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## 1. Object

To define the requirements for proper use of licenses and certificates granted by ITE within the scope of his performance as a notified body over electric energy meters under State legal metrological control. Such performance is restricted to:

- Activities related to the conformity assessment procedures established for the implementation of certain metrological control of the State in the European Union, conducted by ITE as a Notified Body, taking into account the provisions of Directive 2014/32/EU, the specific regulations and technical guidance and coordination emanating from European Union Commission and the Council of Metrology, where appropriate.
- Activities related to the conformity assessment procedures for the implementation of the State metrological control under specific national regulations, namely, the instrument for which there is no European harmonized regulation for a directive, conducted by ITE as a Metrologic Control Body (MCB) whose recognized in the State, taking into account the provisions of Royal Decree 244/2016, of 3 June, the specific regulations and technical guidance and coordination emanating from Council of Metrology.

## 2. Scope

The requirements in this procedure apply to both ITE and all manufacturers of electric energy meters, or its authorized representative, who acting under the responsibility of ITE, and being on placing on the market and putting into use stage, have requested to ITE and passed the conformity assessment activities in accordance with the metrological requirements that apply. Specifically, the scope of this procedure involves:

- The use of the type examination certificates or the design examination certificates issued by ITE once checked the conformity of the instrument with module B.
- The use of the conformity certificates issued by ITE related to examinations and tests carried out under the test provided for in the assessment of conformity based on module F.
- License for NB/MCB identification number use by the manufacturer (or its authorized representative), that at European legislative scope corresponds to its registration number as a Notified Body (NB) and at national legislative scope corresponds to its national registration number as a Metrological Control Body (MCB) [supplementary metrology marking or national marking]
- The use of the quality system approval certificate issued by ITE once passed the evaluation according to module D.

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### 3. Reference documents

- ❖ **Directive 2014/32/EU** of the European Parliament and of the Council, of 26 February 2014, on the harmonization of the laws of the Member States relating to the making available on the market of measuring instruments
- ❖ **Royal Decree 244/2016, of 3 June**, by developing the Law 32/2014, of 22 December, of Metrology.
- ❖ **Order ICT/155/2020, February 7th**, by regulating the State metrological control of certain measurement instruments.
- ❖ **GCA-ENAC-OCML** State metrological control: Technical competence requirements for Notified Bodies (NB), Metrological Control bodies (MCB) and authorized of metrological verification.
- ❖ **CGA-ENAC-CPR** Accreditation general criteria. Technical competence of certifying product entities.
- ❖ **UNE-EN ISO/IEC 17065** Conformity assessment -- Requirements for bodies certifying products, processes and services

Remark: All documents referenced in the text are applied in the current edition.

### 4. Definitions

- ❖ **Conformity certificate:** document issued by a NB or a MCB in relation to a measuring instrument attesting that it complies with the essential, metrological and technical requirements, established by specific regulations applying to it.
- ❖ **Type examination certificate:** shall consist both the EU-type examination certificate issued by a NB within the European legislative scope and the type examination certificate issued by a MCB within the national legislative exclusive.
- ❖ **Design examination certificate:** shall consist both the EU-type design certificate issued by a NB within the European scope and the design examination certificate issued by a MCB within the national legislative exclusive.
- ❖ **Conformity marking:** shall consist both the 'CE' marking and the supplementary metrology marking within the scope of European legislation and shall be affixed in those instruments with specific annexes on Directive 2014/32/EU, which meets the essential requirements, and the national marking which shall be affixed on such others instruments not included in the annexes, under State metrological control, which has specific national regulation and fulfils it (Royal Decree 244/2016 and [ICT/155/2020](#)).
- ❖ **'CE marking':** means a marking by which the manufacturer indicates that the measuring instrument is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.



- ❖ **Supplementary metrology marking:** mark that certifies the conformity of a specific measuring instrument with the essential requirements of European new approach directives and metrological character.
- ❖ **National marking:** set of letters and symbols attesting the conformity of a product, tested with the established evaluation procedures, with specific national regulations.
- ❖ **Placing on the market:** means the first making available of a measuring instrument on the Union market
- ❖ **Making available on the market:** means any supply of a measuring instrument for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.
- ❖ **Putting into use:** means the first use of a measuring instrument intended for the end-user for the purposes for which it was intended.

