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0. REVISION HISTORY

REV.	DATE	SUMMARY OF CHANGES
0	Jun. 2010	Issuing document.
1	Oct. 2010	Cl. 5.1, 5.2 y 5.3.- It includes information relating to decision making by personnel independent from the assessor. Setting of additional requirements and exclusions for module B, D & F certifications. Cl. 12.2.- Inclusion of new numeral 12 & 13.
2	Gen. 2011	Cl. 5.1, 5.2 y 5.3.- Inclusion of clarifications of module B, D and F certification requirements, respectively.
3	Jun. 2011	Cl. 5.2.- Change of 8's numeral for clarifying of follow-up frequency Cl. 10.- Inclusion of reasons for certification suspension.
4	Oct. 2011	Cl. 11.- Inclusion of information related to claim's management procedure Annex 2.- Annex's update
5	Nov. 2012	Cl. 4.- Addition of reference to EN 62058-11, EN 62058-31, PEC-ITE-LCM & Welmec 8.6 Cl. 5.2.- Change of 8's numeral for clarifying of follow-up frequency Cl. 7.- Clarifying of follow-up frequency.
6	Feb. 2014	Addition of sentence related to distribution as an uncontrolled copy Cl.4.- Addition of reference to Welmec 7.2, 11.1 & 11.2 Cl. 5.1.- Setting of additional requirements and exclusions for module B regarding meters with a voltage range and meters with more than one rated frequency. Change of Cl. D4.2.4-1; Cl. D7.6-1, Cl. 9, Cl. 11, Cl. 12.1 y Cl. 12.2 Adaptation of the procedure to new standard ISO/IEC 17065.
7	Nov. 2014	Cl. 0: Addition of 'Revision history' Cl. 4: Addition of reference to OIML Recommendation R46-1/-2 and Welmec 8.7 Cl. 5.1: Addition of new numeral 5 and renumbering of previous numerals 5 & 6 Cl. 5.2: Addition of new numeral 7 and renumbering of numeral 7 & 8. Cl. 5.3: Addition of new numeral 5 and renumbering of previous numeral 5. Setting of additional requirements, clarifying reference documents for checking and testing. Annex A: Updating of process diagrams including review stage
8	July, 2016	Directive 2014/32/UE and Royal Decree 244/2016 implementation.
9	March 2020	Cl. 4 Update of reference documentation for certification Cl. 5 Update of additional requirements and exclusion to certification procedures for module D certification, according ISO 9001:2015
10	July 2020	Addition of new ICT/155/2020. Addition of new clause 10.1 "Reduction"
11	June 2021	Removal of ITC/3022/2007 references.
12	October 2021	Welmec 7.2(2020) & Welmec 11.1(2020) reference upgrade.
13	February 2024	Welmec 7.2(2022) reference upgrade.
14	April 2024	Welmec 7.2(2023) and Welmec 11.1(2022) reference upgrade. NOTE: Changes are identified in blue color text.

1. OBJECT AND SCOPE

This document defines guidelines to fulfil by a measurement instrument manufacturer or supplier, for the following conformity assessment modules:

Modules	Choice 1: (B+D)	Choice 2: (B+F)
B	Type examination	Type examination
D	Declaration of conformity to type based on quality assurance of the production process	
F		Declaration of conformity to type based on product verification

This document covers the following measuring instruments intended for residential, commercial and light industrial use:

- Meters for the measurement of active electrical energy, with precision classes A, B and C
- Active electrical energy meters (without remote management)
- Static active electrical energy meters with the option of reactive energy measurement, time discrimination and remote management, which meet the following characteristics:
  a) They measure active electrical energy, with accuracy classes A, B and C, that can be installed at measurement points classified as type 5 or type 4 or type 3 with low voltage, according to the classification established by Royal Decree 1110/2007, of August 24, which approves the unified regulation of measurement points of the electrical system or by the regulations that replace it and,
  b) That they can optionally incorporate the combined measurement of active electrical energy, with accuracy classes A. B and C, with reactive energy with accuracy classes equal to or better than 3.

2. CRITERIA FOR CONFORMITY ASSESSMENT

Conformity assessment of a measurement instrument with essential requirements, metrological and technical, it's carried out by the application, at the choice of the manufacturer or his authorized representative; provided that it is stipulated in the written mandate from the manufacturer, of one of the conformity assessment procedures listed in the previous paragraph:

a. Module B, type examination, plus module D, conformity to type based on quality assurance of the production process
b. Module B, type examination, plus module F, conformity to type based on product verification

3. GENERAL REQUIREMENTS

3.1 CONFORMITY ASSESSMENT APPLICATION

3.1.1 Necessary documentation

To apply an electrical energy meter assessment the applicant must know the following documents:

- Conformity assessment procedures, both for the application in the specific framework of harmonised legislation in the framework of European Union (Directive 2014/32/EU) and

for the specific framework of Spanish legislation (Royal Decree 244/2016 and Order ICT/155/2020) applicable to instruments and measuring systems;

- Documents about general certification criteria and additional requirements or exclusions which may proceed;
- Conformity assessment application, for completion and signature;
- Assessment process rates;

And submit the duly completed the related "Conformity Assessment Application" form.

You can get these documents from ITE upon request and/or through web: www.ite.es

3.1.2 Certification application (conformity assessment)

The assessment application shall be completed by the applicant (manufacturer or authorised representative) on the related "Conformity Assessment Application" form on which an applicant:

- Defines the certification scope,
- Declares knowledge of ITE's certification system, rights and duties of certified applicants described herein, and in particular, states have been aware that ITE's assessment doesn't imply approval nor a commitment on the part of ITE that this authorization occur,
- Lodge a formal assessment application,
- Undertake to comply the certification requirements, to respect the certification procedure, and in particular, to receive and provide cooperation to the evaluation team, allowing any reasonable check to verify compliance with certification requirements, and bear the expenses of assessment process, and if appropriate, the expenses of subsequent surveillance.

In general, it would be necessary to lodge an application for each energy meter type to assess, and for each chosen assessment module. ITE will assign a docket number application, referring each model included in that docket.

All information obtained before, during or after assessment is treated as strictly CONFIDENTIAL by ITE. Moreover ITE may report the Authority that authorizes and/or to ENAC, about the status of any particular docket.

The applicant must submit the application and the written documentation in one of the languages understandable by ITE's experts (Spanish, English).

