WELMEC 8.3
Issue 1

WELMEC

European cooperation in legal metrology

Measuring Instruments Directive 2004/22/EC
Application of Module B

May 2007

WELMEC

European cooperation in legal metrology

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

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FOREWORD

This guide is one of those who complete the general guide on the assessment and operation of notified Bodies performing conformity assessment in application of MID. Several guides have been established for the detailed application of some modules of MID. These guides should not be read without taking into consideration all relevant aspects in all the guides related to a module. In order to facilitate the understanding of the whole set of guides, a table has been put at the end of each one of this series.

This guide is intended to provide guidance to all those concerned with the application of the module B of the Directive 2004/22/EC. It provides a record of the work of WELMEC Working Group 8 in the area of the common application of the Directive itself and in addition seeks to provide information which is specific to individual member countries.

This guide 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 Guide is purely advisory and does not impose any restrictions or additional technical requirements beyond those contained in the MID. Alternative approaches may be acceptable (in particular see Blue-Guide-2001), but the guidance provided in this guide represents the considered view of WELMEC as to the best practice to be followed. However it is intended that the procedures as described in the guide must be followed if it is to be claimed that the guide has been applied.

This guide covers:

- type examination,
- additions to or amendments of an existing EC type examination certificate,
- renewal of an existing EC type examination certificate,
- change of manufacturer’s or authorised representative’s denomination in an existing certificate.

[Below is the full text of the Annex B with *Guidance notes indicated in italics.]*

Annex B
TYPE EXAMINATION

1. “Type examination” is the part of a conformity assessment procedure whereby a notified body examines the technical design of a measuring instrument and ensures and declares that the technical design meets the appropriate requirements of this Directive.

Guidance notes

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

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

The renewal of a former certificate in order to extend its period of validity is also covered by the directive. Renewal is the privileged moment for the notified body to take into account information coming from past manufactured MI or if available coming from the market surveillance. Those information can be taken into account in particular to confirm or not the conformity of MIs to the point 3 c of the article 10 of the directive. Information coming from instruments already in use can also be considered if possible.

When the denomination of the manufacturer or its authorised representative changes, the notified body changes the existing EC type examination certificate. The recipient of a certificate is the manufacturer in any case. This modification requires additional approval in the form of an addition to the original EC type examination certificate. In this procedure, the design features of the type remain unchanged.

2. Type examination may be carried out in either of the following manners. The notified body decides on the appropriate manner and the specimens required:

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

Guidance notes

General steps concerning the process of conformity evaluation of a type (module B) are given in annex 1.

The notified body has to decide, in each case, the appropriate method of examination (a, b or c) and in particular 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 essential requirements of MID, NBs could used the following criteria of choice for a type examination which depend on instrument design, its complexity and the most economical way to insure conformity.

These criteria are presented in the following table and take into account the fact that the instrument is composed or not of parts that have already been validated by a notified body in the scope of a voluntary WELMEC system of evaluation or in the scope of other recognised systems such as the OIML Certificate System or of previous approvals.

Method		*Instrument composition*		
Method available according to the annex B of the directive 2004/22/EC	*Criteria of choice intended to use by notified body for an initial examination*	*MI composed with unknown critical parts*	*MI composed with some critical parts already approved according a Welmec voluntary system of certification*	*MI only composed with critical parts already approved according a Welmec voluntary system of certification*
a)	*This method is most appropriate when the instrument is not composed of parts having been the subject of a validation of the design formalized by a certificate or a report recognized by Welmec members*	*This method should be used for:* *- First evaluation* *- modifications of the type which can affect the conformity to the type* *- the renewal if conformity of manufactured MI can't be demonstrated*	/	/
b)	*This method is most appropriate when the instrument are the subject of a Welmec test certificate or a OIML report of conformity and the following specific cases :* *(Parts which were not the subject to a preliminary evaluation of their conformity should be examined by the notified body).*	*This method should be used for* *- modifications of at least one critical part of the approved type* *- a renewal if conformity of the past manufactured MI can't be demonstrated and if a critical part was identified to have a correlation with observed non conformities*	*This method should be used for :* *- - First evaluation (especially to check compatibility of sub-assemblies)* *- modifications of at least one critical part of the approved type* *-modification of the type which can affect the conformity of critical part* *- The renewal if conformity of manufactured MI can't be demonstrated*	/
c)	*This method is most appropriate when the critical parts of the measuring instrument are only composed by parts which are the subject of a Welmec test certificate or a OIML report of conformity and the following specific cases :*	*This method should be used for :* *- minor modifications of the type* *- the renewal if conformity of manufactured MI is demonstrated*	*This method should be used for :* *- minor modification of the type* *- a renewal if conformity of manufactured MI is demonstrated*	*This method should be used for :* *- First evaluation* *- modification of the type* *- The renewal if conformity of manufactured MI is demonstrated*

