WELMEC 8.6
2018

WELMEC

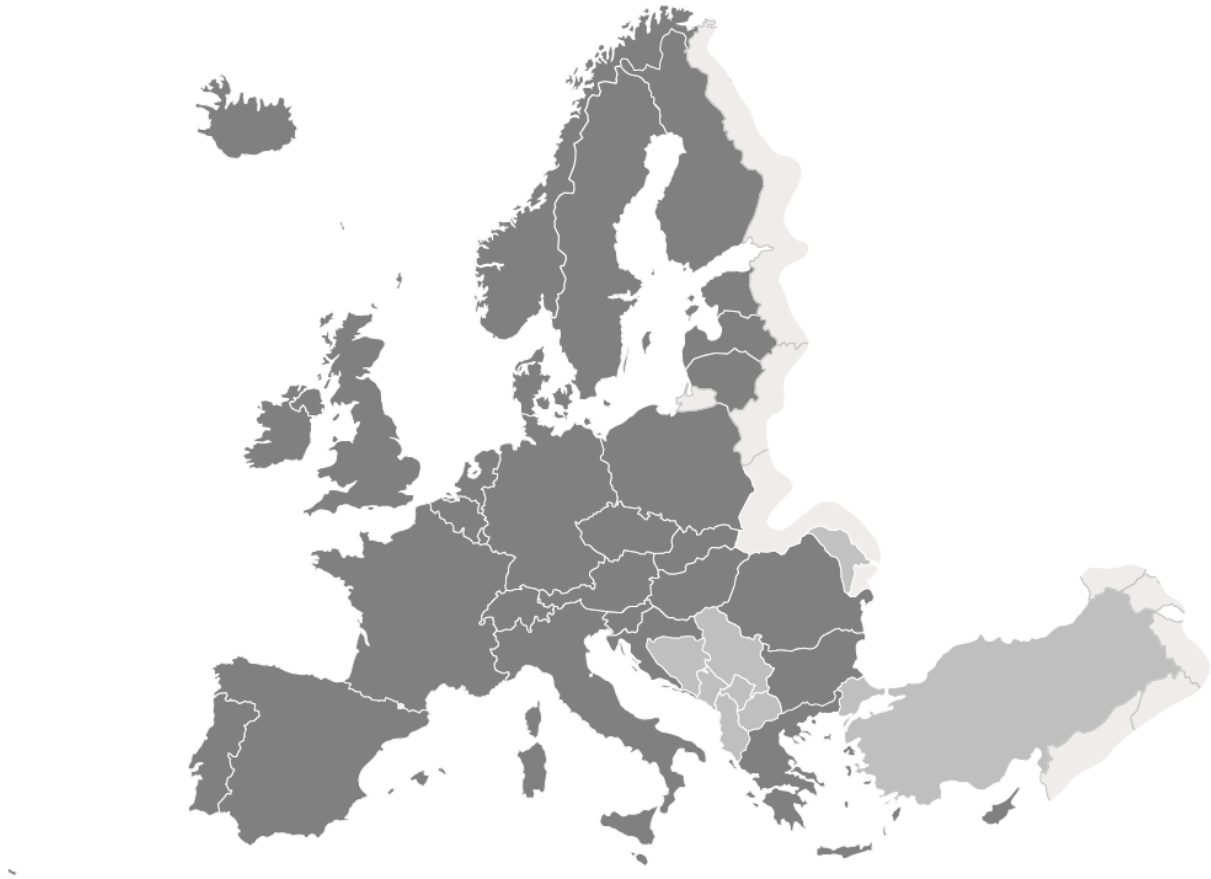
European Cooperation in Legal Metrology

Non-Automatic Weighing Instruments Directive 2014/31/EU

Presumption of Conformity of the Quality System of Manufacturers with Module D when
EN ISO 9001:2015 is applied

Measuring Instruments Directive 2014/32/EU

Presumption of Conformity of the Quality System of Manufacturers with Module D or H1 when
EN ISO 9001:2015 is applied



WELMEC

European Cooperation in Legal Metrology

WELMEC is a cooperation between the legal metrology authorities of the Member States of the European Union and EFTA.

This document is one of a number of Guides published by WELMEC to provide guidance to manufacturers of measuring instruments and to notified bodies responsible for conformity assessment of their products.

The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EU Directives.

Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed.

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Foreword

This Guide is one of a number of Guides published by WELMEC to provide guidance to manufacturers of non-automatic weighing instruments and measuring instruments and to Notified Bodies responsible for conformity assessment of their products in application of Directive 2014/31/EU (NAWID) and Directive 2014/32/EU (MID). Several guides have been established for the detailed application of some modules of NAWID and MID, see the WELMEC website. These guides should not be read without taking into consideration all relevant aspects in all the guides related to a module.

This document is intended to provide guidance in order to facilitate harmonised approvals of quality systems of manufacturers for application of:

- module D of NAWID (Module D: Conformity to type based on quality assurance of the production process)
- module D of MID (Module D: Conformity to type based on quality assurance of the production process
- module H1 of MID (Module H1: Conformity based on full quality assurance plus design examination)

This Guide is intended to support notified bodies also when Annexes D1, E, E1 and H are used. In that case the Guide should be used as appropriate.

As the conformity to EN ISO 9001: 2015 appears to-day the most appropriate generic standard in order to give presumption of conformity for quality assurance, this document is built according to the structure of this standard. Only the titles of this standard are referred in.

This Guide covers both the MID and the NAWID although small differences exist in the text of Module D of the MID compared with the text in the NAWID. The Guide is purely advisory and does not impose any restrictions or additional technical requirements beyond those contained in the NAWID and 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.

The conformity assessment of NAWI instruments according to Module D may be carried out at the manufacturer's works or any other location if transport to the place of use does not require dismantling of the instrument, if the putting into service at the place of use does not require assembly of the instrument or other technical installation work likely to affect the instrument's performance, and if the gravity value at the place of putting into service is taken into consideration or if the instrument's performance is insensitive to gravity variations. In all other cases, it shall be carried out at the place of use of the instrument.

Preliminary considerations

1) In this document "quality system" means "quality management system" in the sense of EN ISO 9001:2015.

   The main part of this guide is made of a five-column cross reference table giving the correspondence between requirements in modules D (MID and NAWID) and H1 (MID), EN ISO 9001: 2015 and a guidance for the approval of manufacturer's quality assurance system.
   Relevant requirements of module D for MID are recalled in the first left column. Relevant requirements of module H1 (MID) are recalled in the second column. Relevant requirements of module D for NAWID are recalled in the third column. The titles of EN ISO 9001: 2015 are in the fourth column. The five (right) column provides the guidance for the approval of manufacturer's quality assurance system.