ITE believes that the entity requesting the assessment meets all regulatory requirements established by the Authorities.

3.1.3 Application review and notification to applicant

Upon receipt an application assessment, ITE will review the documentation enclosed to check if the activity can be assess or if there is any legal reason, statutory or otherwise order (independence) to prevent it. In that case it would be notified to the applicant. It will also evaluate if the scope of certification is clearly defined and if documentation is complete and adequate. In some cases, ITE may request, at the moment or in later stages of the process, additional information to ensure the proper execution of the evaluation process.

Likewise, ITE will submit the Certification Agreement with the aim to inform the applicant about the certification rights and duties. This agreement must be returned to ITE, up in

duplicate and signed by the applicant. Later, ITE will proceed to the return of one of the original, duly signed by ITE

If the documents are not complete or adequate, ITE will ask the applicant to complete.

On this stage, depending on whether the applicant has previous certifications, ITE will decide which requirements and assessment activities are applicable within those described in this procedure.

4. REFERENCE DOCUMENTS FOR CERTIFICATION

- Directive 2014/32/EU of the European Parliament and of the Council, of 26 February 2014, on the harmonisation of the laws of the Members States relating to the making available on the market of measuring instruments (recast) [OJ L no, 96; 29/03/2014]
- Royal Decree 244/2016, 3rd June, which develops the Law 32/2014, 22nd December, of Metrology [BOE n. 137; 07/06/2016]
- Order ICT/155/2020, of February 7, which regulates the metrological control of the State of certain measurement instruments [BOE no. 47; 24/02/2020]
- Harmonized standards or normative documents specifics for measurement instrument technology.
- ISO 9001:2015 standard, for production.
- UNE-EN ISO/IEC 17025 standard, in its revision in force
- EN 62058-11:2010, final product inspection and testing
- EN 62058-31:2010, final product inspection and testing
- ITE's internal documents.
- ITE's conformity assessment procedures.
- PEC-ITE-LCM "Licenses, certificates and conformity marks
- Welmec Guide 7.2 (2023) Software Guide (Measuring Instruments Directive 2014/32/EU)
- Welmec Guide 8.6 (2018) 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 Guide 8.7 (2021) Measuring Instruments Directive (2014/32/EU): Assessment of Notified Bodies Designated for Module F based on EN ISO/IEC 170020.
- Welmec Guide 11.1 (2022) Measuring Instruments Directive 2004/22/EC. Common application for utility meters.

- Welmec Guide 11.2 (Issue 1) Guideline on time depending consumption measurements for billing purposes (interval metering)

- International Recommendation OIML R46-1/-2. Active electrical energy meters.
    - Part 1: Metrological and technical requirements
    - Part 2: Metrological controls and performance tests

- If appropriate (D and F modules) EU-type examination certificate and its annexes for the measuring instrument issued by other Notified Bodies.

- The instrument's technical documentation

5. ASSESSMENT PROCEDURES

At annex 3 to this document, you could find the block diagrams of the assessment processes.

5.1 Procedure to get the EU-type examination certificate (module B)

1) You must submit the corresponding formal application (SEC-B) to perform the EU-type examination on the corresponding type of the measurement instrument, specifying manufacturer's name and address and, if the application is submitted by your authorized representative, his name and address in addition, and also a copy of written mandate received from the manufacturer.

2) In respond to your request, ITE will issue a quotation to provide the requested service.

3) If you accept our terms, you must submit us the documentation indicated on annex 1 to this document, and if that is stated, the number of samples requested.

4) Upon receipt of documentation, ITE shall study it and carry out (or have them carried out) the appropriate examinations and tests foreseen in accordance with the harmonized standards, normative documents or specific developed programs to demonstrate the instrument compliance with metrological requirements.

5) After the evaluation is reviewed all the information and results related to the same. This review is performed by personnel who have not been involved in the assessment process.

6) Then it begins the ending process on decision taken procedure, where considering information about previous stages, evaluator other than those who have participating on previous stages, make a decision about the certification or notification of refusal. When the technical design meets the metrological requirements that apply to the measuring instrument, ITE shall issue an (EU)-type examination certificate to the manufacturer, according to European or national legislative field. Case of not exceeding the evaluation process, ITE will issue a report of noncompliance. The certificate shall have a validity of ten (10) years from the date of its issue, and may be renewed for subsequent periods of equal duration. The manufacturer shall keep available to the national authorities a copy of the (EU)-type examination certificate, its annexes and additions with the technical documentation for 10 years after the instrument has been placed on the market.

Certification requirements for module B conformity assessment

For instrument's conformity assessment with essential requirements mentioned either in the relevant European harmonized standards or in the corresponding parts of the normative documents (metrological and technical) according to module B "type examination", ITE will apply the procedure and criteria laid down in:

- Procedure:
  - European framework: Annex II, Module D Directive 2014/32/EU
  - Spanish framework: Annex I, Article 5 Module B RD 244/2016 & Annex V, clause 3 Order ICT/155/2020, of February 7
    - **Explanatory note**: ITE carry out the Type examination; both European and Spanish framework, through the examination of a specimen, representative of the production envisaged.

- Criteria: The following table indicates, according to meter type and applicable regulatory framework, regulation and standards applied by ITE for assessment of compliance with essential requirements:

European framework:

Active electrical energy meters
Annexes I & V Directive 2014/32/UE ***Active energy:*** EN 50470-1 EN 50470-3 Welmec guide 11.1 ***Software:*** Welmec guide 7.2

Spanish framework:

Electrical meters intended for residential, commercial and light industrial use
Active energy: Annex II and X of Royal Decree 244/2016 & Annex V Appendix I Part I of Order ICT/155/2020 UNE-EN 50470-1 UNE-EN 50470-3 Welmec Guide 11.1 ***Reactive energy (if so):*** Annex V Appendix I Part II of Order ICT/155/2020 UNE-EN 62052-11 UNE-EN 62053-23 or UNE-EN 62053-24 ***Time discrimination and synchronization (if so):*** Annex V Appendix I Part III of Order ICT/155/2020 UNE-EN 62054-21 UNE-EN 62052-21 Welmec 11.2 ***Software:*** Annex IV Royal Decree 244/2016 Welmec Guide 7.2 Annex V Appendix I Part IV of Order ICT/155/2020 (if so)

  - **Explanatory Note:** ITE will apply the criteria listed in the preceding tables, even if the manufacturer has chosen not to apply the solutions in the relevant documents referred to in those tables.