3. The application for type examination shall be lodged by the manufacturer with a notified body of his choice. The application shall include:
- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition;
- a written declaration that the same application has not been lodged with any other notified body;
- the technical documentation as described in Article 10. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the instrument;

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.

The following table gives guidelines to establish the technical documentation in order to fulfil requirements of the art 10 :

Article 10	*Documentation that NB should request*
a)	*A commercial leaflet describing the instrument or a customised note explaining the measurement concept should be acceptable. 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.* *In case of modification of an already approved instrument, the note can be limited and focussed in the modification by itself.*
b)	*Those documents could be those established by the company during the design phase. Nevertheless, the NB could ask to the manufacturer to limit document to those which are necessary for MID evaluation.*
c)	*When the manufacturer as a quality system certified by a accredited certification body, the copy of the ISO 9001:2000 certificate with the pertinent scope ensure that the production is consistent. 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 .*
d) if applicable	*This items should be limited to useful information needed in the scope of this evaluation*
e)	*This item could be limited to a note or a chart dedicated to NB in order to explain links between the documents, drawings, diagrams corresponding to the paragraph b, c, d*
f)	*This item could be presented as a table taken into account the relevant paragraphs of the standard. A table based on the annex ZA of an harmonised standard and updated with data coming from the manufacturer should be acceptable.*
g)	*For elements which do not complies with the harmonized standard or the normative document, evidences having allowed the manufacturer to validate methods and technical solutions should be provided to the notified body. Those Evidences may includes :* *- comparison of results corresponding to methods carried out and those described in the normative document or harmonized standards ;* *- validation of methods based on modelling or numeric simulations* *- results of previous evaluations*
h)	*Those data are limited to evidence useful to NB for its evaluation.*
i)	*the appropriate test results, where necessary, to demonstrate that the type and/or instruments comply with: the requirements of this Directive under declared rated operating conditions and under specified environmental disturbances ,the durability specifications for gas-, water-, heat-meters as well as for liquids other than water.*
j)	*This item could be summarized in a table with the corresponding EC-type examination certificates or EC design examination certificates and technical conditions for compatibility with interfaces and sub-assemblies.*

- the specimens, representative of the production envisaged, as required by the notified body;

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

- *check that the samples, prototypes or equipment correspond to the specifications in the technical file and comply with the regulations,*
- *perform the EC type examination tests required under the regulations in force.*

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 in order 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.

- the supporting evidence for the adequacy of the technical design of those parts of the measuring instrument for which no specimens are required. This supporting evidence shall mention any relevant documents that have been applied, in particular where the relevant documents referred to in Article 13 have not been applied in full, and shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

The required elements concern :

- *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 includes : 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 in order to evaluate methods proposed by the manufacturer and to establish the corresponding evidences.

4. The notified body shall:

For the specimens:

This procedure laid down in § 4.1 to 4.4 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.

4.1. examine the technical documentation, verify that the specimens have been manufactured in conformity with it and identify the elements which have been designed in accordance with the relevant provisions of the relevant documents referred to in Article 13, as well as the elements which have been designed without applying the relevant provisions of those documents;

Guidance notes

The examination corresponding to the description in § 4.1 to 4.4 shall lead to the conclusion that each of the applicable requirements is respected. An exhaustive checking shall be performed in the case where no information on the type is available, but some previous information should be taken into consideration when possible.

Typically, for approval of a new MI of medium complexity, it necessitates:
- *examination of the technical documentation in order to check the conformity to the applicable requirements for aspects for which this checking is possible or necessary on the basis on a review of the technical documentation;*
- *examination of the instrument or of its critical parts in order to check the conformity to the applicable requirements for aspects for which this checking is possible or necessary directly on the concrete instrument or its critical parts (see § 4.2);*
- *checking that the technical documentation is established with a sufficient level of detail in conformity with § 2 of article 10 of the directive, in order to ensure latter the adequate verification of conformity to type;*
- *checking the MI is constructed in conformity with the technical documentation (this is an essential aspect);*
- *testing the instrument (see § 4.2).*

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 elements composing the instrument.

