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WELMEC

European cooperation in legal metrology

Measuring Instruments Directive 2004/22/EC Presumption of Conformity of the Quality System of Manufacturers with Module D or H 1 when EN ISO 9001:2000 is applied



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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 document is intended to provide guidance in order to facilitate harmonised approvals of quality systems of manufacturers for application of module D or of module H1 of MID. As the conformity to EN ISO 9001: 2000 appears to-day the most appropriate generic standard in order to give presumption of conformity, this document is built according to the structure of this standard. Only the titles of this standard are referred in.

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 .

PRELIMINARY CONSIDERATIONS

1 In this document "quality system" means "quality management system" in the sense of EN ISO 9001: 2000.

The main part of this guide is made of a four-column table giving the correspondence between requirements in modules D and H1, the titles of EN ISO 9001: 2000 and the guidance.

Relevant requirements of module D are recalled in the first (left) column. Relevant requirements of module H1 are recalled in the second column. The titles of EN ISO 9001: 2000 are in the third column. The fourth (right) column provides the guidance.

2 This guidance should also be used when the manufacturer has decided to prove the conformity using an other way. Provisions in this column are in fact based on the metrological culture (legal or general) that any good assessor in legal metrology should have, based on the standards, OIML documents or good practice corresponding to the state of the art. As it is not probable that each manufacturer or each assessor would think to all these aspects, it has appeared necessary to establish this document in order to ensure an harmonised approach concerning approval of quality systems.

In all cases, where a provision exists in the right column, it must correspond to a provision in the quality system of the manufacturer demonstrating that he takes the appropriate provisions in order to meet the provision.

Where it is written "applicable such as described" in the right column, this means that the standard applies as such and does not need additional specific guidance.

Whether the manufacturer does not claim conformity to the standard, whatever it is written "applicable such as described" or specific guidance is provided in the right column, he has to implement appropriate general provisions corresponding to the paragraph of the standard in his quality system when they are critical for the conformity of the measuring instruments.

3 Independently of the approval and the surveillance of his quality system by a notified body, any measuring instrument manufacturer could have had or can get the certification of his quality management system by a certification body of his choice, in order to ensure the conformity of his quality system to the standard (1) for the activities in relation with the legal metrology field. When this is the case, the notified body for approval and surveillance of the quality system may take this external certification into consideration for application to its own procedures, but in no case, it may delegate its final decision regarding the approval of the quality system within the legal framework. Also in this case, provisions in the right column of this document shall be checked directly by the audit team of the notified body, which, in agreement with module D or module H1 of MID (§ 3.3, second clause) shall possess appropriate experience in the relevant field of metrology and instrument technology, and knowledge of the applicable requirements of MID.

The certifications of quality systems issued by non accredited certification bodies, or issued "out of accredited field" by accredited certification bodies should not be recognised by the notified body.

4 With exception of § 7.3 (design and development) for which module D does not provide corresponding requirements, all others requirements from EN ISO 9001 : 2000 are applicable **for application to module D**, even those which are accompanied with "Applicable such as described " here under, and even requirements of the standards that do not correspond to requirements of MID when the manufacturer claims conformity to the standard.

The complete document and in particular the paragraph 7.3 are fully applicable to module H1.

In order to facilitate the reading and comprehension of this documentation, the following rule is applied. In the right column:

- the text on a white background applies both to application of modules D and H1,
- the text on a yellow background applies only to application of module D,
- the text on a green background applies only to application of module H1.

TERMINOLOGY AND ABBREVIATION

Accredited certification body

A body in charge of certification of quality management systems, accredited by a body in charge at national level to perform accreditation according to EN 45012 (as long as it is not replaced by ISO/CEI 17021)

Non accredited certification body

A body in charge of certification of quality management systems, but not accredited by a body in charge at national level to perform accreditation according to EN 45012

Central legal metrology authority (CLMA)

Authority in charge of the regulation on legal metrology at national level

Local legal metrology authority (LLMA)

Authority in charge of the application of the regulation on legal metrology in a region of a country

QAS: quality assurance system or quality-system

- (1) Regarding the under referred standards, it has to be noticed that a transitory period was possible until December 14, 2003 in order to switch from an approval or a certification according the standard EN ISO 9001 : 1994 or EN ISO 9002 : 1994 to a an approval or a certification according to EN ISO 9001 : 2000; this period had to be managed by the manufacturer in close relation with the notified body and /or the accredited certification body.
- 2) To this aim, all documents issued by the certification body are to be held available for the notified body.