Additional requirements and exclusions to certification procedures

B. Module B evaluation procedure

Additional requirements:
If the meter is designed for multiple reference voltages, requirements will be assessed for upper and lower value of voltage (Welmec Guide 11.1)

Exclusions:
Due to harmonized standards are valid only for 50 Hz, if the meter is designed for multiple reference frequencies, ITE will not assess rated frequencies other than 50 Hz (Welmec Guide 11.1)

5.2 Procedure to get a Quality system approval (module D)

1) You must submit us the corresponding formal application (SEC-D) for assessment of the quality system, specifying its scope and the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well, and a copy of the written mandated received from the manufacturer.

2) In respond to your request, ITE will issue a quotation to provide the requested service.

3) If you accept our terms, you must submit us the documentation referred to in Annex 2 of this document.

4) After studying the documentation, ITE will agreed with applicant performing a visit to its facilities in order to know them and conduct an audit of the quality system for production, final product inspection and testing of the measuring instruments concerned, according a scheduled plan.

5) As a result of the audit, ITE will make and audit report with the findings and deviations found, which will be issued to the applicant for its information and to proceed to establish a corrective plan for the deviations identified. In some cases, may require the conduct of a second audit to verify the proper implementation of the corrective actions.

6) The applicant must submit the corrective actions plan, which will be evaluated.

7) After the evaluation is reviewed all the information and results related to the same. This review is performed by personnel who have not been involved in the assessment process

8) Then it begins the ending process, where independent evaluator's personal takes the decision about the certification or the notification of refusal. Case of successful resolution, ITE will issue a quality system approval certificate, along to specific instructions to operate under an approved quality system. This certificate is valid for 3 years from the date of issue.

9) During the period of validity of the approval certificate, ITE performs surveillance audits. The first follow-up audit will be conducted within 12 months of the certification decision or 15 months from the date of initial audit, whichever expires before. For later tracking, the deadline is set to 12 months from the date of the last surveillance audit performed. Re-assessment audit will be performed at least two months before the end of the validity period of the quality management system approval certificate.

Certification requirements for module D conformity assessment

For presumption conformity assessment of manufacturer' quality system with module D "Declaration of conformity to type based on quality assurance of the production process", ITE will apply, depending on the regulatory framework, the procedure and criteria laid down in:

- European framework: Annex II, Module D Directive 2014/32/EU
- Spanish framework: Annex I, Article 9 (Module D) Royal Decree 244/2016 & Annex V clause 3 Order ICT/155/2020, February 7

Clarification: ITE will apply as reference the EN ISO 9001 (2015) standard for presumption of conformity of manufacturer' quality System with module D.

Additional requirements and exclusions to certification procedures

D. Module D evaluation procedure

Additional requirements:

The following are additional requirements that applicants must be complying for assessment based on module D. These requirements are identified with a letter that identifies the applicable module and the number of the clause of EN ISO 9001 to which they relate, followed by an additional or serial number.

D4.2 Understanding the needs and expectations of interested parties

D4.2-1 The list of relevant interested parties shall among other 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 / metrological control body involved in conformity assessment procedure.

D4.2-2 The requirements of these interested parties shall among others aim to:

- customer requirements regarding conformity,
- statutory and regulatory requirements for the product,
- notified body / metrological control body requirements, that has approved the quality system, to be informed of any intended change of the quality system.

D4.3 Determining the scope of the quality management system

D4.3-1 When exclusions are requested (the manufacturer indicates that a paragraph of EN ISO 9001 is not applicable), they may only be accepted if:

- *They do not affect the manufacturer' ability to provide instruments conforming to the type certified and the legal requirements,*
- *Such exclusions do not free him from his responsibility,*
- *For application of module D, the exclusions are limited to the requirements of EN ISO 9001 paragraph 8.3 (design and development), 9.1.2 (customer satisfaction),10.1 (improvement) and 10.3 (continual improvement).*

D4.4 Quality Manual

D4.4-1 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 subcontractor(s).

D4.4-2 If the quality management system scope is not limited to the production of measuring instruments subject to legal control, a description of interactions between the different' quality management system processes should enable to identify specific processes for instruments subject to metrological control.

D5.1.2 Customer focus

D5.1.2-1 For the implementation of this chapter, the legal metrology authorities and the notified body / metrological control body shall be considered as "clients".

D5.2.1 Quality Policy

D5.2.1-1 Quality policy should include:

- *Manufacturer' commitment for manufactured instruments compliance with legal applicable requirements and,*
- *Manufacturer' commitment for manufactured instruments compliance with type approved.*

D5.3 Organizational roles, responsibilities and authorities

D5.3-1 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.

Top management shall also appoint a person with responsibility and authority for the everyday relations with the services in charge of implementation of legal requirements (notified body, metrological control body).

The apposition of the marking of conformity is under the responsibility of the manufacturer.

D6.1 Actions to address risks and opportunities

D6.1-1 In determining risks and opportunities regarding conformity of 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 brainstorming, Structured What If Technique (SWIFT) and consequences/probability matrices.

D6.1-2 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 describe in the (EU)-type examination certificates and with requirements of relevant metrology legislation.

D6.2 Quality objectives and planning to achieve them

D6.2-1 The quality objectives, quality planning and quality manual must fully take on board the objective of delivering products that conform to the essential requirements.

D6.3 Planning of changes

D6.3-1 Manufacturer shall establish provisions for adequately take into account the changes in measuring instrument design or characteristics and changes in the harmonised standards, normative documents or in other technical specification by reference to which conformity of measuring instrument is declared (Directive 2014/32/EU, Chapter 2, Article 8.4 – Royal Decree 244/2016, Article 25,4).

D6.3-2 Modifications to instrument' definition documents that might affect to legal characteristics and/or metrological performances and/or the integrity of the type/design instrument must be immediately informed to ITE, at least one month before the effective implementation of such modifications. Those modifications cannot be implemented whereas ITE doesn't give his agreement.

D7.1 Resources

D7.1.1-1 The manufacturer shall ensure that the resources necessary for ensuring the legal conformity of instruments are always available.

D7.1.3-1 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 there characteristics shall be determined (infrastructure qualification) and the adequate recordings shall be realised.