According to the previous knowledge on the instrument or its complexity the procedure may involve only some aspects of the here above described one, but it necessitates at least a review of the technical documentation, and by definition in these cases, the review of the MI or of its critical parts.

As the result of identifying the elements which have been designed in accordance with the relevant provisions of the relevant documents referred to in Article 13 of the directive, for these elements all relevant requirements in these relevant documents become applicable requirements. If the instrument does not respect these requirements, the procedure in § 4.3 applies.

4.2. carry out the appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant documents referred to in Article 13, these have been applied correctly;

Guidance notes :

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 when it cannot be done on drawing or paper work, or in order 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, as a consequence, 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, in order 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.

General considerations where tests are not performed by the NB

Where the NB does not perform himself the tests he shall ensure that:

- *The test program was correctly implemented by the laboratory chosen by the notified body or by the manufacturer itself;*
- *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 in particular include:

- *The laboratory has to 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 with 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.*

If the NB decides to take into account 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 sufficient information on the conditions in which they were performed. Refer to the Guide 8.0 Generalities on the assessment and operation of notified Bodies performing conformity assessment for aspects on confidence, and, for aspects on test conditions, to the Guide 8.6 Presumption of conformity of the quality system of manufacturers with modules D or H1 when EN ISO 9001 : 2000 is applied and to the Guide 8.5 Assessment of notified bodies in charge of type examination Presumption of conformity based on EN 45011.

In any case of recognition of a test report provided by the manufacturer (performed by him or in other circumstances), the notified body shall ensure that the tested instrument was identical to the instrument subject to approval. Also he shall have sufficient information on the test conditions.

General considerations in the case of non-conformities

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

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. In this case, the process of certification is stopped waiting for the written decision of the applicant.

4.3. carry out the appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen not to apply the solutions in the relevant documents referred to in Article 13, the solutions adopted by the manufacturer meet the corresponding essential requirements of this Directive;

This procedure may be relevant, for example, in the case of new technologies or in the case of specific applications which do not necessitate full conformity compliance to the relevant documents referred to in Article 13.

Where the manufacturer has chosen not to apply the solutions in these relevant documents, what is laid down under 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 relevant 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.*

In order to facilitate the certification process, or as a general information in order to promote the adaptation and evolution of the relevant documents, it is advisable that the manufacturer indicates to the NB the reason(s) why he does not refer to these documents. When the manufacturer does not follow a standardised testing method, he should indicate if the method employed is an adaptation of a standardised method or if it is a method developed by the manufacturer himself. Any new test method or other evaluation method shall be documented by the manufacturer in order to demonstrate its suitability.

4.4. agree with the applicant on the location where the examinations and tests shall be carried out.

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.

4.5. 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 4.3 is applicable with the exception there is no MI or part of it.

For the manufacturing process:

4.6. examine the technical documentation to assure that the manufacturer has adequate means to ensure consistent production.

Guidance notes : This aspect is new for legal metrology and remains under consideration.

It may be considered as the strong will to avoid the golden instrument subject to examination, resulting in difficulties to manufacture produced instruments in conformity with the applicable requirements and/or the approved type. This leads to the recommendation to examine the said means in the light of the difficulties eventually encountered in the course of the evaluation process.

When the manufacturer has an approved quality system covering similar applications this requirement is supposed to be fulfilled.

5.1. The notified body shall draw up an evaluation report that records the activities as undertaken in accordance with paragraph 4 and their outcomes. Without prejudice to Article 12(8), the notified body shall release the content of this report, in full or in part, only with the agreement of the manufacturer.

Guidance notes :

The evaluation of the conformity, as the result of the here above 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 related. In particular if non-conformities appeared during the evaluation process of the instrument, they are related in the evaluation report in conjunction with the curative solutions, 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 in order to ensure the traceability of actions carried out.

A suitable information should appear in the evaluation report 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 evaluation report is given in annex 2.