2) This guidance should also be used when the manufacturer has decided to prove the conformity different way. Provisions in the right 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 a 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 measures in order to meet the provision.
Where it is written "applicable such as described" in the right column, this means that the EN ISO 9001: 2015 applies as such and does not need additional specific guidance. Whether the manufacturer does not claim the 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 manufacturer´s quality system by a notified body, any measuring instrument manufacturer could have had or can get the certification of his quality management system by an accredited certification body of his choice, in order to ensure the conformity of his quality system to the standard EN ISO 9001: 2015 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 according to EN ISO 9001: 2015 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 point 3.3 of Annex 2 for module D or module H1 (MID) and with point 2.3.3 of Annex 2 for module D (NAWID), shall possess appropriate experience in the relevant field of metrology and instrument technology, and knowledge of the applicable requirements of MID and NAWID, as appropriate.

   To this aim, all documents issued by the accredited certification body are to be held available for the notified body in charge of approval of quality assurance system.

   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.

   Note:
   ISO 9001:2008 certifications will not be valid after three years from publication of ISO 9001:2015. The expiry date of certifications to ISO 9001:2008 issued during the transition period needs to correspond to the end of the three year transition period (Implementation Guidance for ISO 9001:2015 issued by International Organization for Standardization).

4) With exception of clause 8.3 (Design and development of products and services), 9.1.2 (Customer Satisfaction), 10.1 (Improvement) and 10.3 (Continual improvement) of EN ISO 9001:2015 for which module D (MID and NAWID) does not provide corresponding requirements, all others requirements from EN ISO 9001: 2015 are applicable for application to module D, even those which are accompanied with "Applicable such as described " here under, and even requirements of the standard that do not correspond to requirements of MID when the manufacturer claims conformity to the standard.

   With exception of clause, 9.1.2 (Customer Satisfaction), 10.1 (Improvement) and 10.3 (Continual improvement) of EN ISO 9001:2015 for which module H1 (MID) does not provide corresponding requirements, all others requirements in particular the clause 8.3 of EN ISO 9001:2015 are applicable for application to module H1, even those which are accompanied with "Applicable such as described " here under, and even requirements of the standard that do not correspond to requirements of MID when the manufacturer claims conformity to the standard.

   Note:
   Exceptions in accordance with Table: Conformity assessment procedures in community legislation of Decision No 768/2008/EC.

5) In order to facilitate the reading and comprehension of this guide, the following rule is applied. In the right column:
   - the text on a white background applies both to application of modules D (MID and NAWID) and module H1 (MID),
   - the text on a blue background applies only to application of module D (MID and NAWID),
   - the text on a green background applies only to application of module H1 (MID).

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 ISO/IEC 17021-1:2015.

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 ISO/IEC 17021-1:2015.

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

Quality assurance system (QAS)
Manufacturer´s quality assurance system or quality system.

EU-type examination certificate
The certificate issued by a notified body under module B where the type complies with the provisions of the MID or NAWD, as appropriate. The term “EU-type examination certificate” covers also EC-type examination certificates issued by notified body under Directive 2004/22/EC or EC type-approval certificates issued by notified body under Directive 2009/23/EC, where applicable.

Cross reference table - requirements in modules D (MID and NAWID) and H1 (MID), EN ISO 9001: 2015 and a guidance for the approval of manufacturer's quality assurance system.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.	**3.3.** The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.	**2.3.3.** The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 2.3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.	1 Scope	Application of clause 3 of annex II module D/H1 of MID Application of clause 2.3 of annex II module D of NAWID Note: All the requirements of EN ISO 9001: 2015 are generic and are intended to be applicable to any organization, regardless of its type or size, or the products it provides.
none	none	none	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: 2015: Quality management systems. Requirements – ISO/TS 9002: 2016: Quality management systems -- Guidelines for the application of ISO 9001:2015 – Guides to the expression of uncertainty in measurement (GUM) – EN ISO 10012: 2003 Measurement management systems. Requirements for measurement processes and measuring equipment – ISO 19011: 2011 Guidelines for auditing management systems – EN ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories – WELMEC Guide 2.0 – WELMEC Guide 4.2 – WELMEC Guide 8.0 – WELMEC Guide 8.1 – WELMEC Guide 8.2 – WELMEC Guide 8.4 – WELMEC Guide 8.8

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		**Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1**
				– WELMEC Guide 8.10 – WELMEC Guide 8.21 – WELMEC Guide 10.5 – WELMEC Guide 10.6 – WELMEC Guide 11.1 – WELMEC Guide11.3 – OIML D 30 – JCGM 106 – The 'Blue Guide' on the implementation of EU product rules – All technical standards with provision for each legal instrument category.
none	none	none	**3 Terms and definitions**	The word "organization" in the EN ISO 9001: 2015 standard applies to "instruments manufacturer" in MID or NAWID, as relevant.
			4 Context of the organization	Title only
1. 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 points 2 and 5, and ensures and declares on his sole responsibility that the measuring instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.	**1.** Conformity based on full quality assurance plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.	**2.1.** 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 points 2.2 and 2.5, and ensures and declares on his sole responsibility that the instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.	4.1 Understanding the organization and its context	Applicable such as described
3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.	**3.5.** The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.	**2.3.5.** The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.	4.2 Understanding the needs and expectations of interested parties	The list of relevant interested parties shall among others aim to: – customers and end users of legal controlled instruments – statutory and regulatory authorities (local, regional, national or international) in relation to legal controlled instruments; – notified body involved in conformity assessment procedure