D7.1.4-1 Once determined, the environment for the operation of processes should be suitably maintained and controlled as necessary. Adequate recordings shall be realised.

D7.1.5 Monitoring and measuring resources

D7.1.5.2-1 All working standards used during production and ending control must have their relevant traceable calibration certificates issued by an accredited calibration laboratory or by a National Metrology Institutes. This requirement applies to all sensitive measuring tools used in production and final controls for the performance of critical verifications. Critical verifications are, at least, those related to the adjustment of RTC, the calibration/adjust and the metrological verification of manufactured meters, the dielectric strength and the environmental control (temperature).

D7.1.5.2-2 In all cases, calibration uncertainty shall be adequate according to maximum permissible errors.

D7.1.5.2-3 All critical software used to monitoring control and measurements, and/or for their analysis, shall be subject to validation prior to use and in case of modification.

D7.1.6 Organizational knowledge

D7.6.1-1 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 relevant metrology legislation.

D7.2 Competence

D7.2-1 The manufacturer's personnel shall have appropriate information on the legal requirements and controls applicable to the measuring instrument.

D7.2-2 The personnel involved in the metrological function shall have sufficient training to metrology in general, especially for its standardisation aspects.

D7.2-3 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.*

D7.5 Documented information

D7.5.2-1 Legal requirements applicable to each category of manufactured instruments are part of the documents that must be kept under control.

D7.5.2-2 Manufacturer shall ensure that procedures are in place for series production to remain in conformity to Directive 2014/32/EU (European framework) or Royal Decree 244/2016 (Spanish framework).

D7.5.3-1 Records of the processes that allows to establish the conformity of the manufactured instruments to the certified type and to the applicable provisions - essential requirements, normative documents or harmonized standards..- shall be described in the quality documents, and the storage of these documents shall be organised.

This storage shall allow identifying 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.

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.

Manufacturer shall keep at the disposal of the national authorities for 10 years after the instrument has been placed on the market:

- *The application for assessment of his quality management system and the dossier attached to it.*
- *Information to this body of any update on the quality management system approved.*
- *The decisions and reports issued by this body related to:*
    a. *upgrades of the quality management system approved,*
    b. *periodic monitoring audits,*
    c. *unexpected audits and product tests.*
- *Information related to identification of any economic operator who has supplied them with a measuring instrument or to whom they have supplied a measuring instrument (Directive 2014/32/UE , Art. 13 – Royal Decree 244/2016, Art. 30)*

D7.5.3-2 Storage life of any other quality record will be at least 1 year and from one audit until the following.

D8.2.3 Review of requirements related to the product

D8.2.3-1 Legal requirements applicable to measuring instruments, their evolution, the implementation conditions and testing procedures should be part of such review.

D8.4 Control of externally provided processes, products and services

D8.4-1 Chapter applicable to external controls, tests, calibrations and verifications. For instruments parts, the information about purchase shall include the legal conformity.

D8.4.1-1 Regarding to sub-contracting services, controls, tests, calibrations and verifications, being critical for the quality of manufactured instruments, ITE will assess the capability and competence of manufacturer' subcontracted laboratories, when they are not accredited for the relevant tests nor are national metrological centres signatories of mutual recognition agreements of Metrological Convention.

D8.4.1-2 When manufacturer subcontracts production aspects, fully or in part, ITE may consider that is not necessary to audit a sub-contractor whether the whole set of 3 conditions is fulfilled:

1) *All the critical metrological examination and tests normally intended for such an instrument for application of module D are performed in the framework of the approved quality system of the manufacturer.*
2) *In order to ensure the general quality of the instrument and conformity to type/design, one of the two following conditions is fulfilled:*
    a. *The subcontractor has himself a quality system approved for application of module D 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 and the conformity to type is ensured by the manufacturer.*
3) *All the elements useful for ITE to make its judgement are provided to it.*

D8.4.2-1 A product certification does not exempt the manufacturer for an incoming inspection if the purchased product has specific importance for the quality of manufactured instruments.

D8.5.1 Control of production and service provision

D8.5.1-1 There shall exist written procedures describing clearly the metrological activities of control and verifications, at final stage as well as during the production process, if these processes can have consequences on the metrological conformity of the product. The facilities used and the personnel affected shall be described as well.

D8.5.1-2 Manufacturer shall take all provisions to ensure that all needed 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.

D8.5.1-3 The manufacturer shall drawn up a written declaration of conformity that may apply, according to the applicable regulatory framework, for each instrument type. This declaration shall be continuously updated and shall have the model structure set out in:

- *European framework: EU declaration of conformity based on Annex XIII Directive 2014/32/UE*
- *Spanish framework: National declaration of conformity based on Annex V Royal Decree 244/2016*

D8.5.2 Identification and traceability

D8.5.2-1 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 examination certificate and documents of definition of the certified type and recordings enabling to prove the conformity to type, 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 critical components and sub-contracted parts),*
- *the controls made,*
- *the results of these controls.*

D8.7 Control of nonconforming outputs

D8.7-1 There may not be any exception regarding statutory criteria applicable to the manufactured instruments.

D8.7-2 Manufacturer shall keep up to date records from monitoring when rejecting instruments or instruments group during final control (re-calibration, destruction, refuse, etc.)

D8.7-3 It must be established a correction process by non-conformed instruments.

D8.7-4 The rates of non-conformity must be recorded and classified according to their types and consequences.

5.3 Product verification procedure (module F)

1) You must submit us the corresponding formal application (SEC-F) based on product verification, specifying if verification will be by examination and testing of each instrument or if will be an statistical verification. Additionally, you should inform us about instrument characteristics and number of them (in case of batches, indicate instruments amount per batch)

2) In respond to your request, ITE will issue an economic proposal for requested service provision.

3) If you accept our terms, then you must submit us the EU-type examination certificates of instruments subjected to verification, as well as its annexes or additional.

4) After studying the certificate(s), ITE will carry out the appropriate examinations and functional tests, according a harmonized standard or normative document or essay specific plan, to demonstrate compliance with metrological requirements applicable.

5) After the evaluation is reviewed all the information and results related to the same. This review is performed by personnel who have not been involved in the assessment process.