## 5. General requirements

When State's Metrological Control gets passed, it is stated the instrument conformity with:

- the provisions set out in Directive 2014/32/EU by the presence on it of the 'CE' marking and the supplementary metrology marking or the national marking (see paragraph 7).
- the provisions set out in Royal Decree 244/2016, of 3 June and on specific regulation, by the presence on it of the national marking, according to Annex III of RD 244/2016 (see paragraph 7).

The conformity marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No. 765/2008, of 9 June.

Manufacturer shall affix:

- a) The CE marking and the supplementary marking set out in Directive 2014/32/EU, and, under the responsibility of the notified body involved in phase of control of production (ITE), 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 Directive 2014/32/EU.
- b) The national marking set out in Annex III of Royal Decree 244/2016, and, under the responsibility of the metrological control body involved in phase of control of production (ITE), the latter's identification number to each individual measuring instrument that is in conformity with the type described in the type examination certificate and satisfies the applicable requirements of Royal Decree 244/2016.

Both for the case a) and b), the conformity marking shall be affixed before the measuring instrument is placed on the market, being possible to affix it to the instrument during the fabrication process, if justified.

It can be placed on the market or put into use the measuring instruments under State metrological control that meets the metrological provisions established and determined in the corresponding specific regulation and that, therefore, incorporate, as appropriate, the 'CE' marking and the supplementary metrology marking or national marking.

In order to the commissioning of a measurement instrument it shall be met the requirements of climatic conditions, accuracy class or useful life labelling laid down in specific applicable regulations.

## 6. Specific requirements

### 6.1. Conformity assessment based on type examination (module B)

Where the technical design meets the requirements of metrological regulation that apply to the measuring instrument, ITE delivers an EU-type certificate or a Type-certificate, according to the European or National legislative.

The certificate shall contain the name and address of the manufacturer and, if appropriate, of his authorized representative, conclusions of the examination, conditions (if any) for its validity and the necessary data for identification of the instrument.

Contents of certificate issued:

- a) The metrological characteristics of the type of instrument.
- b) Measures required for ensuring the integrity of the instruments (sealing, identification of software, etc.).
- c) Information on other elements necessary for the identification of the instruments and to check their visual external conformity to type.
- d) If appropriate, any specific information necessary to verify the characteristics of manufactured instruments.
- e) In the case of a sub-assembly, all necessary information to ensure the compatibility with other sub-assemblies or measuring instruments.

The certificate shall have a validity of ten (10) years from the date of its issue, and may be renewed for subsequent periods of ten years.

The manufacturer shall immediately inform ITE of all modifications to the instrument that may affect the conformity of the instruments with the essential requirements or the conditions of validity of the certificate. Such modifications require additional approval in the form of an addition to the original (EU)-type examination certificate.

The manufacturer shall kept a copy of the (EU)-type examination certificate, its annexes and additions with the technical documentation for ten (10) years after the instrument has been placed on the market.

### 6.2. Conformity assessment based on quality assurance of the production process (module D)

ITE will issue a certificate of approval of the manufacturer's quality system, once assessed the same and inspected the manufacturer facilities, whenever the quality system guaranteed that the measuring instruments are in conformity with the type as describe in the (EU)-type examination certificate and satisfies the metrological regulation. This certificate will contain the conclusions of the examination and the reasoned assessment decision.

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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.

The manufacturer shall keep informed ITE of any intended change of the quality system. ITE shall evaluate the modifications proposed and decide whether the changed quality system will still satisfy the requirements of metrological regulation or whether a re-assessment is required.

The manufacturer shall draw up a written declaration of conformity, depending on the applicable regulatory framework, for each instrument model and keep it at the disposal of the national authorities for ten years after the instrument has been placed on the market. The declaration of conformity shall have the model structure set out (Annex XIII Directive 2014/32/EU and/or Annex V Royal Decree 244/2016) and it shall identify the type of the instrument for which it was drawn up, and shall be continuously updated.