5.2. Where the technical design meets the requirements of this Directive that apply to the measuring instrument, the notified body shall issue an EC-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer and, if appropriate, of his authorised representative, conclusions of the examination, conditions (if any) for its validity and the necessary data for identification of the instrument. The certificate may have one or more annexes attached. The certificate and its annexes shall contain all relevant information for conformity evaluation and 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:
re— the metrological characteristics of the type of instrument;
— measures required for ensuring the integrity of the instruments (sealing, identification of softwa, 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 certificate shall have a validity of ten years from the date of its issue, and may be renewed for subsequent periods of ten years each.

Guidance notes :

An example of certificate is given in annex 3. The technical content of the format in this annex is applicable as such but the presentation (location of the logo…) is let at the choice of the Notified body.

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).Consequently, the applicable paragraph of the certificate (paragraph 6) concerning this checking should be limited only to external characteristics easily verifiable.
This visual external conformity has to be distinguished of the necessary conformity to type that must ensured by the technical documentation in order to fulfil point 2 in article 10 of MID.

Additional information, if necessary put in a non-public part, can be annexed to the certificate in order to help establishing the conformity of internal components during disassembling:
- *for Members States in the framework of market surveillance;*
- *for repairers.*

5.3. The notified body shall establish an evaluation report in this regard and keep it at the disposal of the Member State that designated it.

6. The manufacturer shall inform the notified body that holds the technical documentation concerning the EC-type examination certificate of all modifications to the instrument that may affect the conformity of the instrument with the essential requirements or the conditions for validity of the

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

In the case of a modification of an already approved instrument, the application could be limited and focussed on the modification by itself.

The NB shall establish by written 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.

A new certificate is necessary as soon as the instrument do no longer meet at least one aspect of the description of the MI made in the certificate and/or its annexes.

7. Each notified body shall immediately inform the Member State that designated it about:
- EC-type examination certificates and annexes issued;
- additions and amendments relating to certificates already issued.

Each notified body shall immediately inform the Member State that designated it of the withdrawal of an EC-type examination certificate. The notified body shall hold the technical file including the documentation submitted by the manufacturer for a period up to the end of the validity of the 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 EC-type examination certificate, a quick information procedure should be used by the NB to aware its member State as soon as possible.

8. The manufacturer shall keep a copy of the EC-type examination certificate, its annexes and additions with the technical documentation for 10 years after the last measuring instrument has been manufactured.

9. The manufacturer's authorised representative may lodge the application referred to in paragraph 3 and carry out the obligations mentioned in paragraphs 6 and 8. Where the manufacturer is not established within the Communities and where he does not have an authorised representative, the obligation to make the technical documentation available on request shall be the responsibility of the person designated by the manufacturer.

