

WELMEC 8.4  
Issue 1

# WELMEC

European cooperation in legal metrology

## Measuring Instruments Directive 2004/22/EC Application of Module D



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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 Module D of the Measuring Instruments Directive (MID). It provides guidance for manufacturers of measuring instruments, notified bodies (NBs) responsible for conformity assessment and the notifying authorities.

For more information on the requirements applicable to the quality systems of manufacturers, the specific WELMEC Guide 8.6 Presumption of conformity of the quality system of manufacturers with modules D or H1 when EN ISO 9001 : 2000 is applied should be considered.

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, but the guidance provided in this document 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.

Some aspects of module D may necessitate further consideration. A revision of the guide may therefore be necessary.

In many cases the manufacturer will already have an appropriate quality system in place. The task for the notified body will then be to build on the work done by the body certifying the quality system, taking into account all the specific requirements of Annex D, and to have a particular focus on the legal metrology application. In this way the notified body will avoid duplicating work that already has been done by a certification body. (See WELMEC Guide 8.6 Presumption of conformity of the quality system of manufacturers with modules D or H1 when EN ISO 9001 : 2000 is applied)

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

## ANNEX D

### DECLARATION OF CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. "Declaration of conformity to type based on quality assurance of the production process" is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex and ensures and declares that the measuring instruments concerned are in conformity with the type as described in the EC-type examination certificate and satisfy the appropriate requirements of this Directive.

*Quality assurance of the production process is where the manufacturer has in place an approved quality system for manufacture and final product inspection and testing of the measuring instrument with all the requirements to demonstrate a priori the ability to consistently provide a product in conformity with the approved type and that meets appropriate requirements of the Directive.*

#### **Manufacturing**

2. The manufacturer shall operate an approved quality system for production, final product inspection and testing of the measuring instrument concerned as specified in paragraph 3 and shall be subject to surveillance as specified in paragraph 4.

#### **Quality system**

3.1. The manufacturer shall lodge an application for assessment of the quality system with a notified body of his choice.

*The notified body shall be a body designated by the Member State after having been found to satisfy the criteria as laid down in article 12 of the Directive for this activity. For more information see the WELMEC Guide 8.0 Generalities on the assessment and operation of notified Bodies performing conformity assessment.*

The application shall include:

- all relevant information for the instrument category envisaged;

*The relevant information will include the category, or sub-category if applicable, of the instrument(s) described by the specific relevant Annex MI-OXY.*

- the documentation concerning the quality system;

*The documentation shall provide information on the structure of the quality system and on conformity with an appropriate international standard, in particular EN ISO 9001:2000, and shall contain in any case the appropriate information as laid down in this standard. It is advisable to indicate the existence of certificates issued by other accredited certification bodies, where the scope of these certificates may be of interest or help for the approval of the QS. Also relevant to QS documentation would be alignment with the WELMEC Guide 8.6 Presumption of conformity of the quality system of manufacturers with modules D or H1 when EN ISO 9001 : 2000 is applied.*

*The use of test procedures detailed in OIML recommendations or other International standards is encouraged, in particular those in normative documents and harmonised standards, in application of Point 4 in article 13 of MID .*

*This documentation shall be in the official language(s) of the Member State where the notified body carrying out the Conformity assessment procedures is established, or in a language accepted by that body.*

*The quality system shall cover the type of instrument as described in the technical documentation required by Article 10.*

*The scope of the QS shall be in accordance with the scope of the manufacturing and with the description of manufactured approved types. If the scope of certification requested by the manufacturer is different from the description of manufactured approved types, the QS approval certificate established by the NB should clearly states about this.*

*It is up to the notified body to approve the scope of the quality system and therefore to decide whether a new approved type of MI is covered by the scope. Therefore an assessment of the quality system may not be necessarily required for each new approved type of instrument where the notified body decides it is within the scope already covered by the existing quality system.*

*Where the quality system is modified to include an extension to the range of activities performed by the manufacturer so that new type(s) of instrument(s) can be covered by the quality system, an application shall be made, which will require a further assessment of the quality system.*

- the technical documentation of the approved type and a copy of the EC-type examination certificate.