6) Then it begins the ending process on decision taken procedure, where considering information about previous stages, evaluator other than those who have participating on previous stages, make a decision about the certification or notification of refusal. ITE shall issue a certificate of conformity in respect of the examinations and tests carried out for those instruments which fulfilled the evaluation process. The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

Certification requirements for module F conformity assessment

For instrument's conformity assessment with essential requirements mentioned either in the relevant European harmonized standards or in the corresponding parts of the normative documents (metrological and technical) according to module F "Conformity to type based on product verification", ITE will apply, according the regulatory framework, the procedure and criteria laid down:

- European framework: Annex II, Module F Directive 2014/32/EU
- Spanish framework: Annex I, Art. 13 (module F) Royal Decree 244/2016 & Annex V clause 3 Order ICT/155/2020.

The measurement instruments shall be examined and tested in order to assure its compliance with metrological requirements laid down in the following harmonized standards and normative documents:

- Conformity to metrological requirements for active energy:
  - *EN 50470-3 & EN 62058-31*
  - *Annex V ICT/155/2020*
- Conformity to metrological requirements for reactive energy:
  - *EN 62053-23 & EN 62058-31*
  - *Annex V ICT/155/2020*
- Conformity to software requirements
  - *Welmec Guide 7.2*
- Conformity to additional software requirements
  - *Annex IV Royal Decree 244/2016*
  - *Annex V ICT/155/2020*
- *Conformity to remote management and breaker requirements*
  - *Annex V ICT/155/2020*

Additional requirements and exclusions to certification procedures

F. Module F evaluation procedure

Additional requirements:

For checks and functional tests shall be taken of the provisions of the following documents:

- Directive 2014/32/EU
- Royal Decree 244/2016
- ICT/155/2020
- International Recommendation OIML R46-1/-2
- Welmec Guide 8.7
- Welmec Guide 11.1

Exclusions:

It has not been set exclusions.

6. VALIDITY OF THE CERTIFICATION

The Type examination certificate shall have a validity of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each, as long as manufacturer meet the criteria established by ITE and obligations arising from certification.

The Quality System approval certificate shall have a validity of 3 years from the date of its issue, and may be renewed for subsequent periods of 3 years each, as long as manufacturer meet the criteria established by ITE and obligations arising from certification.

The product verification certificate shall have a validity of 10 years from the date of its issue.

Both the certification requirements established in the regulations as the criteria used by ITE in its application undergo changes over time in order to keep abreast of technological developments and to ensure at all time that certifications are appropriate for the purpose for which are granted. Therefore, manufacturers must adapt certificates during the term of their certification to the new requirements and criteria established. ITE will always communicate changes to certified manufacturers in sufficient time and will establish adequate adaptation periods, depending on the nature of the changes.

The certification will expire if the manufacturer so request or in case of dissolution. In this case, ITE will put this matter to the attention of the public administration that appointed him.

7. MAINTENANCE OF CERTIFICATION

The type certification will be kept during the issued certificate force (10 years) as long as the manufacturer applies for renewal in writing in advance of 3 months before its maturity.

During the validity of certification approval of quality management system, QMS, (3 years) and for the maintenance of quality certification approval, ITE will make periodical surveillance audits. The frequency of surveillance is established in Art. 5.2 item 8), of this document. As a part of the evaluation process may be carried out control visits out of previous audit program.

After the period of 3 years from the initial date of approval of the QMS certification, ITE should reassess that the quality management system implemented remains effective, making an audit equivalent to the initial. In this case, the manufacturer shall submit with at least 3 months before the scheduled reassessment audit, the necessary information, using the relevant application forms. Don't receiving this information by the deadline means the manufacturer is not interested in maintaining its certification.

8. EXTENSION OF CERTIFICATION SCOPE

When a manufacturer already certified, wants to expand the scope of its QMS certification approval with new measuring instruments models, should request to ITE the extension of its reach. To do this, the manufacturer must use the application form for this purpose. The extension process will follow the same development as that established for an initial certification.

Requests for extension must be made with at least 4 months before the scheduled date for the next follow-up visit in order to manage both processes simultaneously.

9. NOTIFICATION OF CHANGES

The applicant must inform to ITE, without delay, through the notification of changes form, about the changes that are proposed to be conducted and which could affect his capability for certification requirement fulfilment. Among others, the following:

- Changes over the certified product;
- Changes over production method, manufacturing process;
- Relevant change over the quality management system;
- Organization and management (for instance, key management, personal decision-maker or technical staff);

As well as, any other fundamental change that occurs in the initial conditions, under which certification is granted.

In face of change notification, ITE will review them, establishing evaluation activities as proceed, and if needed modifying the certificates of conformity or their additional, as appropriate.

10. REDUCTION, SUSPENSION AND WITHDRAWAL OF CERTIFICATION

The failure by an Entity to comply with certification liabilities will result in the following measures that will be adopted depending on the gravity of the infringement:

10.1 Reduction

Reduction is defined as the removal of a certified product variant from a (EU) Type Examination Certificate or the removal of a product or product variant from the module D certification scope. The process can be initiated:

- At request of the client
- As a result of an evaluation process, when the expiration of the validity of a (EU) type examination certificate covered by the certification or the existence of any product or product variant that does not comply with the requirements of certification due to the annulment or repeal of a regulatory reference document for certification

The reductions will be decided by the Certification Committee. The reductions will be reliably notified to the interested party.

The reduction implies, from the date of notification thereof:

- The prohibition of use of the ON or OCM number in the manufactured products affected by the reduction.
- The prohibition of the commercialization of the certified product that has led to the reduction of the certification, providing ITE with evidence of its realization.

When ITE confirms nonconformity to certification requirements, either as a result of surveillance or otherwise, ITE may consider and decide to reduce the scope pf certification by eliminating nonconforming product variants.

10.2 Suspension

The following are laid down reasons for certification suspension:

- Voluntary temporary suspension: Certified entities may apply a voluntary temporary suspension, at any moment*, of all or part of its certification scope.
- Serious non-fulfilments (or repeated) on certification requirements, being understood as serious those involving a lack of efficacy in the management of critical processes that challenge the assurance of conformity of manufactured instruments with the model described in the type examination certificate, with applicable regulatory requirements and the requirements of certification scheme.
- Serious non-fulfilments (or repeated) of the liabilities established on the certification procedures, related to deadlines and information to be provided to ITE.
- Unjustified non-fulfilments of the commitments undertaken by the entity before ITE.
- Failure to pay the cost of evaluation and management of the certification process in its different phases.
- In any case, when it is revealed the manipulation, misrepresentation or concealment of records that serve as the basis for demonstrating compliance with certification requirements.