Provisions in annex D	Provisions in annex H1	EN ISO 9001 : 2000 (chapters headings only)	Guide for the approval of quality system of measuring instruments manufacturers Presumption of conformity to EN ISO 9001 : 2000 standard for modules D or H1)
		1 Scope	Title only
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.	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 in the Official Journal.	1.1 General	Application of § 3 of annex D/H1 of Directive 2004/22/CE (EU OJ 4/30/04 page 135/223)
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.	Manufacturing 2. The manufacturer shall operate an approved quality system for design, manufacture and 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 5.	1.2 Application	When exclusions are requested (the manufacturer claims that a paragraph of EN ISO 9001 : 2000 is not applicable), they may only be accepted if: - they do not affect the manufacturer's ability to provide instruments conforming to the type/design certified and the legal requirements, - they do not free him from this responsibility, - for application of module D, the exclusions are limited to the requirements of § 7.3 (design and development).
		2 Normative reference	The following documents contain provisions to be taken into consideration for application to module D/H1 : - International vocabulary of basic and general terms in metrology (VIM) - EN ISO 9001 : 2000 : Quality management systems requirements - Guide to the expression of uncertainty in measurement (GUM) - EN ISO 10012 : measurement management systems ; requirements for measurement processes and measuring equipment - ISO 19011 : guidelines for quality and/or environmental management systems auditing - ISO/IEC 17025:2005, Conformity assessment – General requirements for the competence of testing and calibration laboratories - WELMEC Guide 8.0 Generalities on the assessment and operation of notified Bodies performing conformity assessment - WELMEC guide 4.2 Elements for deciding the appropriate level of confidence in regulated measurements - All technical standards accurate for each legal instrument category.

		3 Terms and definitions	The word “organization” in the EN ISO 9001 : 2000 standard applies to “measuring instruments manufacturer” in MID.
		4 Quality management system	Title only
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	3.2.The quality system shall ensure compliance of the instruments with the appropriate requirements of this Directive.	4.1 General requirements	The externalisation of processes in relation with the conformity of instruments to the legal requirements, at the stage of the realisation (§7), or measurement, analysis and improvement (§8), shall be kept under control. The manufacturer shall be able to prove that he has, continuously, the ability to monitor the externalised processes, even in the case of failure of his sub-contractor(s).
		4.2 Documentation requirements	Title only
		4.2.1 General	Applicable such as described
3.2. 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	3.2 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.	4.2.2 Quality manual	If the quality management system field is not limited to the production of measuring instruments subject to legal control, the description of interactions between the different quality management systems processes should enable to identify the specific processes for legal controlled instruments.
3.2. 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	3.2 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.	4.2.3 Control of documents	The legal requirements applicable to each category of manufactured instruments is part of the documents that must be kept under control. The instruments' definition documents shall allow to check the conformity to the certified type/design. Without prejudice of having to comply with the legal requirements, the manufacturer shall have a clear policy and a procedure about the evolution of the instruments' definition documents, that might affect the legal characteristics and/or the metrological performances and/or the integrity of the type/design of instrument. In addition and in the case of application of module D, the previous provision applies without prejudice of having to comply with the obligations towards the notified body in charge of the type approval. To this purpose, these policy and documents shall contain the following provisions. The notified body in charge of type approval shall

			<p>be immediately informed of these evolutions, and the notified body in charge of approval of the quality system at least one month before the effective implementation of modifications of the instruments. The manufacturer may not consider that the module D is applicable within the framework before one month after this information is given, unless the notified body in charge of the approval of the quality system has duly and punctually informed the manufacturer of its agreement.</p> <p>In the case of module H1, the above paragraph applies by analogy to evolution or modification of the design outside of the scope resulting from the description of the design in the design examination certificate and from the demonstration of the competence in the manufacturer's QAS.</p>
<p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <ul style="list-style-type: none"> - the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc; <p>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.</p> <p>6. The manufacturer shall, for 10 years after the last instrument has been manufactured, keep at the disposal of the national authorities:</p> <ul style="list-style-type: none"> - 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. 	<p>3.2 It shall contain in particular an adequate description of:</p> <ul style="list-style-type: none"> - the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.; <p>6.2.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 and shall mention the number of the design examination certificate. 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.</p> <p>7. The manufacturer shall, for 10 years after the last instrument has been manufactured, keep at the disposal of the national authorities:</p> <ul style="list-style-type: none"> - 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, 5.3 and 5.4. 	<p style="text-align: center;">4.2.4 Control of records</p>	<p>The recordings of the processes that allow to establish the conformity of the manufactured instruments to the certified type/design and to the applicable provisions (essential requirements, normative document or harmonised standard...) shall be described in the quality documents, and the storage of these documents shall be organised.</p> <p>This storage shall allow to identify quickly and with certitude the controls to which an instrument put on the market for less than two years has been subjected, as well as the results and the sanctions of these controls.</p> <p>A register for legal marking on instruments and declaration of conformity shall be kept up to date (number and identification).</p> <p>The software qualification files and data transfer ones shall be kept under control.</p> <p>If recordings are under electronic format, the software and data transfers of these recordings shall be qualified under the manufacturer's responsibility.</p> <p>The duration for conservation of quality recordings is of one year at minimum, and from one audit until the following.</p> <p>For application of module H1, the records concerning the development verification and the development validation shall be kept at least ten years after the last manufacturing of instruments according to the design.</p>