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		**Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1**
5.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual measuring instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive. **5.2**. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request. **6.** The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities: (a) the documentation referred to in point 3.1, (b) the information relating to the change referred to in	**4.4** The manufacturer shall keep the notified body that has issued the EU design examination certificate informed of any modification to the approved design that may affect the conformity with the essential requirements of this Directive or the conditions for validity of the certificate. Such modifications shall require additional approval – from the notified body that issued the EU design examination certificate – in the form of an addition to the original EU design examination certificate. **4.6.** The manufacturer shall keep a copy of the EU design examination certificate, its annexes and additions with the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market. **6.1.** The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual instrument that satisfies the applicable requirements of this Directive.	**2.5.1.** The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 2.3.1, the latter's identification number to each individual instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive. **2.5.2.** The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request. **2.6.** The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities: (a) the documentation referred to in point 2.3.1; (b) the information relating to the change referred to in point		The requirements of these interested parties shall among others aim to: – customer requirements regarding conformity, – statutory and regulatory requirements for the product – notified body requirements, that has approved the quality system, to be informed of any intended change of the quality system. – notified body requirements, that has issued the EU design examination certificate, to be informed of any modification to the approved design that may affect the conformity with the essential requirements of this Directive or the conditions for validity of the certificate.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		**Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1**
point 3.5, as approved; (c) the decisions and reports from the notified body referred to in points 3.5, 4.3 and 4.4.	**6.2.** The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up and shall mention the number of the design examination certificate. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request. **7.** The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities: (a) the documentation concerning the quality system referred to in point 3.1, (b) the information relating to the change referred to in point 3.5, as approved; (c) the decisions and reports of the notified body referred to in points 3.5, 5.3 and 5.4.	2.3.5, as approved; (c) the decisions and reports of the notified body referred to in points 2.3.5, 2.4.3 and 2.4.4.		
2. Manufacturing The manufacturer shall operate an approved quality system for production, final product inspection and testing of the measuring instruments concerned as specified in point 3 and shall be subject to	**2. Manufacturing** The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the measuring instruments concerned as specified in point 3, and shall be subject to	**2.2. Manufacturing** The manufacturer shall operate an approved quality system for production, final product inspection and testing of the instruments concerned as specified in point 2.3, and shall be subject to surveillance as	4.3 Determining the scope of the quality management system	The scope of the organization's quality management system shall state the types of measuring instruments defined in the instrument-specific Annexes III to XII of MID or the non-automatic weighing instrument of NAWID, as appropriate. When exclusions are requested (the manufacturer claims that a requirement of EN ISO 9001: 2015 is not applicable), they may only be accepted if:

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
surveillance as specified in point 4.	surveillance as specified in point 5.	specified in point 2.4.		– the manufacturer provides justification do not apply the requirement, – 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 can include the requirements of articles 8.3 (Design and development of products and services), 9.1.2 (Customer Satisfaction), 10.1 (Improvement) and 10.3 (Continual improvement). For application of module H1, the exclusions can include the requirements of articles 9.1.2 (Customer Satisfaction), 10.1 (Improvement) and 10.3 (Continual improvement).
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them.	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.	4.4 Quality management system and its processes	The externalisation of processes in relation with the conformity of instruments to the legal requirements, at the stage of the instrument realisation (article 8), or performance evaluation (article 9), 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). 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.
			5 Leadership	Title only
			5.1 Leadership and commitment	Title only
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them.	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.	5.1.1 General	Applicable such as described