*Unless the Certification Committee had previously dictated a temporary suspension.

Suspensions will be decided by the Certification Committee which shall indicate, where appropriate, the entity's obligation to solve, in the term specified (maximum 6 months), the causes that led to it; including, when necessary, the withdrawal from the market of the certified product with possible defects (product stored and installed). The suspensions shall be notified to the interested in reliable way. The Certification Committee may discretionary extend the period granted to reasonable request of the entity.

If within 7 calendar days the applicant does not show his displeasure with the agreement, the suspension shall be notified to the competent public authority which appoints ITE and the Administrative Cooperation Body, by the procedure to be established. Otherwise, the Certification Committee may reconsider its decision in view of the data supporting such nonconformity.

The suspension of all or part of the products or sites included in the scope of certification involves, from date of notification of the suspension and while duration of the same:

- Prohibition of use of the ON or OCM number at products manufactured affected by the suspension.
- The prohibition of the marketing of the certified product with possible defects which has led to suspension of certification, providing evidences to ITE of its realization
- During the suspension period, the manufacturer must stop using; in the media, all advertising which has any reference to certified product condition, of the product with possible defects which has motivated the suspension of the certification. Also, the manufacturer may not rely on certification to disclose, sell or carry out activities affected by the suspension. Additionally, the Certification Committee may establish specific conditions to be observed by the manufacturer whose certification has been suspended.
- It requires the manufacturer to warn current and potential buyers on the status of certification, providing evidences of their realization to ITE.

Generally, the products manufactured before of suspension, don't lose its condition of certified. However, if in the opinion of the Certification Committee, the reasons that led to the suspension, question the validity of previously certified products, it shall expressly setting out the measures that the entity should take with the above products.

Once notified the suspension, the entity will has 15 calendar days, for the sending to ITE of the corresponding corrective action plan.

Once solved the reasons that motivated the suspension, the entity must apply its lifting, being necessary to perform an extraordinary assessment to determine the fulfilment of the certification requirements. This assessment shall be made within six (6) months from the date of the agreement of Certification Committee (unless the entity has requested, through reasoned written, a prorogation and it has been granted by the Certification Committee, in which case, the assessment must be done before ending of the prorogation). If suspension causes haven't been solved on deadline, the Committee will assess the proposal of withdrawal, partial or full, of certifications affected.

10.3 Withdrawal

The following are laid down reasons for certification withdrawal:

- Very serious non-fulfilments (or repeated) of the obligations of the certified company, for example:
    - The non-systematic notification of changes to a certified instrument model.
    - The non-systematic notification of changes into quality management system of those aspects that can affect performance of metrological specifications of the measuring instrument covered by the certification scope.
- Failure to remedy the causes that motivated a suspension agreement
- If the manufacturer's performance threatens the credibility and prestige of ITE or certification.
- Improper and deliberate use of notified ITE's number as notified body, on models don't included in the scopes of certification issued by ITE.

If ITE knows this situation shall notify the applicant, which in within 1 month may make the necessary allegations. In case of not receiving them, shall proceed to the withdrawal of certification and its submission to the concerned and competent public administration and to the Administrative Cooperation Body. The withdrawal of certification will mean disqualification for the use of the reference to the number of notified body or metrological control over the instruments concerned and has immediate effect from the notification thereof. The withdrawal of certification involves the annulment of certificate and its annexes.

11. COMPLAINTS

At any time of certification process, may be expressed a dissatisfaction, other than appeal, regarding the activities performed by the certification entity, through the submission of a formal complaint. Means by you can send us your complaint can be email, fax or regular mail. Additionally, if requested, ITE offers a claim form, which may request by email to calidad@ite.es. Once received your complaint, ITE will register it; accusing its receiving, analyse and will establish its appropriateness or inappropriateness and, if necessary, will propose adequate solutions. Ended the process it will be notified the result to the claimer.

12. APPEALS

Against certification decisions and withdrawal of certification may be brought before ITE. In all cases the appeals shall be instituted by written notification within 1 month of receipt of the agreement is challenged, accompanying the claims that they deem necessary and, where appropriate, the proposal to create appropriate tests. The lodging of an appeal shall not have suspensory effect at any time for that decision. In order to enlarge it information about the appeals process in case of appeal, you must request a copy of the appeals procedure (PG-ITE-35) to the following e-mail: calidad@ite.es

NOTE: See also Art. 66 of Royal Decree 244/2016, 3 of June.

13. RIGHTS AND DUTIES OF APPLICANTS

12.1 Rights

The applicant of an evaluation conformity process has the following rights:

1) Choose freely a Notified Body.
2) Use ITE's notified body number / metrological control number, in case in case has successfully passed the evaluation procedures which proceed, and as long as ITE has authorised it.
3) All information provided to ITE, is treated as confidential, unless specified otherwise in regulations published by him.
4) Have the reports related to audits, surveillance visits, test and exams.
5) To appeal ITE's decisions, as set herein.
6) Claim to ITE in relation to the service provided.
7) When the scope of certification refers to a specific system or type of system implemented by ITE, the applicant shall be provided any necessary clarification
8) If the applicant requires additional information regarding to application, ITE should provide it.

12.2 Duties

An assessment procedure applicant shall comply at all times the obligations arising from its certification, which are:

a) The applicant of certification shall comply at all times relevant provisions of the certification program, including the implementation of the proper changes when certification body communicates these.
b) If certification applies to the current production, certified product must continue to meet product requirements.
c) The applicant shall take necessary measures to:
    1. Carry out the assessment and surveillance (if required), including provisions for reviewing documentation and records, and access to equipment, locations, areas, staff and subcontractors relevant;
    2. Investigate the complaints;
    3. Observer participation, if applicable;
d) Make statements about the certification consistent with the scope of certification
e) Not to use product certification such that cause bad reputation for ITE, and don't make any statement regarding its product certification which ITE may consider misleading or unauthorized;
f) Immediately after suspension, withdrawal or finishing of the certification, stop using all advertising matter that contains any reference thereto and return any document related to it when required by ITE and take any other action required;
g) If supply copies of certification documents to others, such documents will be reproduced in full or as specified by the certification scheme;
h) When referring its certification products on media such us documents, brochures or advertising, meet the requirements of certification body or specified by the certification scheme;
i) Comply with all requirements that may provide the certification scheme in relation to the use of marks of conformity and product-related information;
j) Keep a record of all complaints known related to the compliance with certification requirements and make such record available to ITE when requested, and

1. Take appropriate actions with respect to such complaints and the deficiencies found in products that affect compliance with certification requirements;
2. Document the actions taken;

k) Inform to ITE, without delay; about the changes that could affect his capability to comply with certification requirements.

l) Comply in all the cases with the regulatory requirements, which have been established by Administration, where appropriate, to develop the activity for which is certified

m) To pay the costs arising to the assessment and maintenance of certification.