*The approval of the QS by the NB shall succeed or shall not be effective before the first approval of a type of measuring instrument manufactured.*

3.2. The quality system shall ensure compliance of the instruments with the type as described in the EC-type examination certificate and the appropriate requirements of this Directive. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc;
- the means to monitor the achievement of the required product quality and the effective operation of the quality system.

*The existence of the above information in the QS shall be established. This could be done through a checklist.*

*A cross-reference table is a helpful tool to provide access to the quality system documentation. It may be produced by the manufacturer or by the notified body.*

*The description of examinations and tests that will be carried out in the process of the evaluation of individual MS in the process of manufacture and final control shall contain details on how the manufacturer controls the configuration of the instrument(s).*

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2. It shall presume conformity with these requirements in respect of a quality system that complies with the corresponding specifications of the national standard that implements the relevant harmonised standard, from the moment its references have been published.

*To that purpose the NB shall take into account the aspects specific to legal metrology and the particular application (see WELMEC Guide 8.6 Presumption of conformity of the quality system of manufacturers with modules D or H1 when EN ISO 9001 : 2000 is applied).*

In addition to experience in quality management systems, the auditing team shall possess appropriate experience in the relevant field of metrology and instrument technology, and knowledge of the applicable requirements of this Directive. The evaluation procedure shall include an inspection visit to the manufacturer's premises.

*The "evaluation procedure" consists of a documentation audit and an operational audit. The operational audit can only take place when the documentation audit is completed successfully.*

*For guidance, the time needed for the documentation and operational audit can be derived from annex 2 (auditor time) of EA 7/01 (Guideline on the application of EN45012).*

*Using this guide it is not necessary to estimate the audit time from the total number of employees of the manufacturer, but only from the number of employees working on the measuring instruments covered by the quality system to be approved. The audit time may also be reduced if the manufacturer already operates a certified or accredited quality system.*

*The audit team shall include, but need not be made up entirely, of persons having appropriate experience in the relevant field of metrology and instrument technology, and knowledge of the applicable requirements of the Directive.*

*The terms "provide experience in quality management systems" mean that the audit team shall consist of a lead auditor who:*

- has completed an auditor/lead auditor course, which is recognised by the International Register of Certificated Auditors, or*
- functions as a lead auditor in a EN 45012 accredited organisation, or*
- functions as a lead auditor in a accreditation organisation, and*
- has demonstrated the required competence to the relevant notified body*

*The term "appropriate experience in the relevant field of metrology and instrument technology" means that the experts (who focus on instrument specific requirements) will have completed an auditor/lead auditor or internal auditor course which is internationally recognised, or functions as an expert in an EN 45012 accredited body or functions as an expert auditor in an accreditation organisation, and have sufficient knowledge of metrology and the measuring instrument technologies to enable them to assess conformity of a measuring instrument on the basis of information supplied in accordance with Annex B.*

*In practice some general understanding of manufacturing processes will be a necessary competence in establishing the conformity of a product from manufacturing information.*

*Experience as a verification officer may contribute to the knowledge necessary for production control.*

*The “knowledge of the applicable requirements of the Directive” means that a member of the audit team possesses general knowledge that relates to MID requirements that are not instrument specific, such as labelling.*

*The lead auditor, the expert auditor(s) and the generalist member can be one person.*

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

*The "conclusions of the examination" shall contain:*

- *scope of the audit,*
- *references to the used standards , and/or recommendations and/or test procedures,*
- *examination and conclusion,*
- *summary of findings with reference to non-conformity reports; and*
- *recommendation of the audit team to the issuing authority of the Notified Body.*

*The conclusions of the examination may be laid down in one or more audit reports that cover the documentation and operational audits, plus an audit report for the purpose of verifying the corrective actions implemented to clear non-conformities.*

*The “notification to the manufacturer” means:*

- *in the case of a positive decision: a certificate issued by the issuing authority of the Notified Body based on the advice of the audit team, or*
- *in the case of a negative decision: a letter from the issuing authority of the Notified Body with reference to the audit report.*