		5 Management responsibility	Title only
<p>3.1. The manufacturer shall lodge an application for assessment of the quality system with a notified body of his choice. The application shall include:</p> <ul style="list-style-type: none"> - all relevant information for the instrument category envisaged; - the documentation concerning the quality system; - the technical documentation of the approved type and a copy of the EC-type examination certificate. <p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <p>the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;</p> <p>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</p>	<p>3.1. The manufacturer shall lodge an application for assessment of the quality system with a notified body of his choice. The application shall include:</p> <ul style="list-style-type: none"> - all relevant information for the instrument category envisaged; - the documentation concerning the quality system. <p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <p>the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;</p> <p>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</p>	5.1 Management commitment	Applicable such as described
		5.2 Customer focus	For the implementation of this chapter, the legal metrology authorities (CLMA and LLMA) and the notified body shall be considered as "clients"
<p>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.</p> <p>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.</p>	<p>3.2. The quality system shall ensure compliance of the instruments with the appropriate requirements of this Directive.</p> <p>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.</p>	5.3 Quality policy	<p>The quality policy shall among others aim to:</p> <ul style="list-style-type: none"> - the conformity of manufactured instruments to the legal requirements, - including the conformity of the manufactured instruments to the type, - for module H1, the conformity of designed instruments and the demonstration of conformity in line with the present document.

		5.4 Planning	Title only
3.2. It (quality system documentation) 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;	3.2. It (quality system documentation) shall contain in particular an adequate description of : the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;	5.4.1 Quality objectives	Applicable such as described
3.2. It (quality system documentation) shall contain in particular an adequate description of : - the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;	3.2 It (quality system documentation) shall contain in particular an adequate description of: - the technical design specifications, including standards, that will be applied and, where the relevant documents referred to in Article 13 will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the instruments will be met; - the design control and design verification techniques, processes and systematic actions that will be used when designing the instruments pertaining to the instrument category covered; - the corresponding 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;	5.4.2 Quality management system planning	Applicable such as described
		5.5 Responsibility, authority and communication	Title only
3.2. It (quality system documentation) 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;	3.2. It (quality system documentation) shall contain in particular an adequate description of : the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;	5.5.1 Responsibility and authority	Applicable such as described
3.2. It (quality system documentation) shall contain in particular an adequate description of:	3.2. It (quality system documentation) shall contain in particular an adequate description of :	5.5.2 Management representative	This management representative is also responsible for the definition, and the processes concerning purchasing or supplying, control, apposition and destruction as far as legal markings is concerned.

<p>- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;</p> <p>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.</p>	<p>- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;</p> <p>6.1. 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 satisfies the appropriate requirements of this Directive.</p>		<p>Descriptive procedures of these processes shall be approved by the notified body and may not be modified without its agreement.</p> <p>The apposition of the marking of conformity is under the responsibility of the manufacturer.</p> <p>The same person shall be named responsible for the everyday relations with the services in charge of the implementation of the legal requirements (CLMA, LLMA, notified body)</p>
		<p>5.5.3 Internal communication</p>	<p>Applicable such as described</p>
		<p>5.6 Management review</p>	<p>Title only</p>
<p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <p>- the means to monitor the achievement of the required product quality and the effective operation of the quality system.</p>	<p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <p>- the means to monitor the achievement of the required product quality and the effective operation of the quality system.</p>	<p>5.6.1 General</p>	<p>Applicable such as described</p>
		<p>5.6.2 Review input</p>	<p>Applicable such as described</p>
		<p>5.6.3 Review output</p>	<p>Applicable such as described</p>
		<p>6 Resource management</p>	<p>Title only</p>
		<p>6.1 Provision of resources</p>	<p>The manufacturer shall ensure that the resources necessary for ensuring the legal conformity of instruments are always available.</p>
		<p>6.2 Human resources</p>	<p>Title only</p>
		<p>6.2.1 General</p>	<p>Applicable such as described</p>
<p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <p>- the quality records, such as inspection reports and test data, calibration data, qualification</p>	<p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <p>- the quality records, such as inspection reports and test data, calibration data, qualification</p>	<p>6.2.2 Competence, awareness and training</p>	<p>The manufacturer's personnel shall have appropriate information on the legal requirements and control applicable to the measuring instruments.</p> <p>In addition, for module H1, the validation responsible person (see 7.3) shall have an exhaustive knowledge of the applicable essential requirements, of the applicable</p>