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
It (quality system documentation) shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality; **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.	It (quality system documentation) shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality; **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.	It (quality system documentation) shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality; **2.3.4.** 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.		
			5.1.2 Customer focus	For the implementation of this chapter, the legal metrology authorities (CLMA and LLMA) and the notified body shall be considered as "clients"
			5.2 Policy	Title only
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the	**3.2**. The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the quality programmes, plans, manuals and records.	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. 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. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans,	5.2.1 Establishing the quality policy	The quality policy shall among others aim to: – the conformity of manufactured instruments to the legal requirements, and – for module D, the conformity of the manufactured instruments to the EU-type examination certificate, – for module H1, the conformity of instrument design to the legal requirements, the conformity of the manufactured instruments to the EU design examination certificate and the demonstration of conformity in line with the present documents.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
quality programmes, plans, manuals and records. It (quality system documentation) shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;	It (quality system documentation) shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;	manuals and records. It (quality system documentation) shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;		
			5.2.2 Communicating the quality policy	Applicable such as described
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (a) the quality objectives and the	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. 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. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure,	5.3 Organizational roles, responsibilities and authorities	Top management shall appoint one or more persons with responsibility and authority for processes concerning purchasing or supplying, manufacturing, product quality, quality control, quality assurance techniques, monitoring, apposition and destruction as far as producing instruments in compliance with legal requirements and legal markings is concerned. In addition, for module H1, top management shall appoint the one or more persons with responsibility and authority for processes concerning the design control and design verification of measuring instruments. Top management shall also appoint a person with responsibility and authority for the everyday relations with the services in charge of the implementation of the legal requirements (CLMA, LLMA, notified body). The apposition of the marking of conformity is under the responsibility of the manufacturer.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
organisational structure, responsibilities and powers of the management with regard to product quality; **3.5.** The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system. **5.1.** The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual measuring instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.	of the management with regard to design and product quality; **3.5.** The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system. **6.1.** The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual instrument that satisfies the applicable requirements of this Directive.	responsibilities and powers of the management with regard to product quality; **2.3.5.** The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system. **2.5.1.** The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 2.3.1, the latter's identification number to each individual instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.		
			6 Planning	Title only
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques,	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of: (b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or normative documents will not be	**2.3.2**. The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be	6.1 Actions to address risks and opportunities	In determining risks and opportunities regarding conformity of the instrument(s), the organization can consider using the outputs of techniques such as SWOT or PESTLE. Other approaches can include techniques such as Failure Mode and Effects Analysis (FMEA); Failure Mode, Effects and Criticality Analysis (FMECA). It is for the organization to decide which methods or tools it should use. Simpler approaches include techniques such as brainstorming, Structured What If Technique (SWIFT) and consequences/probability matrices. Risks and opportunities for the quality management system and relevant actions to address them shall, inter alia, relate to the manufacturing of instrument in accordance with the type described in the EU-type examination certificate and with requirements of MID or NAWID, as appropriate.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		**Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1**
processes and systematic actions that will be used; (c) the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out;	applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the measuring instruments will be met, applying other relevant technical specifications; (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered; (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;	used; (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;		Risks and opportunities for the quality management system and relevant actions to address them shall, inter alia, relate to the manufacturing of instrument in accordance with the design described in the EU design examination certificate and with the requirements of MID, as appropriate.
3.2 It (quality system) shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;	**3.2** It (quality system) shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;	**2.3.2** It (quality system) shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;	6.2 Quality objectives and planning to achieve them	The quality objectives, quality planning and quality manual must fully take on board the objective of delivering products that conform to the essential requirements.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
3.2 It (quality system) shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; 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 any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.	**3.2** It (quality system) shall, in particular, contain an adequate description of: (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system. The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary. It shall notify the manufacturer or his authorised representative of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.	**2.3.2** It (quality system) shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; 2.3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system. The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 2.3.2 or whether a reassessment is necessary. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.	6.3 Planning of changes	Without prejudice of having to comply with the legal requirements, the manufacturer shall have a clear policy and a procedure about the evolution or modification of the instrument 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 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 frame work 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. 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.
			7 Support	Title only
			7.1 Resources	Title only
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them.	**3.2**. The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.	7.1.1 General	The manufacturer shall ensure that the resources necessary for ensuring the legal conformity of instruments are always available.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them.	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.	**2.3.2**. The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.	7.1.2 People	Applicable such as described
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of: (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered; (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;	7.1.3 Infrastructure	In determining the necessary infrastructure, the manufacturer shall consider what facilities, equipment, computer software, services and/or transportation, etc., is needed to provide conforming instruments. When specific characteristics in infrastructures can have an impact on the realisation, surveillance or measurement of the instrument, the conditions for obtaining these characteristics shall be determined (infrastructure qualification) and the adequate recordings shall be realised. For module H1, this applies also to aspects in relation with the verification and validation of the design.
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of:	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of: (c) the design control and design verification	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of:	7.1.4 Environment for the operation of processes	This concerns more specifically the environment parameters having an impact on measurements such as vibrations, electromagnetic disturbances, temperature, hygrometry, etc. Once determined, the environment for the operation of processes should be suitably maintained and controlled as necessary. Adequate recordings shall be realised.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;	techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered; (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;	(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;		
			7.1.5 Monitoring and measuring resources	Title only
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the quality programmes, plans, manuals and records.	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. 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. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an	7.1.5.1 General	EN ISO 10012 standard is the relevant standard for the management of measurement processes and metrological confirmation of measuring equipment used to support and demonstrate compliance with metrological requirements. The measurement management system shall consist of the control of designated measurement processes and metrological confirmation of measuring equipment. All measuring equipment within the measurement management system shall be confirmed. The metrological characteristics of measuring equipment shall be suitable for its intended use. All measuring equipment necessary to satisfy the specified metrological requirements shall be available and identified.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned; (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	adequate description of: (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered; (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned; (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.	adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.; (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.		Metrological confirmation shall be designed and implemented to ensure that the metrological characteristics of the measuring equipment satisfy the metrological requirements for the measurement and monitoring process. Metrological confirmation comprises measuring equipment calibration and measuring equipment verification. Software used in the measurement processes and calculations of results shall be documented, identified and controlled to ensure suitability for continued use. Software, and any revisions to it, shall be tested and/or validated prior to initial use, approved for use, and archived. Measuring equipment and technical procedures used in the measurement management system shall be clearly identified. There shall be an identification of the status of the metrological confirmation of equipment. Equipment used in the measurement management system shall be distinguishable from other equipment. Measuring equipment used to monitor and record the influencing quantities shall be included in the measurement management system. The management of the metrological function shall establish, maintain and use documented procedures for receiving, handling, transporting, storing and dispatching measuring equipment, in order to prevent abuse, misuse, damage and changes to its metrological characteristics. There shall be procedures for processing measuring equipment introduced into or removed from the measurement management system. Records of the metrological confirmation process shall be dated and approved by an authorized person to attest to the correctness of the results, as appropriate. These records shall be maintained and available.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		**Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1**
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned; (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered; (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. 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. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.; (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	7.1.5.2 Measurement traceability	For all sensitive measuring tools used in production and in final controls, and excepted specific category provision, all the working standards shall be accompanied with their traceable calibration certificate issued by an EA accredited calibration laboratory, calibration laboratory accredited by an accreditation body that is signatory to the ILAC MRA (International Laboratory Accreditation Cooperation Mutual Recognition Arrangement) or a national metrology institute that is signatory of the mutual recognition arrangement of the Metre Convention, and the ability required for these tools shall be officially defined. In all cases, calibration uncertainties of working standards shall be compatible with the acceptable uncertainties. When the applicable standard does 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. The measurement uncertainty evaluation shall comply with the general principles described in the GUM. The manufacturer shall identify and quantify all relevant sources of uncertainty and make reasonable estimation for expanded uncertainty. The expanded uncertainty shall be in line with acceptable level for measurement uncertainty in conformity assessment required by applicable standards. 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. In the measuring fields where there is no calibration chain under accreditation or demonstrated through national metrology authority, 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.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
	(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.			All the software and data transfers used for monitoring the controls and measurements, and/or for their analysis, shall be subject to a preliminary verification and then to periodically programmed reverification (see also clause 8.5.1). For more general information on measurements uncertainties refer to the relevant parts in the WELMEC guides referred to in clause 2. Note: By "accredited laboratory", it is understood a calibration laboratory accredited by an accreditation body that has signed the mutual recognition agreement EA or by an accreditation body that is signatory to the ILAC MRA (International Laboratory Accreditation Cooperation Mutual Recognition Arrangement) in the calibration field. In all the cases, the accreditation scope shall include calibration capabilities and relevant measurement uncertainties.
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them.	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.	7.1.6 Organizational knowledge	The manufacturer shall take into account, inter alia, applicable harmonised standards, publication of the references to normative documents in the Official Journal, WELMEC guides and the generally acknowledged state of the art or any changes in them, which indicate that the measuring instrument may no longer comply with the applicable requirements of the Directive.
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them. 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	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them. 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 permit a consistent	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. 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. The quality system	7.2 Competence	The manufacturer's personnel shall have appropriate information on the legal requirements and controls applicable to the measuring instruments. See also article 7.1.6. In addition, for module H1, the validation responsible person (see article 8.3) shall have an exhaustive knowledge of the applicable essential requirements, of the applicable harmonised standards and/or normative documents and a good knowledge of this document, in particular article 8.3. The personnel involved in the metrological function shall have sufficient training to metrology in general, especially for its standardisation aspects such as described in article 2, article 7.1.5 and, for module H1, article 8.3.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality; (c) the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;	interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality; (b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or normative documents 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 measuring instruments will be met, applying other relevant technical specifications; (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered; (e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out; (f) the quality records, such as	documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality; (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;		The personnel in charge of the final control and testing shall also know: – the legal requirements attached to these instruments and their control, – the control and verification procedures. The technical competence of the personnel in charge of activities in relation with application of MID or NAWID, as appropriate, shall be ensured (recording of the initial and continuous training and qualifications). See also article 7.1.6.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
	inspection reports and test data, calibration data, qualification reports on the personnel concerned;			
			7.3 Awareness	Applicable such as described
			7.4 Communication	Applicable such as described
			7.5 Documented information	Title only
			7.5.1 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 shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (c) the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out;	**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 permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered; (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic	**2.3.2** 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. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;	7.5.2 Creating and updating	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 and applicable provisions MID or NAWID, as appropriate. For updating documented information, see also article 6.3.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.	actions that will be used; (b) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out; **3.5.** The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system. **4.4.** The manufacturer shall keep the notified body that has issued the EU design examination certificate informed of any modification to the approved design that may affect the conformity with the essential requirements of this Directive or the conditions for validity of the certificate. Such modifications shall require additional approval – from the notified body that issued the EU design examination certificate – in the form of an addition to the original EU design examination certificate.	**2.3.5.** The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.		
3.2 It (quality system) shall, in particular, contain an adequate description of: (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned; **5.2.** The manufacturer shall draw up a written EU declaration of conformity for	**3.2** It (quality system) shall, in particular, contain an adequate description of: (f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned; **4.6.** The manufacturer shall keep a copy of the EU design examination certificate, its	**2.3.2.** It (quality system) shall, in particular, contain an adequate description of: (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.; **2.5.2.** The manufacturer shall draw up a written EU declaration	7.5.3 Control of documented information	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 (MID or NAWID, harmonised standard or normative document …) shall be described in the quality documents. The storage of these documents shall be organised. 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.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		**Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1**
each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up. A copy of the EU declaration of conformity 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 a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities: (a) the documentation referred to in point 3.1, (b) the information relating to the change referred to in point 3.5, as approved; (c) the decisions and reports from the notified body referred to in points 3.5, 4.3 and 4.4.	annexes and additions with the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market. **6.2.** The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up and shall mention the number of the design examination certificate. A copy of the EU declaration of conformity 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. **7.** The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities: (a) the documentation	of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up. **2.6.** The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities: (a) the documentation referred to in point 2.3.1; (b) the information relating to the change referred to in point 2.3.5, as approved; (c) the decisions and reports of the notified body referred to in points 2.3.5, 2.4.3 and 2.4.4.		A register for legal marking on instruments and declaration of conformity shall be kept up to date (number and identification). The software qualification files and data transfer ones shall be kept under control. If recordings are under electronic format, the software and data transfers of these recordings shall be qualified under the manufacturer's responsibility. The duration for conservation of quality recordings is of one year at minimum, and from one audit until the following. The manufacturer shall be able to present, on request to the market surveillance authorities, the information about any economic operator to whom he has supplied a measuring instrument for 10 years after he has supplied the measuring instrument. 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.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
	concerning the quality system referred to in point 3.1, (b) the information relating to the change referred to in point 3.5, as approved; (c) the decisions and reports of the notified body referred to in points 3.5, 5.3 and 5.4.			
			8 Operation	Title only
3.2. It (quality system) shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;	**3.2.** It (quality system) shall, in particular, contain an adequate description of: (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered; (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;	**2.3.2.** It (quality system) shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;	8.1 Operational planning and control	Applicable such as described
			8.2 Requirements for products and services	Title only
6. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities: (a) the documentation referred to in point 3.1, (b) the information relating to the change referred to in	**7.** The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities: (a) the documentation concerning the quality system referred to in point	**2.6.** The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities: (a) the documentation referred to in point 2.3.1; (b) the information relating to the change referred to in point	8.2.1 Customer communication	Professional secrecy of the manufacturer is not valid versus the administrative authorities (CLMA, LLMA, etc) for all matters regarding directly or indirectly instruments under legal metrology, nor versus the notified body, for all matters regarding the certification of instruments. Manufacturers shall to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the instrument with MID or