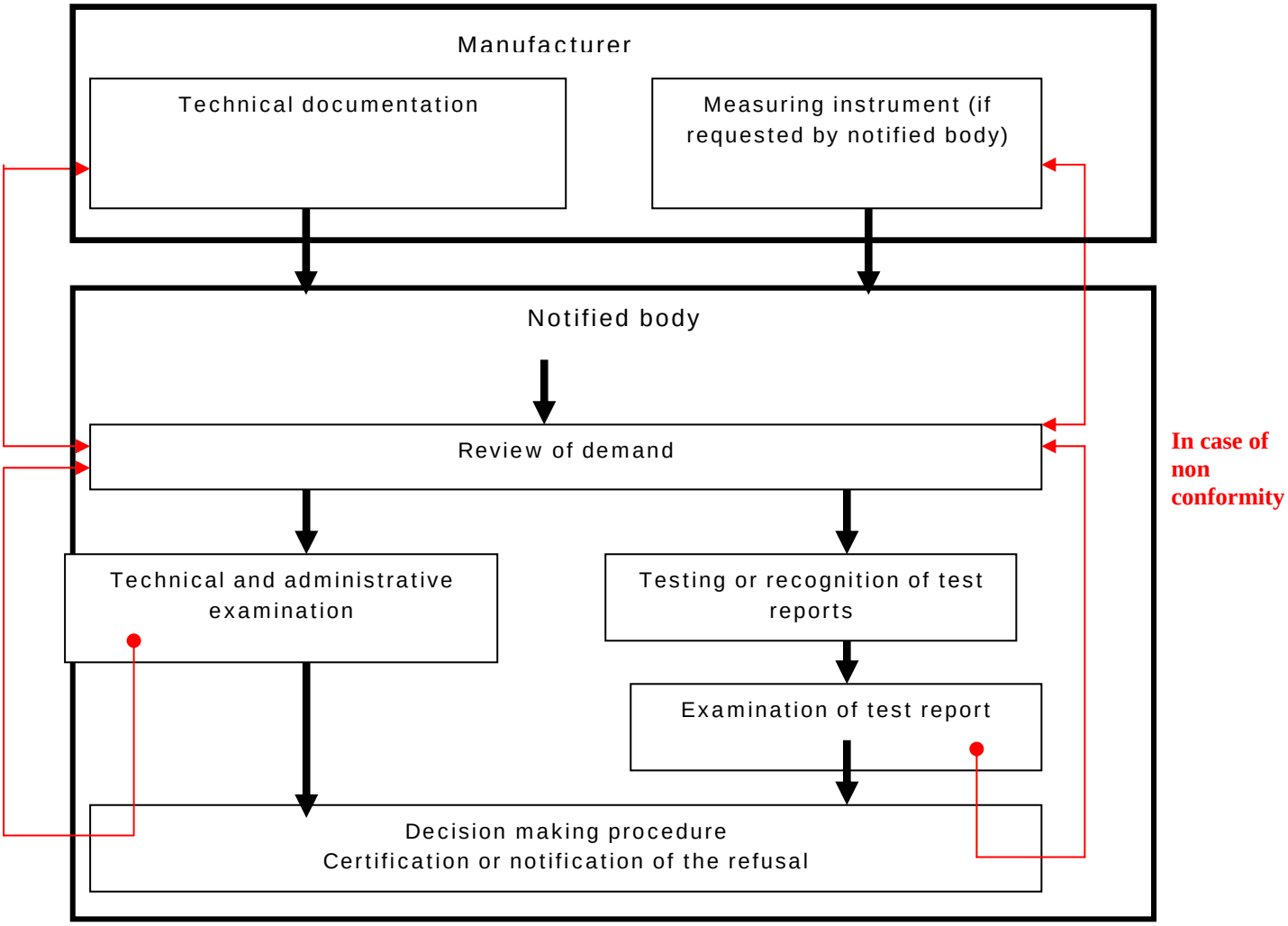
When the application is established by an authorized representative, the NB should aware this representative of its obligations especially those corresponding to paragraphs 6 and 8 of the annex B.

A specific declaration form could be requested by the NB to the representative.

The representative shall be authorized by the manufacturer to apply. Under this condition, it is recommended to NBs to ask for the original version of this authorization established by written by the manufacturer. At least a copy is requested.

Annexe 1 : Example of process of an EC type examination

General statements concerning process of conformity evaluation of a type (module B) are usually the following:



Annexe 2 : Example for a model of type examination report

(Informative)

NB XXXX

Type evaluation report

for issuing EC-type examination certificates according to directive 2004/22/EC

NB internal reference :
Date :

A) GENERAL

☐ Initial Certificate ☐ Supplement No. __ ☐ Revised form No.

No. of type examination certificate: ..... _____

Category of instrument ..... _____

_____

Manufacturer: ..... _____

_____

Authorised representative : _____

_____

Instrument type: ..... _____

_____

Relevant legal regulations: ..... _____

_____

B) APPLICATION DOCUMENTS

		Yes	No	NA*	Rem. (cf. F)
1.	Written and legally signed application and declaration that the same application has not been lodged with any other notified body	☐	☐	☐	☐No.
2.	Completeness of technical documents (MID article 10)..... ..	☐	☐	☐	☐No.
3.	Specimens.....	☐	☐	☐	☐No.
4.	Supporting evidence.....	☐	☐	☐	☐No.

C) METHOD OF EXAMINATION

acc. to MID Annex B 2. ..... ☐ a) ☐ b) ☐ c)

Risk-Class [A-F] ___	P/U	L	T	S	D	I		NA*	Rem. (cf. F)
	☐/☐	☐	☐	☐	☐	☐No.___		☐	☐No.

D) RESULTS OF EVALUATION

Serial number of the specimen (if applicable) : _____
Reference of the documentation : _____

	Yes	No	NA*	Rem. (cf. F)
1. Conformity of elements with harmonised standards and normative documents (MID B 4.1 and 4.2)				
standard/document:	☐	☐	☐	☐No.
standard/document:	☐	☐	☐	☐No.
standard/document:	☐	☐	☐	☐No.