reports of the personnel concerned, etc;	reports of the personnel concerned, etc;		<p>harmonised standards and/or normative documents and a good knowledge of this document, in particular paragraph 7.3.</p> <p>The personnel involved in the metrological function shall have sufficient training to metrology in general, especially for its standardisation aspects such as described in § 2, § 7.6 and, for module H1, § 7.3.</p> <p>The personnel in charge of the final control shall also know:</p> <ul style="list-style-type: none"> - the legal requirements attached to these instruments and their control, - the control and verification procedures. <p>The technical competence of the personnel in charge of activities in relation with application of MID shall be ensured (recording of the initial and continuous training and qualifications).</p>
3.2. It (quality system documentation) shall contain in particular an adequate description of : - the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;	3.2. It (quality system documentation) shall contain in particular an adequate description of : - the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;	6.3 Infrastructures	<p>When specific characteristics in infrastructures can have an impact on the realisation, surveillance or measurement of the product, the conditions for obtaining these characteristics shall be determined (infrastructure qualification) and the adequate recordings shall be realised.</p> <p>For module H1, this applies also to aspects in relation with the verification and validation of the design.</p>
3.2. It (quality system documentation) shall contain in particular an adequate description of : - the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;	3.2. It (quality system documentation) shall contain in particular an adequate description of : - the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;	6.4 Work environment	<p>This concerns more specifically the environment parameters having an impact on measurements such as vibrations, electromagnetic disturbances, temperature, hygrometry, etc ...Adequate recordings shall be realised.</p>
		7 Product realization	Title only
3.2. It (quality system documentation) shall contain in particular an adequate description of : - the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;	3.2 It (quality system documentation) shall contain in particular an adequate description of: - the design control and design verification techniques, processes and systematic actions that will be used when designing the instruments pertaining to the instrument category covered; - the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;	7.1 Planning of product realization	Applicable such as described
		7.2 Customer-related processes	Title only
1. "Declaration of conformity to type based on quality assurance of the production process" is the part of a conformity assessment procedure	1. "Declaration of conformity based on full quality assurance plus design examination" is the conformity assessment procedure whereby the	7.2.1 Determination of requirements	Applicable such as described

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.	manufacturer fulfils the obligations laid down in this Annex and ensures and declares that the measuring instruments concerned satisfy the appropriate requirements of this Directive.	related to the product	
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.	1. "Declaration of conformity based on full quality assurance plus design examination" is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex and ensures and declares that the measuring instruments concerned satisfy the appropriate requirements of this Directive.	7.2.2 Review of requirements related to the product	The legal requirements applicable to the measuring instruments, their evolution, the implementation conditions and the testing procedures are part of the review.
		7.2.3 Customer communication	Professional secrecy of the manufacturer is not valid versus the administrative authorities (CLMA, LLMA, etc) for all matters regarding directly or indirectly measuring instruments under legal metrology, nor versus the notified body, for all matters regarding the certification of measuring instruments.
		7.3 Design and development	Title only
	3.2 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 ... shall contain in particular an adequate description of: <ul style="list-style-type: none"> — the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality; — the design control and design verification techniques, processes and systematic actions that will be used when designing the instruments pertaining to the instrument category covered. 	7.3.1 Design and development planning	No requirement corresponding to module D For application to module H1: The manufacturer shall establish a clear policy in order to demonstrate conformity to the following provisions: 1 Whatever is the process of evaluation, any MI shall be capable to meet all applicable requirements without adjustment (others than possibilities intended to be let at the disposal of the users) or modification during the process of evaluation, whether or not adjustments or modifications are performed during this process (here after called the basic principle) 2 The conditions for such possible adjustments or modifications are clearly described. 3 In particular that no modification or adjustment are implemented in the phase of verification and validation of the design without referring to the validation responsible person (as defined here under). The manufacturer shall designate a representative responsible for the validation of the design of measuring instruments, here after called the validation responsible person. This validation responsible person shall have an appropriate rank in the manufacturer's organisation so that he has enough authority in the verification and validation process.

			<p>The manufacturer shall have established a policy in order to clearly distinguish the stages of designing and developing the MI and the stages of verifying (see 7.3.5) and validating (see 7.3.6) the design of the MI, taking into consideration possible iterative actions.</p> <p>In the case of a family of instruments the detailed programme of evaluation (what examination and tests to be performed on what kind of instrument of the family) shall be established before the verification of the design.</p> <p>There shall be provisions in order to register and to analyse the consequences on the conformity of a modification of a MI if it is not intended to perform the whole set of examination and tests resulting from the regulation after the modification;</p> <p>The validation responsible person shall have the authority for deciding when the stages of verification and validation of the design may start and for implementing the programme of evaluation. See also 6.2.2.</p> <p>When it is intended to subcontract some tests, the list of these tests shall be established before starting the evaluation programme. The analysis on the consequence of sharing some tests on two or more instruments on the capability of the instruments to meet all the requirements without modification or non-allowed adjustment shall be made as well.</p>
	<p>3.2 This quality system ... shall contain in particular an adequate description of:</p> <ul style="list-style-type: none"> – the technical design specifications, including standards, that will be applied and, where the standards referred to in Article 13 will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the instruments will be met; – the means to monitor the achievement of the required design and product quality and the effective operation of the quality system. 	<p style="text-align: center;">7.3.2 Design and development inputs</p>	<p>No requirement corresponding to module D</p> <p>For application to module H1:</p> <p>Inputs shall include all applicable requirements in MID and where applicable other requirements in harmonised standards or normative documents.</p> <p>Where the manufacturer chooses an other route for proving the conformity to essential requirements, this shall be documented with a clear demonstration of the conformity to essential requirements. In the latter case, excepted particular reason at least one of the following conclusion shall appear in this demonstration:</p> <ul style="list-style-type: none"> - the requirements in the harmonised standards or normative documents giving presumption of conformity are not relevant for the application, - the solution implemented by the manufacturer provides an equivalent level of conformity to those in the corresponding requirements in the harmonised standards or normative documents giving presumption of conformity, - additional evidence to those in the harmonised standards or normative documents giving presumption of conformity needing to be implemented, in particular in the case of a new technology. <p>Inputs shall include the examination and test procedures validated by the NB (see 8.2.4). It shall also include, in particular, all the policy to be written and implemented according to this clause 7.3.</p>