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		**Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1**
point 3.5, as approved; (c) the decisions and reports from the notified body referred to in points 3.5, 4.3 and 4.4.	3.1, (b) the information relating to the change referred to in point 3.5, as approved; (c) the decisions and reports of the notified body referred to in points 3.5, 5.3 and 5.4.	2.3.5, as approved; (c) the decisions and reports of the notified body referred to in points 2.3.5, 2.4.3 and 2.4.4.		NAWID, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by instruments which they have placed on the market.
1. 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 points 2 and 5, and ensures and declares on his sole responsibility that the measuring instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.	**1.** Conformity based on full quality assurance plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.	**2.1.** 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 points 2.2 and 2.5, and ensures and declares on his sole responsibility that the instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.	8.2.2 Determining the requirements for products and services	Applicable such as described
1. 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 points 2 and 5, and ensures and declares on his sole responsibility that the measuring instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.	**1.** Conformity based on full quality assurance plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.	**2.1.** 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 points 2.2 and 2.5, and ensures and declares on his sole responsibility that the instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.	8.2.3 Review of the requirements for products and services	The legal requirements applicable to the instruments, their evolution, the implementation conditions and the testing procedures are part of the review.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
1. 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 points 2 and 5, and ensures and declares on his sole responsibility that the measuring instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.	**1.** Conformity based on full quality assurance plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.	**2.1.** 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 points 2.2 and 2.5, and ensures and declares on his sole responsibility that the instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.	8.2.4 Changes to requirements for products and services	Changes in measuring instrument design or characteristics and changes in the harmonised standards, normative documents or in other technical specifications by reference to which conformity of a measuring instrument is declared shall be adequately taken into account. The manufacturer shall ensure that relevant persons are aware of any changes to the legal requirements for instruments and that relevant documented information is amended.
			8.3 Design and development of products and services	Title only
	3.2 It shall, in particular, contain an adequate description of: (b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or normative documents 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 measuring instruments will be met, applying other relevant technical specifications; (c) the design control and design verification techniques, processes and systematic actions that will		8.3.1 General	No requirement corresponding to module D. Applicable such as described