	Yes	No	NA*	Rem. (cf. F)
2. Conformity of specimens - technical documents (MID B 4.1)	☐	☐	☐	☐No.
Adequacy of the technical design of the other parts of the measuring instrument (MID B 4.5)	☐	☐	☐	☐No.
Suitability of means to ensure consistent production. (MID B 4.6)	☐	☐	☐	☐No.
3. Conformity to essential requirements (MID Annex 1)				
Allowable Errors (1):	☐	☐	☐	☐No.
Reproducibility (2):	☐	☐	☐	☐No.
Repeatability (3):	☐	☐	☐	☐No.
Discrimination and Sensitivity (4):.....	☐	☐	☐	☐No.
Durability (5):	☐	☐	☐	☐No.
Reliability (6):	☐	☐	☐	☐No.
Suitability (7):	☐	☐	☐	☐No.
Protection against corruption (8):	☐	☐	☐	☐No.
Information to be borne by and to accompany the instrument (9):	☐	☐	☐	☐No.
Indication of result (10):	☐	☐	☐	☐No.
Further processing of data to conclude the trading transaction (11):	☐	☐	☐	☐No.
Conformity evaluation (12):	☐	☐	☐	☐No.

** NA: not applicable

	Yes	No	NA*	Rem. (cf. F)
4. Conformity to essential requirements (MID Annex MI-XXX)	☐	☐	☐	☐No.

E) RELEVANT TEST REPORTS

Serial number of the specimen : _____

Identification/No.	issued by	dated
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

(if applicable) When fittings or modifications were carried out during the tests, justification making that it is possible to conclude that this change does not influence the conformity of the measuring instrument:
.....
.....
.....

F) REMARKS

No. Text of remark	

☐ Further remarks see annex

G) OVERALL EVALUATION FOR ISSUING THE TYPE EXAMINATION CERTIFICATE

☐ possible without specific requirements/conditions/ restrictions
☐ possible only with specific requirements/conditions/ restrictions (cf.H, Rem. No.)
☐ not possible (cf.H, Rem. No.)

Name of the evaluator: _____ Unit: _____ Date: _____

Supervisor : _____ Unit: _____ Date: _____

Number and identification of annex(es) : ____

Annexe 3 : Example for a model of certificate

Accreditation n° of the NB (if applicable) & Logo of the accreditation body

Notified body n°XXXX

DDC/22/XXXX

CERTIFICATE OF EC TYPE EXAMINATION

N° *XXXXXXXXX* dated *XX. XX.* 2006

XXX *Model or Series or Type marking* XXX

Issued by: *Name and address*

Issued to : *Name and address*

Authorised representative (if applicable): *Name and address*

in respect of:

in accordance with: *The decree n[r] XXX dated XX. XX. 2006 and …the ordinance dated XXXX, transposing in the NB's country law the directive 2004/22/EC of 31 March 2004.*

Applicable essential requirements: *Annex 1 & annex MI-0XX, if applicable the subpart.*

Rated operating conditions *(optional in the first page)*:

Measurand:	*(optional)*	**Measurement range**	*(optional)*
Accuracy class:	*(optional)*	**Climatic environment class**	*(optional)*
Mechanical environment class:	*(optional)*	**Electromagnetic environment class**	*(optional)*

valid until : ***XX. YY. ZZZZ***

The principal characteristics, approval conditions are set out in the appendix hereto, which forms part of the approval documents and consists of XX pages.
All the plans, schematic diagrams and documentations are recorded under reference file XXXXXXX

On behalf of the General Director

The instruments / measuring systems shall correspond to the following specifications:

1 Design of the instrument

1.1 Construction

(short description of purpose, principle, main components of the instrument,

relevant harmonized Norms or normative documents or parts of them, if appicable)

1.2 Sensor

1.3 Measurement value processing

- Hardware
- Software

1.4 Indication of the measurement results

1.5 Optional equipment and functions subject to MID requirements

(Optional equipment or functions integrated in the instrument or suitable for connection, which are not required by MID, but which must fulfil MID requirements if present; e.g. Tara function of an automatic weighting instrument)

1.6 Technical documentation

(List of technical documents of the manufacturer on which this certificate bases and which are necessary for market surveillance)