ANNEX 1. Technical Documentation to submit with module B assessment application

Chapter III Art. 18.3 Directive 2014/32/EU Article 13.3 R.D.244/2016	*Documentation to request and evaluate by ITE*
1)	A general description of the instrument - Commercial information describing the instrument and measurement concept. It must be completed on tabular with a definition of the metrological characteristics of the instrument, taken into account metrological parameters, listed in a specific annex.
2)	Analysis and assessment of instrument risks – Identify all possible risks that the product may pose and determine the essential requirements applicable to the product. This analysis has to be documented and included in the technical documentation. In addition, the manufacturer needs to document the assessment of how he is addressing the risks identified to ensure that the product complies with the applicable essential requirements. Note: In order to clarify concepts, it's recommended to consult the Commission Notice "Blue Guide" on the implementation of EU product rules 2016
3)	Conceptual design and manufacturing drawings and plans of components, sub-assemblies, circuits, etc.
4)	Manufacturing procedures to ensure consistent production.
5) (if applicable)	A description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation.
6)	Descriptions and explanations necessary for the understanding of points 3), 4) and 5), including the operation of the instrument. *This point may be limited to a note, list, outline or diagram, in order to explain the links between documents, drawings and diagrams that correspond to paragraphs 3), 4) and 5).*
7)	A list of the harmonised standards and/or normative documents referred to in Article 14 of Directive 2014/32/EU and Article 14 of Royal Decree 244/2016, applied in full or in part, the references of which have been published in the Official Journal of the European Union.
8)	Descriptions of the solutions adopted to meet the essential requirements where the harmonized standards and/or normative documents referred to in Article 14 of Directive 2014/32/EU and Article 14 of Royal Decree 244/2016, have not been applied, including a list of other relevant technical specifications applied.
9)	Results of design calculations, examinations, etc.
10) (where necessary)	The appropriate test results, where necessary, to demonstrate that the type and/or instruments comply with the applicable requirements of Directive 2014/32/EU and/or Royal Decree 244/2016 or determined on specific regulation, under declared rated operating conditions and under specified environmental disturbances.
11)	The (EU)-type examination certificates in respect of instruments containing parts identical to those in the design.- *This paragraph can be summarizing on tabular with related (EU)-type examination certificates and the technical conditions for compatibility with interfaces and sub-assemblies*.

ÍNDEX

A possible index which takes into account the previous points could be:

1) General description of the instrument
    - 1.1) Instrument introduction (by photo)
        - 1.1.1) Mark, model or models, versions
        - 1.1.2) Physical architecture
    - 1.2) Main characteristics
        - 1.2.1) Measure units. Measure functions.
        - 1.2.2) Technical specifications
        - 1.2.3) Accessories (rates, recorder, maxi meter, …)
        - 1.2.4) Time synchronization
    - 1.3) Description of faceplate features
    - 1.4) Wiring
    - 1.5) Data presentation
        - 1.5.1) States diagram display
        - 1.5.2) Presentation of data in automatic mode
        - 1.5.3) Presentation of data in manual mode
    - 1.6) Technical specifications
        - 1.6.1) Electrical
        - 1.6.2) Environmental conditions
        - 1.6.3) Accuracy class
        - 1.6.4) Mechanical
        - 1.6.5) Connections
        - 1.6.6) Terminal box
        - 1.6.7) Electromagnetic compatibility
        - 1.6.8) Pulse emisor
        - 1.6.9) Energy reserve items
        - 1.6.10) External dimensions
        - 1.6.11) Triangle fixing
2) Analysis and assessment of instrument risks
3) Design and manufacturing schemes, plan of components, subassemblies, circuits
    - 3.1) Outline dimensions and position of the parts
    - 3.2) External and internal connections scheme
    - 3.3) Block diagram of the logic cell associated with each of the physical outputs and LEDs
    - 3.4) Keyboard and display
    - 3.5) Architecture of information screens
4) Manufacturing procedure
    - 4.1) Manufacturing process phases
    - 4.2) Process control
    - 4.3) Electrical safety
    - 4.4) Applicable regulations
5) If appropriate, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation

6) Instrument performance
    6.1) Reception tests and safety advice
    6.2) Instrument performance by means of PC
    6.3) Indicators

7) List of the standards and/or normative documents applied.
8) Descriptions of the solutions adopted to meet the essential requirements (Annexes I & V Directive 2014/32/EU; Annexes II & X Royal Decree 244/2016)
    8.1) Compliance to MPE (maximum permitted error) for each influence quantity
    8.2) Mechanical environment
    8.3) Electromagnetic environment
    8.4) Climatic environment
    8.5) Aptitude (fraud, inadequate use, …)
    8.6) Protection against corruption
9) Results of design calculations and examinations.
10) Tests results related to compliance of specific regulation
11) Type examination certificates
12) Specify where seals and markings have been applied.
13) Conditions for compatibility with interfaces and sub-assemblies.