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	Provisions in Annex II, module H1	Provisions in Annex II, module D		
	be used when designing the measuring instruments pertaining to the instrument category covered;			
	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 permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality; (b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or normative documents 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 measuring instruments will be met, applying other relevant technical		8.3.2 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. The manufacturer shall have established a policy in order to clearly distinguish the stages of designing and developing the measuring instrument and the stages of verifying and validating (see article 8.3.4) the design of the measuring instrument, taking into consideration possible iterative actions. 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.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system
Provisions in Annex II, module D	Provisions in Annex II, module H1	Provisions in Annex II, module D		Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
	specifications; (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered;			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 article 7.2. 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.
	3.2. It (quality system documentation) shall, in particular, contain an adequate description of: (b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or normative documents 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 measuring instruments will be met, applying other relevant technical specifications; (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.		8.3.3 Design and development inputs	No requirement corresponding to module D. For application to module H1: Inputs shall include all applicable MID requirements and where applicable other requirements in harmonised standards or normative documents. Where the manufacturer chooses 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: – 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. Inputs shall include the examination and test procedures validated by the NB (see article 8.6). It shall also include, in particular, all the policy to be written and implemented according to this article 8.3.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		**Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1**
	3.2. The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality; (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered; (f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;		8.3.4 Design and development controls.	No requirement corresponding to module D. For application to module H1: Reviews shall be organised at least: – 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 also articles 8.3.6 and 8.5.6), – each time a modification on the policy for subcontracting some tests is intended. 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 measuring instrument are implemented in the course of the phase of evaluation or that these situations were controlled under the responsibility of the validation responsible person. The verification of the conformity shall be consistent with the basic principle laid down in introduction of guidance to article 8.3 in any case, in particular for: – initial design approval, – modification of approved design, – family of instruments… The evaluation report shall clearly identity what tests have been performed on each kind of instrument. 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. A programme of tests can includes evaluation and tests on parts of the instrument or on a complete instrument.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
	(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.			The request for approval shall be accompanied with a clear demonstration that any measuring instrument conforming to the design is capable to fulfil the whole set of requirements without modification or non-allowed adjustment in any case. It is recommended that the manufacturer provides a complete cross reference list of requirements against evidences.
	3.2. It (quality system documentation) shall, in particular, contain an adequate description of: (b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or normative documents 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 measuring instruments will be met, applying other relevant technical specifications; (c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned; Note : This is without prejudice of the necessity to establish the technical documentation, as required in article 18 (not specific to annex H1).		8.3.5 Design and development outputs	No requirement corresponding to module D. For application to module H1: 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 other route for establishing the conformity to essential requirements. 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. The outputs shall also include: – 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. The technical documentation as specified in article 18 of MID and the supporting evidence for the adequacy of the technical design are part of the quality system and of the development outputs. The technical documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). It shall, as far as relevant for such assessment, cover the design and operation of the instrument. The supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	Provisions in Annex II, module H1	Provisions in Annex II, module D		
				standards and/or normative documents have not been applied in full, and shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications, by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.
	3.2. It (quality system documentation) shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality; (b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or normative documents 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 measuring instruments will be met, applying other relevant technical specifications; (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered; (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be		8.3.6 Design and development changes	No requirement corresponding to module D. For application to module H1: This paragraph concerns only changes made to the design after the issuing of the EU design examination certificate. They shall be managed as follows: There shall be a clear policy and processes stating in what conditions authorised modifications or evolutions may be made to the approved design. The validation responsible person shall be associated with any initiative and decision concerning whether modifications of the measuring instrument should be considered to may affect the conformity with the essential requirements of MID or the conditions for validity of the EU design examination certificate and to be approved by the NB. There shall be records of all these decisions where all the modifications made to the design will appear.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
	used; (e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out; (f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned; (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system. **4.4** The manufacturer shall keep the notified body that has issued the EU design examination certificate informed of any modification to the approved design that may affect the conformity with the essential requirements of this Directive or the conditions for validity of the certificate. Such modifications shall require additional approval – from the notified body that issued the EU design examination certificate – in the form of an addition to the original EU design examination certificate.			
			8.4 Control of externally provided processes, products and services	Title only Critical chapter regarding the services, controls, tests, calibrations and verifications that are sub-contracted.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		**Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1**
1. 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 points 2 and 5, and ensures and declares on his sole responsibility that the measuring instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them. **3.2.** The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the quality programmes, plans, manuals and records.	**1.** Conformity based on full quality assurance plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them. **3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the quality programmes, plans, manuals and records.	**2.1.** 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 points 2.2 and 2.5, and ensures and declares on his sole responsibility that the instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them. **2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. 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. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.	8.4.1 General	The manufacturer is responsible for ensuring that externally provided processes, products and services conform to MID or NAWID requirements. The manufacturer shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers (sub-contractors). The manufacturer may not transfer its responsibility to the sub-contractors. This statement does not concerns the specific tasks for which the manufacturer may designate an authorised representative for application of MID or NAWID. The specified requirements for purchasing shall include the conformity to type/design when the purchase is about parts of instruments, and particularly if the whole manufacturing is sub-contracted. When sub-contracting is critical regarding the instruments quality, the quality insurance requirements implemented for the manufacturing also apply to the subcontracted part, taking into consideration the following, in particular: 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. The manufacturer shall not subcontract the activities concerning judging on the conformity (global or partial). It applies also in cases where EC or PC according to WELMEC Guide 8.8 are used. Concerning production aspects, NB in charge of the quality system approval should consider the necessity to audit a sub-contractor.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	Provisions in Annex II, module H1	Provisions in Annex II, module D		
				The Notified Body should take into consideration two main issues when reviewing subcontractors: a) Whether the subcontractor has a substantial involvement with the design and/or production of the measuring instrument. b) Whether the subcontractor is undertaking the supply of a part, material or service, which may affect the compliance of the measuring instrument with the essential requirements. If the answer to both a) and b) above is NO, no further action is required. If the answer to a) and/or b) above is YES, then the Notified Body shall evaluate whether there is provided sufficient evidence of the ability of the subcontractor to undertake the supply of the part, material or service in relation to the measuring instrument in question. The evaluation will consider various matters including the control exercised by the manufacturer over the subcontractor and the certification held by the subcontractor. In this regard, the provision of clause 4.2.4 of the Welmec guide 8.8 should be taken into consideration. The Notified Body must be allowed to review the relevance or criticality of the subcontractor to the measuring instrument and, if not satisfied by the evidence available from the manufacturer, undertake an audit/assessment of the subcontractor or require the manufacturer to undertake a re-evaluation of the subcontractor. Note: The notified body may not need to undertake an audit/assessment of the subcontractor when one of the two following conditions is fulfilled: 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.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		**Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1**
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned; (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered; (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. 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. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.; (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	8.4.2 Type and extent of control	The manufacturer shall establish the controls for external providers and for purchased parts and services, in order to have confidence that the parts of instruments or services to be provided will meet applicable legal requirements and his ability to consistently deliver conforming instruments. The intent of these controls is also to ensure that the parts of instrument or services provision will be carried out according to planned arrangements. The presence, on purchased parts of instruments, of the recognized marking: – does not exempt the manufacturer from ensuring the conformity of these parts, – does not modify the responsibility of the manufacturer. 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. 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.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
	(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.			
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the quality programmes, plans, manuals and records.	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the quality programmes, plans, manuals and records.	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. 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. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.	8.4.3 Information for external providers	Chapter applicable to external controls, tests, calibrations and verifications. The specified requirements for purchasing shall include the conformity to type/design when the purchase is about parts of instruments.
			8.5 Production and service provision	Title only
3.2. It (quality system) shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (c) the examinations and tests that will be carried out before, during, and after manufacture, and the	**3.2.** It (quality system) shall, in particular, contain an adequate description of: (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (e) the examinations and tests that will be carried out before, during and after manufacture, and the	**2.3.2.** It (quality system) shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which	8.5.1 Control of production and service provision	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. When a part of the metrological verification takes place during the production process, the requirements that apply to the verification also apply.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		**Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1**
frequency with which they will be carried out; **5.2.** The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request. A copy of the EU declaration of conformity 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 a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities: (a) the documentation referred to in point 3.1, (b) the information relating to the change referred to in	frequency with which they will be carried out; **6.2**. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up and shall mention the number of the design examination certificate. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request. A copy of the EU declaration of conformity 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. **7.** The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the	they will be carried out; **2.5.2**. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request. **2.6.** The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities: (a) the documentation referred to in point 2.3.1; (b) the information relating to the change referred to in point 2.3.5, as approved; (c) the decisions and reports of the notified body referred to in points 2.3.5, 2.4.3 and 2.4.4. **7.1.** The conformity assessment according to Module D, D1, F, F1 or G may be carried out at the manufacturer's works or any other location if transport to the place of use does not require		Common provisions specified in clause 7 of NAWID, Annex II for NAWI instruments regarding module D shall be taken into consideration. Providing the documents for properly using of the instrument and the guarantee of their conformity (instruction manual, written declaration of conformity …) is part of the due service. Also keeping the information at the disposal of the national authority is part of the due service. Note: The EU declaration of conformity shall have the model structure set out in Annex XIII of MID or Annex IV of NAWID, as appropriate. The manufacturer shall take all provisions to ensure that all the necessary documents (legally required or indicated in the type examination certificate) are properly complemented and accompany the instruments (instruction manual, owner's maintenance booklet, written declaration of conformity, total or partial verification, certificate if applicable, etc.). 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. When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the manufacturer shall ensure that: – computer software is documented in sufficient detail and is suitably validated as being adequate for use; – procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing; – computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
point 3.5, as approved; (c) the decisions and reports from the notified body referred to in points 3.5, 4.3 and 4.4.	disposal of the national authorities: (a) the documentation concerning the quality system referred to in point 3.1, (b) the information relating to the change referred to in point 3.5, as approved; (c) the decisions and reports of the notified body referred to in points 3.5, 5.3 and 5.4.	dismantling of the instrument, if the putting into service at the place of use does not require assembly of the instrument or other technical installation work likely to affect the instrument's performance, and if the gravity value at the place of putting into service is taken into consideration or if the instrument's performance is insensitive to gravity variations. In all other cases, it shall be carried out at the place of use of the instrument. **7.2**. If the instrument's performance is sensitive to gravity variations the procedures referred to in point 7.1 may be carried out in two stages, with the second stage comprising all examinations and tests of which the outcome is gravity-dependent, and the first stage all other examinations and tests. The second stage shall be carried out at the place of use of the instrument. If a Member State has established gravity zones on its territory the expression 'at the place of use of the instrument' may be read as 'in the gravity zone of use of the instrument'. **7.2.1.** Where a manufacturer has opted for execution in two stages of one of the procedures mentioned in point 7.1, and where these two stages will be carried out by different parties, an		