	<p>3.2 This quality system ... shall contain in particular an adequate description of:</p> <ul style="list-style-type: none"> – the technical design specifications, including standards, that will be applied and, where the standards referred to in Article 13 will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the instruments will be met; – the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.; <p>Note : This is without prejudice of the necessity to establish the technical documentation, as required in article 10 (not specific to annex H1).</p>	<p style="text-align: center;">7.3.3 Design and development outputs</p>	<p>No requirement corresponding to module D</p> <p>For application to module H1:</p> <p>The outputs shall include the evaluation report (results and conclusion of tests and examination or other evidence) establishing the complete conformity to all the applicable requirements in harmonised standards or normative documents or to other provisions whether the manufacturer chooses an other route for establishing the conformity to essential requirements.</p> <p>The outputs shall also include information on modifications or adjustment performed in the course of the whole development of the design and analysis of the consequences on the conformity.</p> <p>The outputs shall also include:</p> <ul style="list-style-type: none"> - the list or nature of evolutions and modifications the manufacturer intends to perform within the scope of the design, that is without having to request for an addition to the initial certificate. - the elements for demonstration of its competence to do so. <p>The technical documentation as specified in article 10 of MID is part of the quality system and of the development outputs.</p>
	<p>3.2 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:</p> <ul style="list-style-type: none"> – the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality; – the design control and design verification techniques, processes and systematic actions that will be used when designing the instruments pertaining to the instrument category covered; – 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 design and product quality and the effective operation of the quality system. 	<p style="text-align: center;">7.3.4 Design and development review</p>	<p>No requirement corresponding to module D</p> <p>For application to module H1:</p> <p>Such reviews shall be organised at least:</p> <ul style="list-style-type: none"> - at the beginning of the implementation of the stages of verification and validation of the design, - each time a change in the evaluation programme is intended, - each time a modification or a non allowed adjustment appears necessary, - each time a modification of the policy concerning evolution and modification of an approved design is intended (see 7.3.7), - each time a modification on the policy for subcontracting some tests is intended.

	<p>3.2 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:</p> <ul style="list-style-type: none"> – the design control and design verification techniques, processes and systematic actions that will be used when designing the instruments pertaining to the instrument category covered; – 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 design and product quality and the effective operation of the quality system. 	<p>7.3.5 Design and development verification</p>	<p>No requirement corresponding to module D</p> <p>For application to module H1:</p> <p>The configuration of the instrument under verification and validation shall be controlled and traceable in order to allowing further checking that no modification or adjustment of the MI are implemented in the course of the phase of evaluation or that these situations were controlled under the responsibility of the validation responsible person.</p> <p>The verification of the conformity shall be consistent with the basic principle laid down in introduction of guidance to clause 7.3 in any case, in particular for:</p> <ul style="list-style-type: none"> - initial design approval, - modification of approved design, - family of instruments... <p>The evaluation report shall clearly identify what tests have been performed on each kind of instrument .</p>
	<p>3.2 This quality system documentation ... shall contain in particular an adequate description of:</p> <ul style="list-style-type: none"> – 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 design and product quality and the effective operation of the quality system. 	<p>7.3.6 Design and development validation</p>	<p>No requirement corresponding to module D</p> <p>For application to module H1:</p> <p>At the end of the design and development verification, the validation responsible person shall check the conformity of the design versus all applicable metrological requirements and validate the evaluation.</p> <p>A programme of tests can includes evaluation and tests on parts of the instrument or on a complete instrument.</p> <p>The request for approval shall be accompanied with a clear demonstration that any MI conforming to the design is capable to fulfil the whole set of requirements without modification or non allowed adjustment in any case.</p> <p>It is recommended that the manufacturer provides a complete cross reference list of requirements against evidences.</p>
	<p>3.2 This quality system documentation ... shall contain in particular an adequate description of:</p> <ul style="list-style-type: none"> – the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality; – the technical design specifications, including standards, that will be applied and, where the 	<p>7.3.7 Control of design and development changes</p>	<p>No requirement corresponding to module D</p> <p>For application to module H1:</p> <p>This paragraph concerns only changes made to the design after the issuing of the design examination certificate. They shall be managed as follows.</p> <p>There shall be a clear policy stating in what conditions authorised modifications or</p>