1.7 Integrated equipment and functions not subject to MID

(Additional equipment or functions integrated in the instrument, which are not subject to MID; e.g. indication for other measurands)

2 Technical data

2.1 Rated operating conditions

- Measurand
- Measurement range
- Accuracy class (MPE)
- Environment / influence quantities
- climatic
- mechanic (class M1...M3)
- electromagnetic (class E1...E3)

2.2 If applicable, other operating conditions

3 Interfaces and compatibility conditions

(List of interfaces with information on purpose, necessary restrictions, sealings , transfer protocols, codes)

4 Requirements on production, putting into use and utilisation

4.1 Requirements on production, if applicable

(e.g. special requirements for consistent production))

4.2 Requirements on putting into use, if applicable

(e.g. adjustment and inspection being in the responsibility of the manufacturer and/or

specific conditions for the conformity evaluation)

4.3 Requirements for consistent utilisation, if necessary.

(e.g. mandatory descriptions to be given in the operating manual by the manufacturer))

5 Control of the measuring tasks of the instrument in use

(This control may be performed by the user himself or by national verification authorities according to the individual regulations by the member state)

5.1 Documentation of the procedure

5.2 Special equipment or software, if applicable

5.3 Identification of

- Hardware
- Software

5.4 Calibration-/adjustment procedure, if applicable (e.g. Exhaust gas analysers)

6 Security measures

6.1 Sealing

6.2 Data logger

7 Labelling and inscriptions

7.1 Information to be borne by and to accompany the instrument

7.2 Markings and inscriptions in accordance to Annex I (chapter 9)

8 List of drawings annexed to the certificate:

(If drawings are used to convey the information, than those drawings should be annexed to the certificate)
(If it is in the interest of the manufacturer, also a list of the trade names could be added.)

Annexe 4 : Overview of documents useful for the application of mid

(This document is indicated as white in between shaded areas)

Module	General guide	QS of NB according to	Specific guide for assessment of bodies	Specific guide for application of the module	QS of manufacturer according to	Specific guide for QS of manufacturers
A	Generalities on the assessment and operation of notified bodies performing conformity assessment ***	No NB	Not applicable	No	Not applicable	Not applicable
A1		EN ISO/IEC 17020 or EN 45011 *	?	?	Not applicable	Not applicable
B		EN 45011 ***	Assessment of notified bodies in charge of type examination ***	Application of module B	Not applicable	Not applicable
C		No NB	Not applicable	No	Not applicable	Not applicable
C1		EN ISO/IEC 17020 or EN 45011 *	?	?	Not applicable	Not applicable
D		EN 45012 **	No	Application of module D	EN ISO 9001 + EN ISO/IEC 17025 for tests	Presumption of conformity of the quality system of manufacturers
D1		EN 45012 **	No	?	EN ISO 9001+ EN ISO/IEC 17025 for tests	?
E		EN 45012 **	No	?	EN ISO 9001+ EN ISO/IEC 17025 for tests	?
E1		EN 45012 **	No	?	EN ISO 9001+ EN ISO/IEC 17025 for tests	?
F		EN ISO/IEC 17020 or EN 45011 *	To be drafted	?	Not applicable	Not applicable
F1		EN ISO/IEC 17020 or EN 45011 *	?	?	Not applicable	Not applicable
G		EN 45011 or EN ISO/IEC 17020 *	?	?	Not applicable	Not applicable
H		EN 45012 **	No	?	EN ISO 9001+ EN ISO/IEC 17025 for tests	?
H1		DEC: EN 45011	?	Application of module H1	EN ISO 9001+ EN ISO/IEC 17025 for tests	Presumption of conformity of the quality system of manufacturers
		QS: EN 45012 **	No			

* The following can be said concerning the alternative for A1, C1, F, F1 and G. In general the choice of one of these two standards is depending on whether the NB practices most of its activities on design certification of products (EN 45011) or product verification (EN ISO/IEC 17020 ; only type A inspection bodies). But in practice a specific consideration should be paid on the complexity of the instrument's category: in the case where the study of the design is complex for application of module G, preference should be given to EN 45011.

** As long as it is not replaced by ISO/CEI 17021

*** See foreword of Guide 8.0

For testing refer to 3.3 of Guide 8.0

A question mark indicates that until now no need was identified or no decision was taken.