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		**Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1**
		instrument which has undergone the first stage of the procedure shall bear the identification number of the notified body involved in that stage. **7.2.2.** The party which has carried out the first stage of the procedure shall issue for each of the instruments a certificate containing the data necessary for identification of the instrument and specifying the examinations and tests that have been carried out. The party which carries out the second stage of the procedure shall carry out those examinations and tests that have not yet been carried out. The manufacturer or his authorised representative shall ensure that he is able to supply the notified body's certificates of conformity on request. **7.2.3.** A manufacturer who has opted for Module D or D1 in the first stage may either use this same procedure in the second stage or decide to continue in the second stage with Module F or F1 as appropriate. **7.2.4.** The CE marking and the supplementary metrology marking shall be affixed to the instrument on completion of the second stage, along with the identification number of the notified body which took part in the second stage.		

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
3.2. It (quality system) shall, in particular, contain an adequate description of: (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;	**3.2.** It (quality system) shall, in particular, contain an adequate description of: (f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;	**2.3.2.** It (quality system) shall, in particular, contain an adequate description of: (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;	8.5.2 Identification and traceability	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: – 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.
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them.	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.	8.5.3 Property belonging to customers or external providers	Applicable such as described.
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques,	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of: (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (f) the quality records, such as	**2.3.2**. The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be	8.5.4 Preservation	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.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
processes and systematic actions that will be used; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;	inspection reports and test data, calibration data, qualification reports on the personnel concerned;	used; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;		
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the quality programmes, plans, manuals and records.	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them. 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 permit a consistent interpretation of the quality programmes, plans, manuals and records.	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. 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. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.	8.5.5 Post-delivery activities	When deemed appropriate with regard to the performance of an instrument, manufacturer shall carry out sample testing of measuring instruments made available on the market, investigate and, if necessary, keep a register of complaints, of non-conforming measuring instruments and measuring instrument recalls, and shall keep distributors informed of any such monitoring.
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques,	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of: (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be	8.5.6 Control of changes	There shall be a clear policy and processes stating in what conditions authorised modifications or evolutions may be made to the approved the quality system. The personnel in charge of activities in relation with application of MID or NAWID shall be associated with any intended change of the quality system. The manufacturer shall retain documented information describing the results of the review where any intended change of the quality system will appear and actions arising from the review. The manufacturer shall keep the notified body that has approved his quality system informed of any intended change of the quality system. See also paragraph 6.3.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
processes and systematic actions that will be used; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned; **3.5.** The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.	(f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned; **3.5.** The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.	used; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.; **2.3.5.** The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.		
3.2. It (quality system) shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (c) the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned; (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	**3.2.** It (quality system) shall, in particular, contain an adequate description of: (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered; (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out; (f) the quality records, such as inspection reports and test data, calibration data,	**2.3.2.** It (quality system) shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.; (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system. **7.1.** The conformity assessment	8.6 Release of products and services	All the processes of surveillance and of measure of the instrument during production process shall be submitted to the approval of the notified body. The examination and tests performed in the course of article 8.3.4 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 product verification (module F). The person(s) who authorizes final release of the instrument, and if applicable the design of the measuring instrument for application of article 8.3.4, should be suitably defined by, for example, their job description or authority level, and should be traceable. This can be achieved through the retention of documented information (e.g. the signature of the authorizing person, etc.)