	<p>standards referred to in Article 13 will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the instruments will be met; the design control and design verification techniques, processes and systematic actions that will be used when designing the instruments pertaining to the instrument category covered;</p> <ul style="list-style-type: none"> – the corresponding 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 design and product quality and the effective operation of the quality system. <p>4.4 The manufacturer shall keep the notified body that has issued the EC design examination certificate informed of any fundamental modification to the approved design. Modifications to the approved design must receive additional approval from the notified body that issued the EC design examination certificate where such changes may affect the conformity with the essential requirements of this Directive, the conditions for validity of the certificate or the prescribed conditions for use of the instrument.</p>		<p>evolutions may be made to the approved design.</p> <p>The validation responsible person shall be associated with any initiative and decision concerning whether modifications of the measuring instrument should be considered as fundamental and to be approved by the NB according to the provisions in 4.4 of annex H1 of MID.</p> <p>There shall be records of all these decisions where all the modifications made to the design will appear.</p>
		<p>7.4 Purchasing</p>	Title only
<p>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</p>	<p>1. "Declaration of conformity based on full quality assurance plus design examination" is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex and ensures and declares that the measuring instruments concerned satisfy the appropriate requirements of this Directive.</p>	<p>7.4.1 Purchasing process</p>	<p>Critical chapter regarding the services, controls, tests, calibrations and verifications that are sub-contracted.</p> <p>The manufacturer may not transfer its responsibility to the sub-contractors. This statement does not concern the specific tasks for which the manufacturer may designate an authorised representative for application of MID.</p> <p>The specified requirements for purchasing shall include the conformity to type/design</p>

<p>and satisfy the appropriate requirements of this Directive.</p> <p>3.3 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.</p>	<p>3.3 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.</p>		<p>when the purchase is about parts of measuring instruments, and particularly if the whole manufacturing is sub-contracted.</p> <p>When sub-contracting is critical regarding the instruments quality, the quality insurance requirements implemented for the manufacturing also apply to the sub-contracted part, taking into consideration the following, in particular.</p> <p>The NB in charge of approval of the QAS shall evaluate the capability and the competence of the subcontracting laboratory and consider the necessity to assess it. The assessment shall be necessary when the subcontracting laboratory is not accredited for the relevant tests.</p> <p>Subcontracting of judgement on conformity (global or partial) is not allowed.</p> <p>Concerning production aspects, the notified body in charge of the quality system approval may consider that it is not necessary to audit a sub-contractor whether the whole set of 3 conditions is fulfilled:</p> <p>1) All the critical metrological examination and tests normally intended for such an instrument for application of module D or module H1 are performed in the framework of the approved quality system of the manufacturer.</p> <p>2) In order to ensure the general quality of the instrument and conformity to type/design, one of the two following conditions is fulfilled:</p> <ul style="list-style-type: none"> - a) The subcontractor has himself a quality system approved for application of modules D or H1 and it can be proved that this quality system ensures the conformity to type/design of subcontracted parts, - b) The sub-contractor has himself a quality system approved for application of module D or H1 and the conformity to type is ensured by the manufacturer. <p>3) All the elements useful for the notified body to make its judgement are provided to it.</p> <p>This provision maybe be fulfilled by a clear policy or an exhaustive list of subcontractors.</p>
		<p>7.4.2 Purchasing information</p>	<p>Chapter applicable to external controls, tests, calibrations and verifications. For the parts of instruments, the information about purchase shall include the legal conformity.</p>
<p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <ul style="list-style-type: none"> - 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 	<p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <ul style="list-style-type: none"> - 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 	<p>7.4.3 Verification of purchased product</p>	<p>The presence, on purchased parts of instruments, of the recognized marking :</p> <ul style="list-style-type: none"> - does not exempt the manufacturer from ensuring the conformity of these parts, - does not modify the responsibility of the manufacturer. <p>A product certification does not exempt the manufacturer from a control at reception if the purchased product has a specific importance for the quality of the manufactured instruments.</p>