ANNEX 2 - Documentation to submit to assess the Quality System

- *Conformity assessment application for module D*

- *The technical documentation of approved type and a copy of the (EU)-type examination certificate, its annexes and possible amendments, covered by the QS.*

- *The Quality System descriptive and support documentation, in particular:*

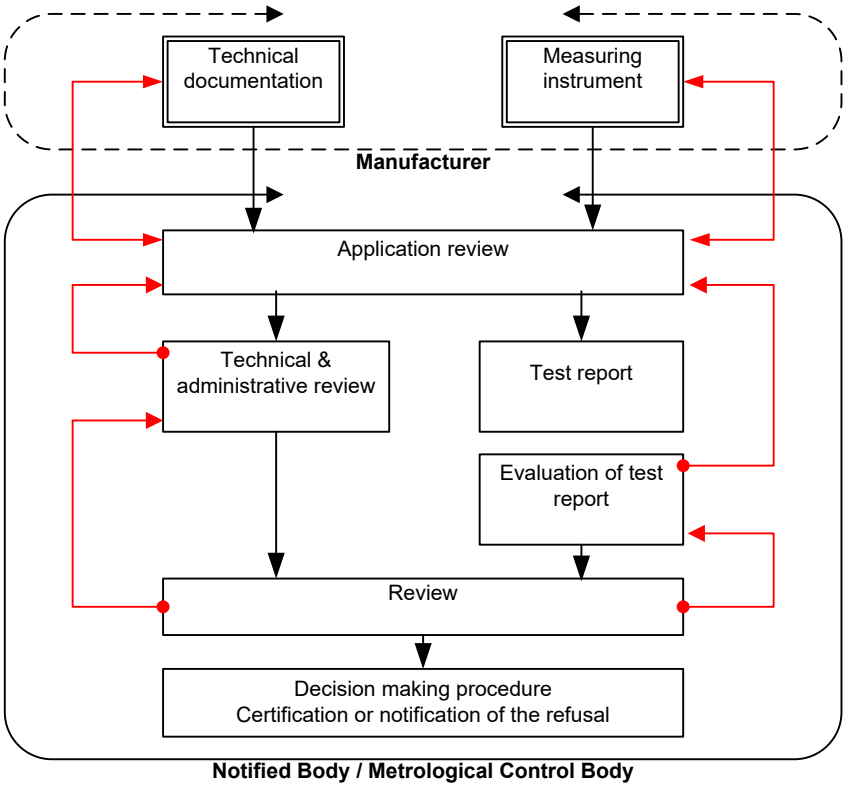
	Documentation to assess the QS
☐	*The quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality*
☐	*The corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used.*
☐	*The examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out.*
☐	*Quality Manual and if appropriate, general procedures that develop it.*
☐	*List of personnel involved in the QS.*
☐	*Qualification reports on the personnel concerned*
☐	*List of standards, facilities and equipment used to do the examinations and tests*
☐	*Standards and equipment's calibration plan*
☐	*Copy of internal calibration procedures for standards and equipment (if appropriate).*
☐	*Copy of test procedures and instructions to check the controlled instruments.*
☐	*Copy of calibration certificates for standards and equipment used to check the controlled instruments.*
☐	*Information about the essay facilities, as well as information about environmental conditions*
☐	*Pattern of conformity declaration which will be issued with each measurement instrument to commercialize, according the applicable regulatory framework.*
☐	*Records & booklets test forms*
☐	*Other models: claim records, suppliers control, non-conformities records, etc.*

- *And undertake declaration to fulfill the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient, and to keep the notified body informed of any intended change of the quality system.*

- *In case of outsourcing the manufacturing of measuring instruments, the applicant must provide evidence showing the existence of a contractual relationship between the parties to ensure that the owner of the location of manufacture is responsible for complying with all obligations under the certification.*

ANNEX 3 - Block diagrams for evaluation processes

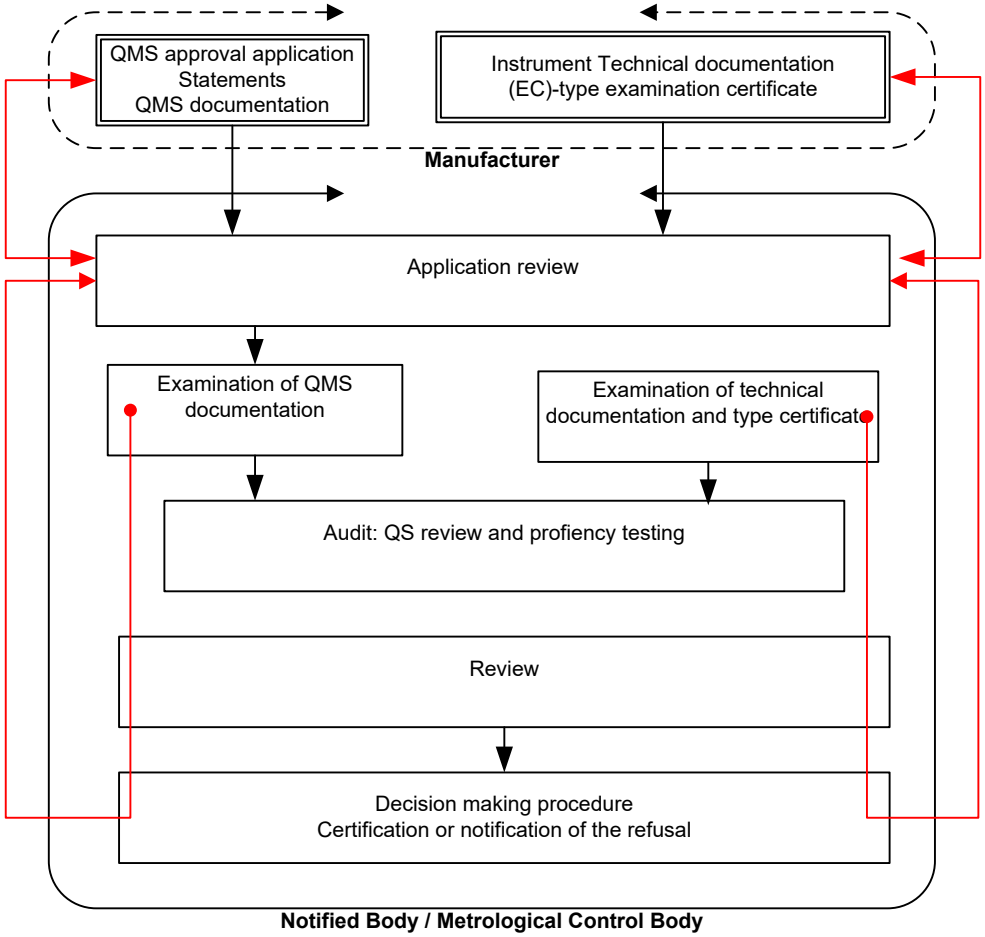
A.3.1 EU-type evaluation process (module B)



In case of nonconformity

***Reference:** Annex 1 WELMEC 8.3

A.3.2 Process for the Quality System approval (module D)



In case of nonconformity

A.3.3 Process for product verification (module F)