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the changed quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

*All changes that might affect the subjects covered by the bullets under 3.2 shall be notified to the Notified Body. Changes of staff do not need to be notified, but records of staff experience and qualifications (which may include education, training, skills, experience etc.) for the personnel concerned shall be maintained.*

*Changes to the quality system that are purely administrative e.g. spelling corrections, need not be notified.*

It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

*Information shall be provided as for the initial audit (3.3).*

## **Surveillance under the responsibility of the notified body**

4.1. The purpose of surveillance is to make sure that the manufacturer fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall allow the notified body entrance for inspection purposes to the locations of manufacture, inspection, testing and storage, and shall provide it with all necessary information, in particular:

- the quality system documentation;
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

*After the initial audit (see 3) a periodic surveillance takes place with a scope generally limited to the areas which are critical for the conformity of instruments. The frequency of periodic audits may vary according to the past performance of the manufacturer, the frequency of any changes to the quality system, and the complexity of the products, but shall take place in a period not exceeding 12 months since the last audit.*

*The conclusions of the periodic audit shall contain:*

- *scope of the audit,*
- *references to the used standards,*
- *examination and conclusion,*
- *summary of findings with reference to non conformity reports; and*
- *recommendation of the audit team to the issuing authority of the Notified Body.*

*The conclusions of the periodic audit shall be laid down in an audit report which references the initial (documentation and operational) audit reports.*

*The conclusions of the re-assessment may be laid down in a separate audit report or as additions to the initial (documentation and operational) audit reports.*

*For guidance the time needed for the periodic audit can be derived from annex 2 (auditor time) of EA 7/01 (Guideline on the application of EN45012).*

4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, to verify that the quality system is functioning correctly. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

*The necessity and frequency of such unexpected visits will be determined by the Notified Body after consideration of the initial assessment of the QS, previous information relating to the manufacturer, the manufactured instruments and any complaints received. To minimise costs such visits should focus on points where further assurance is required in the light of the above considerations.*

*The practicality of performing such unexpected visits and of obtaining suitable results shall be taken into consideration before deciding approval of the QS, in particular where access to a manufacturer may be restricted.*

*The "conclusions of the examination" shall contain:*

- *scope of the audit and duration,*
- *references to the used standards , and/or recommendations and/or test procedures,*
- *examination and conclusion,*
- *summary of findings with reference to non-conformity reports; and*
- *recommendation of the audit team to the issuing authority of the Notified Body and*
- *test reports, if tests have been carried out.*

*The result of the unexpected visit and the tests (when carried out) may be laid down in a separate report or as additions to the initial (documentation and operational) audit reports. Report formats from European Standards, WELMEC or OIML Recommendations shall be used if available.*

### **Written declaration of conformity**

5.1. The manufacturer shall affix the "CE" marking, the supplementary metrology marking and, under the responsibility of the notified body referred to in paragraph 3.1, the latter's identification number to each measuring instrument that is in conformity with the type as described in the EC-type examination certificate and satisfies the appropriate requirements of this Directive.

5.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for 10 years after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up.

A copy of the declaration shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

6. The manufacturer shall, for 10 years after the last instrument has been manufactured, keep at the disposal of the national authorities:

- the documentation referred to in paragraph 3.1, second indent;
- the change referred to in paragraph 3.5, as approved;
- the decisions and reports from the notified body referred to in paragraphs 3.5, 4.3 and 4.4.

7. Each notified body shall periodically make available to the Member State that designated it the list of quality system approvals issued or refused, and shall immediately inform the Member State that designated it of the withdrawal of a quality system approval.

*The Member State will inform all the Member States. They will make this information available to the bodies they have notified.*

*[The methods for making this information available are currently under discussion within WELMEC and the outcome will be referenced in the next revision of this guide.]*

### **Authorised representative**

8. The manufacturer's obligations contained in paragraphs 3.1, 3.5, 5.2 and 6 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

## Annexe : 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.