<p>- the means to monitor the achievement of the required product quality and the effective operation of the quality system.</p>	<p>- the means to monitor the achievement of the required product quality and the effective operation of the quality system.</p>		<p>For application of module H1, the manufacturer remains responsible for checking the conformity of subcontracted tests to the applicable requirements, and the capability of the instruments to meet all the requirements without modification or non-allowed adjustment.</p>
		<p>7.5 Production and service provision</p>	<p>Title only</p>
<p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <ul style="list-style-type: none"> - 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 <p>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.</p> <p>6. The manufacturer shall, for 10 years after the last instrument has been manufactured, keep at the disposal of the national authorities:</p> <ul style="list-style-type: none"> - 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. 	<p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <ul style="list-style-type: none"> - 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 <p>6.2. 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 and shall mention the number of the design examination certificate. 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.</p> <p>7. The manufacturer shall, for 10 years after the last instrument has been manufactured, keep at the disposal of the national authorities:</p> <ul style="list-style-type: none"> - 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, 5.3 and 5.4. 	<p>7.5.1 Control of production and service provision</p>	<p>There shall exist written procedures describing clearly the metrological activities of control and verifications, at final stage as well as during the production processes, if these processes can have consequences on the metrological conformity of the product. The facilities used and the personnel concerned shall be described as well.</p> <p>Providing the documents for the good usage of the instrument and the guarantee of their conformity (instruction manual, written declaration of conformity ...) is part of the due service.</p> <p>Also keeping the information at the disposal of the national authority (§ 6 in annex D and § 7 in annex H1) is part of the due service.</p> <p>When a part of the metrological verification takes place during the production process, the requirements that apply to the verification also apply.</p>
<p>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</p>	<p>6. 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</p>	<p>7.5.1 f)</p>	<p>The manufacturer shall take all provisions to ensure that all the necessary documents (legally required or indicated in the type examination certificate) are properly</p>

<p>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.</p>	<p>after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up and shall mention the number of the design examination certificate. 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.</p>		<p>complemented and accompany the instruments (instruction manual, owner's maintenance booklet, written declaration of conformity, total or partial verification certificate if applicable, etc...).</p>
		<p>7.5.2 Validation of process for production and service provision</p>	<p>The manufacturer shall, among others, validate all the production processes which use a software and check periodically this validation taking in account the elements from surveillance processes , measurements and analysis.</p>
<p>3.2. It (quality system documentation) shall contain in particular an adequate description of: - the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc;</p>	<p>3.2. It (quality system documentation) shall contain in particular an adequate description of: - the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc;</p>	<p>7.5.3 Identification and traceability</p>	<p>Procedures shall be implemented to each produced instrument. Documented processes shall allow, a posteriori, for each instrument or part of instrument likely to be checked during or at the end of the production chain to determine:</p> <ul style="list-style-type: none"> - it's identification (type/design examination certificate and documents of definition of the certified type/design and recordings enabling to prove the conformity to type/design, including the software implemented in the instruments), - as far as possible, its destination (subject to legal control or not, client, etc), - it's composition (including the origin of the sub-contracted parts), - the controls made, - the results of these controls.
		<p>7.5.4 Customer property</p>	<p>Applicable such as described</p>
		<p>7.5.5 Preservation of product</p>	<p>Specific storage conditions shall be defined in close relation with the analysis of the critical and sensitive points for the final quality of the manufactured instrument. Besides, some storage can be considered as manufacturing operations or controls (material stabilisation, "de-worming" room in order to reveal defaults, etc): these storage processes shall therefore be kept under control and registered.</p>
		<p>7.6 Control of monitoring and measuring devices</p>	<p>EN ISO 10012 standard is the relevant standard for the management of the metrological function of the manufacturer. Moreover for all the sensitive measuring tools used in production and in final controls, and excepted specific category provision, all the working standards shall be</p>

<p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <ul style="list-style-type: none"> - 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 	<p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <ul style="list-style-type: none"> - 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 		<p>accompanied with their traceable calibration certificate issued by an EA accredited calibration laboratory, or a national metrology institute signatory of the mutual recognition arrangement of the Metre Convention, and the ability required for these tools shall be officially defined.</p> <p>In all the cases, calibration uncertainties shall be compatible with the global acceptable uncertainties. When the applicable standard do not require an uncertainty calculation, it is at least necessary to prove that the calibration working standards are appropriate and that the uncertainty due to their implementation is low enough according to maximal permissible errors.</p> <p>When the standards foresee specifications for calibration working standards or measuring and testing means, these specifications shall be implemented. If other means are used, they shall provide at least equivalent guarantees.</p> <p>In the measuring fields where there is no calibration chain under accreditation, the calibration process shall provide confidence enough in the measurements by proving the traceability to appropriate standards such as specified methods and/or contractual standards which shall be clearly described and validated by inter comparison with laboratories tools and means enabled to practice in legal metrology.</p> <p>In all the cases, uncertainty evaluation shall comply with the general principles described in the GUM. The manufacturer shall at least identify and quantify all the components of the first degree uncertainties and make reasonable estimations for the global uncertainties.</p> <p>All the software and data transfers used for monitoring the controls and measurements, and/or for their analysis, shall be subject to a preliminary qualification and then to periodically programmed requalifications.</p> <p>For more general information on measurements uncertainties refer to the relevant parts in the WELMEC guides referred to in clause 2.</p> <p>Note : by “accredited laboratory”, it is understood a calibration laboratory accredited by an accreditation body that has signed the mutual recognition agreement EA in the calibration field. In all the cases, the accreditation scope shall include calibration capabilities and relevant measurement uncertainties.</p>
		<p>8 Measurement, analysis and improvement</p>	Title only
<p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <ul style="list-style-type: none"> - the manufacturing, quality control and quality 	<p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <ul style="list-style-type: none"> - the manufacturing, quality control and quality 	<p>8.1 General</p>	Applied such as described