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

### 6.3. Conformity assessment based on product verification (module F)

ITE shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for ten years after the instrument has been placed on the market.

The manufacturer shall affix the conformity marking to each measuring instrument that is in conformity with the approved type and satisfies the appropriate metrological requirements (see paragraph 7)

The manufacturer shall draw up a written declaration of conformity, depending on the applicable regulatory framework, for each instrument model and keep it at the disposal of the national authorities for ten years after the instrument has been placed on the market. The declaration of conformity shall have the model structure set out (Annex XIII Directive 2014/32/EU and/or Annex V Royal Decree 244/2016) and it shall identify the type of the instrument for which it was drawn up, and shall be continuously updated.

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



If agreed upon by ITE, the manufacturer shall also affix the notified body/metrological control body identification number to the measuring instruments under ITE's responsibility, depending on the applicable regulatory framework.

## 7. Content

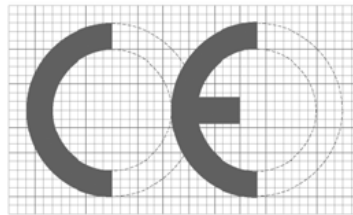
It is strictly forbidden any different use from the indicated in this section.

### 7.1. Format and layout of the conformity marking

For the format and layout of the conformity marking shall address the following specifications:

#### 'CE' marking

The 'CE' marking consists of the symbol 'CE' according to the design laid down in point 1 of Annex II of Regulation (EC) No. 765/2008. The 'CE' marking shall be at least 5 mm high, according to the following model:



If the 'CE' marking is reduced or enlarged the proportions given must be respected.

#### Supplementary metrology marking:

The supplementary metrology marking consist of the capital letter "M" and the last two digits of the year of its affixing, surrounded by a rectangle. The height of the rectangle shall be equal to the height of the 'CE' marking. The supplementary metrology marking shall immediately follow the 'CE' marking.



#### National marking:

The national marking consist of the minuscule letter "m" with a tilde over and the last two digits of the year of its affixing, on white, surrounded by a rectangle which shall be at least 5 mm high.



#### Identification number of the Notified Body / Metrological Control Body:

The CE marking and the supplementary metrology marking or national marking shall be followed by the identification number of the body or bodies involved on phase of control of production (modules D or F). The identification number of the control body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

Examples of conformity marking:

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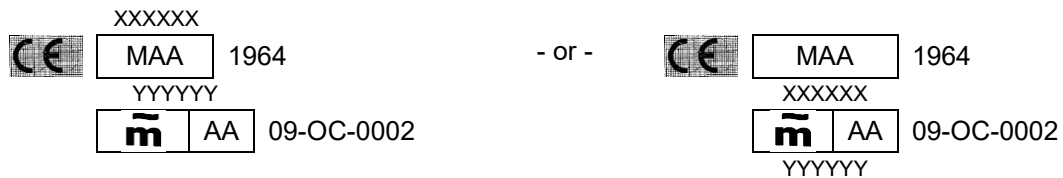
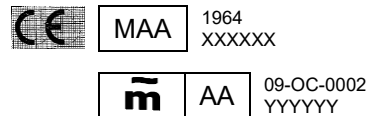
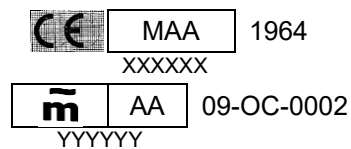
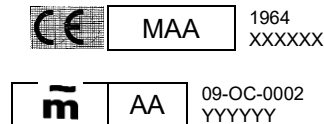
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**Example 1:**


- or -


**Example 2:**

**Example 3:**

**Example 4:**

**Example 5:**

**Example 6:**

**Where:**

XXXXXX: Is the EC-Type examination certificate number (issued by a Notified Body)

YYYYYY: Is the type examination certificate number (issued by a Metrological Control Body)

