documentation as described in Article 18.</p> |        | <p>(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;</p> <p>(b) a written declaration that the same application has not been lodged with any other notified body;</p> <p>(c) The technical documentation shall make it possible to assess the instrument's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s).</p> <p>The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.</p> <p>The technical documentation shall contain, wherever applicable, at least the following elements:</p> <ul style="list-style-type: none"> <li>(i) a general description of the instrument;</li> <li>(ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;</li> <li>(iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;</li> <li>(iv) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;</li> </ul> |         |

| Number     | Module B MID                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Number       | Module B NAWI                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Remarks |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|            | <p>The application shall in addition contain, wherever applicable:</p> <p>(d) the specimens, representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;</p> <p>(e) the supporting evidence for the adequacy of the technical design solution.<br/>This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards, and/or normative documents have not been applied in full.</p> <p>The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.</p> |              | <p>(v) results of design calculations made, examinations carried out, etc.;</p> <p>(vi) test reports;</p> <p>(d) the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;</p> <p>(e) the supporting evidence for the adequacy of the technical design solution.<br/>This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full.</p> <p>The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer or by another testing laboratory on his behalf and under his responsibility.</p> |         |
| <b>4</b>   | The notified body shall:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>1.4</b>   | The notified body shall:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |         |
| <b>4.1</b> | <p>For the instrument:</p> <p>examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the instrument;</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>1.4.1</b> | <p>For the instrument:</p> <p>examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the instrument;</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |         |
| <b>4.2</b> | <p>For the specimen(s):</p> <p>verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or normative documents, as</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>1.4.2</b> | <p>For the specimen(s):</p> <p>verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements which have been</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |         |

| Number | Module B MID                                                                                                                                                                                                                                                                                                                                                                                                                                           | Number | Module B NAWI                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Remarks |
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|        | well as the elements which have been designed in accordance with other relevant technical specifications;                                                                                                                                                                                                                                                                                                                                              |        | designed in accordance with other relevant technical specifications;                                                                                                                                                                                                                                                                                                                                                                                                                           |         |
| 4.3    | carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and normative documents, these have been applied correctly;                                                                                                                                                                                                    | 1.4.3  | carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly;                                                                                                                                                                                                                                                                    |         |
| 4.4    | carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards, and/or normative documents have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Directive;                                                                                      | 1.4.4  | carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Directive;                                                                                                                                                          |         |
| 4.5    | agree with the manufacturer on the location where the examinations and tests will be carried out.                                                                                                                                                                                                                                                                                                                                                      | 1.4.5  | agree with the manufacturer on a location where the examinations and tests will be carried out.                                                                                                                                                                                                                                                                                                                                                                                                |         |
| 4.6    | For the other parts of the measuring instrument:<br><br>examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the other parts of the measuring instrument.                                                                                                                                                                                                                                     |        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         |
| 5      | The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes.<br>Without prejudice to its obligations vis-à-vis, the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.                                                                                                  | 1.5    | The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 1.4 and their outcomes.<br>Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.                                                                                                                                         |         |
| 6      | Where the type meets the requirements of this Directive, the notified body shall issue an EU-type examination certificate to the manufacturer.<br><br>That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached. | 1.6    | Where the type meets the requirements of this Directive, that apply to the instrument concerned, the notified body shall issue an EU-type examination certificate to the manufacturer.<br><br>That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached. |         |

| Number | Module B MID                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Number | Module B NAWI                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Remarks |
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|        | <p>The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured measuring instruments with the examined type to be evaluated and to allow for in-service control.</p> <p>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, content shall include:</p> <ul style="list-style-type: none"> <li>— the metrological characteristics of the type of instrument;</li> <li>— measures required for ensuring the integrity of the instruments (sealing, identification of software, etc.);</li> <li>— information on other elements necessary for the identification of the instruments and to check their visual external conformity to type;</li> <li>— if appropriate, any specific information necessary to verify the characteristics of manufactured instruments;</li> <li>— in the case of a sub-assembly, all necessary information to ensure the compatibility with other sub-assemblies or measuring instruments.</li> </ul> <p>The EU-type examination certificate shall have a validity of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each.</p> <p>Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and</p> |        | <p>The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured instruments with the examined type to be evaluated and to allow for in-service control.</p> <p>The EU-type examination certificate shall have a validity period of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each.</p> <p>In the event of fundamental changes to the design of the instrument, e.g. as a result of the application of new techniques, the validity of EU-type examination certificate may be limited to two years and extended by three years.</p> <p>Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and</p> |         |

| Number | Module B MID                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Number | Module B NAWI                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Remarks |
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|        | shall inform the applicant accordingly, giving detailed reasons for its refusal.                                                                                                                                                                                                                                                                                                                                                                                                                                                                |        | shall inform the applicant accordingly, giving detailed reasons for its refusal.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         |
| 7      | <p>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.</p> <p>If so, the notified body shall inform the manufacturer accordingly.</p>                                                                                                                                                             | 1.7    | <p>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.</p> <p>If so, the notified body shall inform the manufacturer accordingly.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |         |
| 8      | <p>The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the instrument with the essential requirements of this Directive or the conditions for validity of that certificate.</p> <p>Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.</p>                                                          |        | <p>The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the instrument with the essential requirements of this Directive or the conditions for validity of that certificate.</p> <p>Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.</p>                                                                                                                                                                                                                                                                                                                                                                          |         |
| 9      | <p>Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.</p> <p>The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto.</p> | 1.8    | <p>Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.</p> <p>Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.</p> <p>The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto.</p> |         |

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|           | <p>On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.</p> <p>The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer until the expiry of the validity of that certificate.</p> |        | <p>On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.</p> <p>The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.</p> |         |
| <b>10</b> | The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market.                                                                                                                                                                                | 1.9    | The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market.                                                                                                                                                                                 |         |
| <b>11</b> | The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 8 and 10, provided that they are specified in the mandate.                                                                                                                                                                                                                                      | 1.10   | The manufacturer's authorised representative may lodge the application referred to in point 1.3 and fulfil the obligations set out in points 1.7 and 1.9, provided that they are specified in the mandate.                                                                                                                                                                                                                                  |         |