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	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		
		8.2 Monitoring and measurement	Title only
		8.2.1 Customer satisfaction	Regarding the information about client satisfaction, the manufacturer should provide methods allowing to collect information from installers, repairers and verification bodies.
3.2. It (quality system documentation) shall contain in particular an adequate description of: - the means to monitor the achievement of the required product quality and the effective operation of the quality system.	3.2. It (quality system documentation) shall contain in particular an adequate description of: - the means to monitor the achievement of the required product quality and the effective operation of the quality system.	8.2.2 Internal audit	Applied such as described
3.2. It (quality system documentation) shall contain in particular an adequate description of: - the means to monitor the achievement of the required product quality and the effective operation of the quality system.	3.2. It (quality system documentation) shall contain in particular an adequate description of: - the means to monitor the achievement of the required product quality and the effective operation of the quality system.	8.2.3 Monitoring and measurement of processes	Applied such as described
3.2. It (quality system documentation) shall contain in particular an adequate description of: - 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 means to monitor the achievement of the required product quality and the effective operation of the quality system.	3.2. It (quality system documentation) shall contain in particular an adequate description of: - the design control and design verification techniques, processes and systematic actions that will be used when designing the instruments pertaining to the instrument category covered; - the corresponding 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 means to monitor the achievement of the required design and product quality and the effective operation of the quality system.	8.2.4 Monitoring and measurement of product	All the processes of surveillance and of measure of the MI shall be submitted to the approval of the notified body. The examination and tests performed in the course of § 7.3.5 and 7.3.6 shall be conforming to standards (in particular harmonised standards and OIML normative documents) or shall provide a quality and conformity level at least equivalent. They shall allow demonstration of the conformity to all applicable essential requirements and where applicable to harmonised standards or normative documents, even in the case where all the tests are not performed in the process of evaluation of the design, such as in the case of a modification of a design previously approved. The final controls and tests shall be conforming to standards (in particular harmonised standards and OIML normative documents) or shall provide a quality and conformity level at least equivalent, in particular equivalent to the one provided by a traditional initial verification (module F). The final controls and tests, and if applicable the examination and tests procedures for application of § 7.3.5 and 7.3.6, shall be the object of a serious documented qualification, reviewed and updated as often as necessary, in order to ensure the conformity to the essential requirements and conformity to type/design and if applicable, the equivalency mentioned above.

			<p>The final control procedures, and if applicable the examination and tests procedures for application of § 7.3.5 and 7.3.6, are subject to the agreement and formal validation of the notified body in charge of approval of the QAS before implementation.</p> <p>The notified body shall be informed in writing details of the modifications of these procedures at least one month before their implementation.</p> <p>In the case where a verification certificate is issued, it shall comply with the corresponding model provisions in the relevant standards.</p>
<p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <ul style="list-style-type: none"> - 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 means to monitor the achievement of the required product quality and the effective operation of the quality system. 	<p>3.2. It (quality system documentation) shall contain in particular an adequate description of:</p> <ul style="list-style-type: none"> - 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 means to monitor the achievement of the required product quality and the effective operation of the quality system. 	<p>8.3 Control of non conforming product</p>	<p>There may not be any exception regarding statutory criteria applicable to the manufactured instruments.</p> <p>The manufacturer shall keep up to date recordings of the follow up in the cases of rejection of instruments or group of instruments at the final control (re-calibration, destruction, rejects, etc).</p> <p>The correction processes of a non conforming instrument shall be defined.</p> <p>The rates of non conformity shall be recorded and classified according their types and their consequences.</p>
		<p>8.4 Analysis of data</p>	<p>The use of the statistical standards is recommended. This use does not exempt from a clear definition of the rejection criteria and of the pre-agreement from the notified body.</p>
		<p>8.5 Improvement</p>	<p>Title only</p>
<p>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. It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.</p> <p>Surveillance under the responsibility of the notified body</p>	<p>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. It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.</p> <p>Surveillance under the responsibility of the notified body</p>	<p>8.5.1 Continual improvement</p>	<p>Applicable such as described</p>

<p>4.1. The purpose of surveillance is to make sure that the manufacturer fulfils the obligations arising out of the approved quality system.</p> <p>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:</p> <ul style="list-style-type: none"> - the quality system documentation; - the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc. <p>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.</p> <p>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.</p>	<p>5.1. The purpose of surveillance is to make sure that the manufacturer fulfils the obligations arising out of the approved quality system.</p> <p>5.2. The manufacturer shall allow the notified body entrance for inspection purposes to the locations of design, manufacture, inspection, testing and storage, and shall provide it with all necessary information, in particular:</p> <ul style="list-style-type: none"> - the quality system documentation; - the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc; - the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc. <p>5.3. 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.</p> <p>5.4. 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 under its responsibility, 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.</p>		
		8.5.2 Corrective action	Applicable such as described
		8.5.3 Preventive action	Applicable such as described

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.