AA: Are the last two digits of the year of marking affixing over the meter

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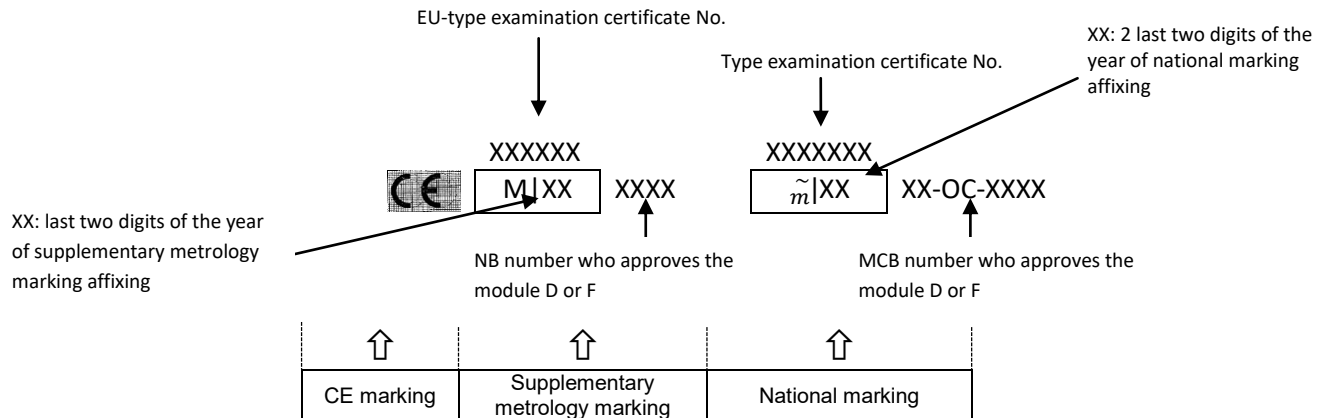
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The CE marking, the supplementary metrology marking and national marking, as appropriate, shall be affixed visibly, legibly and indelibly to the measuring instrument or to its data plate. Where that is not possible or not warranted on account of the nature of the measuring instrument, they shall be affixed to the accompanying documents and to the packaging, if any.

The CE marking, the supplementary marking, the national marking and the identification number of the body involved in the production control phase may be followed by any other mark indicating a special risk or use.

## 8. Restricted uses

### 8.1. Type examination certificates

The (EU)-type-examination certificates issued by ITE are only applicable to the instrument and type identified and during the validity period specified in the license (10 years from the date of issue), provided that the type does not undergoes changes that may affect the conformity of the instrument with the essential requirements.

Partial reproductions of certificates issued are strictly forbidden

### 8.2. Conformity marking

Unduly affixed of the 'CE' marking and the supplementary metrology marking or the national marking, and the use of marking or labels with designs not authorized or confusing.

The affixing of markings on a measuring instrument that are likely to deceive third parties as to the meaning and/or form is forbidden. Any other marking may be affixed on a measuring instrument, provided that the visibility and legibility of the 'CE' marking and the supplementary metrology marking (or national marking) is not thereby reduced.

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Where it is determined that a conformity marking has been unduly affixed, the manufacturer or its authorized representative, or as appropriate the person who sells or distributes the instrument, it shall be obliged to meet provisions on conformity marking and to end the infringement.

In the event of further noncompliance described above, it shall take appropriate measures to ensure they are removed from market or banned its use in accordance with existing procedures.

Appropriate measures are taken to treat incorrect references to the certification system to a misleading use of licenses, certificates or marks that appear in advertisements, brochures, etc.

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REVIEW No.	DATE	CHANGES OR CONTENTS SUMMARY
0	25/05/2010	First issue
1	13/11/2012	Page 1. Substitution of e-mail reference <u>calidad@ite.es</u> by <u>ocp@ite.es</u> Updated in par. 3. Reference standards Incorporation under par. 6.3 of the distinction between NB number and MCB number, depending of the European or national scope, and incorporation of specifications relating to the declaration of conformity. Par. 7.1, replacing of the structure of the body identification number, inclusion of examples of conformity marking.
2	25/07/2016	Implementation of changes due to Directive 2014/32/EU and Royal Decree 244/2016.
3	14/07/2020	Incorporation of ICT/155/2020 references.
4	29/06/2021	Removal of ITC/3022/2007 references. Remark: Changes are identified in blue text