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		**Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1**
	qualification reports on the personnel concerned; (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.	according to Module D, D1, F, F1 or G may be carried out at the manufacturer's works or any other location if transport to the place of use does not require dismantling of the instrument, if the putting into service at the place of use does not require assembly of the instrument or other technical installation work likely to affect the instrument's performance, and if the gravity value at the place of putting into service is taken into consideration or if the instrument's performance is insensitive to gravity variations. In all other cases, it shall be carried out at the place of use of the instrument. **7.2**. If the instrument's performance is sensitive to gravity variations the procedures referred to in point 7.1 may be carried out in two stages, with the second stage comprising all examinations and tests of which the outcome is gravity-dependent, and the first stage all other examinations and tests. The second stage shall be carried out at the place of use of the instrument. If a Member State has established gravity zones on its territory the expression 'at the place of use of the instrument' may be read as 'in the gravity zone of use of the instrument'. **7.2.1.** Where a manufacturer has		The final controls and tests, and if applicable the examination and tests procedures for application of article 8.3.4, 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. Common provisions specified in clause 7 of NAWID, Annex II for NAWI instruments regarding module D shall be taken into consideration. The final control procedures, and if applicable the examination and tests procedures for application of article 8.3.4, are subject to the agreement and formal validation of the notified body in charge of approval of the QAS before implementation. The notified body shall be informed in writing details of the modifications of these procedures at least one month before their implementation.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
		opted for execution in two stages of one of the procedures mentioned in point 7.1, and where these two stages will be carried out by different parties, an instrument which has undergone the first stage of the procedure shall bear the identification number of the notified body involved in that stage. **7.2.2.** The party which has carried out the first stage of the procedure shall issue for each of the instruments a certificate containing the data necessary for identification of the instrument and specifying the examinations and tests that have been carried out. The party which carries out the second stage of the procedure shall carry out those examinations and tests that have not yet been carried out. The manufacturer or his authorised representative shall ensure that he is able to supply the notified body's certificates of conformity on request. **7.2.3.** A manufacturer who has opted for Module D or D1 in the first stage may either use this same procedure in the second stage or decide to continue in the second stage with Module F or F1 as appropriate. **7.2.4.** The CE marking and the		

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
		supplementary metrology marking shall be affixed to the instrument on completion of the second stage, along with the identification number of the notified body which took part in the second stage.		
3.2. It (quality system) shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (c) the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned; (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	**3.2.** It (quality system) shall, in particular, contain an adequate description of: (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered; (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out; (f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned; (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.	**2.3.2.** It (quality system) shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.; (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	8.7 Control of nonconforming outputs	There may not be any exception regarding statutory criteria applicable to the manufactured instruments. 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.). The correction processes of a non-conforming instrument shall be defined. The nature of non-conformity shall be recorded and classified according their types and their consequences.

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
			9 Performance evaluation	Title only
			9.1 Monitoring, measurement, analysis and evaluation	Title only
3.2. It (quality system) shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (c) the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned; (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	**3.2.** It (quality system) shall, in particular, contain an adequate description of: (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered; (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out; (f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned; (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.	**2.3.2.** It (quality system) shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.; (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	9.1.1 General	Applied such as described

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
			9.1.2 Customer satisfaction.	No requirement corresponding to module D. No requirement corresponding to module H1.
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them.	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.	9.1.3 Analysis and evaluation	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.
3.2. It (quality system) shall, in particular, contain an adequate description of: (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	**3.2.** It (quality system) shall, in particular, contain an adequate description of: (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.	**2.3.2.** It (quality system) shall, in particular, contain an adequate description of: (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	9.2 Internal audit	Applied such as described.
			9.3 Management review	Title only
3.2. It (quality system) shall, in particular, contain an adequate description of: (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	**3.2.** It (quality system) shall, in particular, contain an adequate description of: (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.	**2.3.2.** It (quality system) shall, in particular, contain an adequate description of: (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	9.3.1 General	Applicable such as described
3.2. It (quality system) shall, in particular, contain an adequate description of: (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	**3.2.** It (quality system) shall, in particular, contain an adequate description of: (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.	**2.3.2.** It (quality system) shall, in particular, contain an adequate description of: (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	9.3.2 Management review inputs	Applicable such as described

DIRECTIVE 2014/32/EU (MID)		DIRECTIVE 2014/31/EU (NAWID)	EN ISO 9001: 2015 (chapters title only)	Guidance for the approval of manufacturer's quality assurance system Presumption of conformity to EN ISO 9001: 2015 standard for modules D or H1
Provisions in Annex II, module D	**Provisions in Annex II, module H1**	**Provisions in Annex II, module D**		
3.2. It (quality system) shall, in particular, contain an adequate description of: (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	**3.2.** It (quality system) shall, in particular, contain an adequate description of: (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.	**2.3.2.** It (quality system) shall, in particular, contain an adequate description of: (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	9.3.3 Management review outputs	Applicable such as described
			10 Improvement	Title only
			10.1 General	No requirement corresponding to module D. No requirement corresponding to module H1.
3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU- type examination certificate and comply with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;	**3.2.** The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of: (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;	**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. It shall, in particular, contain an adequate description of: (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;	10.2 Nonconformity and corrective action	Manufacturer who consider or have reason to believe that a instrument which they have placed on the market is not in conformity with MID or NAWID, as appropriate, shall immediately take the corrective measures necessary to bring that instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the instrument presents a risk, manufacturer shall immediately inform the competent national authorities of the Member States in which they made the instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.
			10.3 Continual improvement	No requirement corresponding to module D. No requirement corresponding to module H1.