

Transition of conformity assessment under the EU Directive 2004/22/EC to the new Directive 2014/32/EU (MID) and the Royal Decree 889/2006 to the new Royal Decree 244/2016

Scope and aim of the document

This information sheet prescribes the approach and principles of Notified Body no. 1964 and Metrological Control Body no. 09-OC-0002 (further referred to as ITE) to the transition of conformity assessment under Directive 2004/22/EC to the new one 2014/32/EU (MID) in relation to modules B, D and F and to the transition of conformity assessment under Royal Decree 889/2006 to the new Royal Decree 244/2016, in relation to modules B, D and F. This sheet is intended for the manufacturers whose measuring instruments were approved by ITE.

Conclusions

Within the scope of the introduction of the new legal framework of the European Union, Directive 2004/22/EC was replaced last 20.04.2016 by the Directive 2014/32/UE [1]. These means that all instruments placed on the market after 20th April 2006 have to comply with the requirements in the new Directive 2014/32/EU.

No changes have been made to the scope, the essential requirements or the specific requirements for active electrical energy meters, and neither the possible conformity assessment procedures between which manufacturer can choose. Therefore, the harmonized standards and the normative documents which have been valid for the previous directive, maintain their presumption of conformity also for the new Directive. [2]

Directive 2014/32/EU, has been transposed into Spanish domestic legal system through the Royal Decree 244/2016, June 3rd [3], which also repeals the Royal Decree 889/2006, July 21st. Royal Decree 244/2016, entered into force the last 8 of June of 2016, these means that all instruments placed on the Spanish market after 08.06.2016 have to comply with the requirements in the new Royal Decree 244/2016.

I. Main changes introduced by the Directive 2014/32/EU and implications:

The new Directive implement the requirements of EU Regulation (EC) 765/2008 for accreditation and market surveillance [4] and of EU Decision 768/2008/EC on a common legal framework for the marketing of products [5].

For a better comprehension it is recommend to consult the Blue Guide (version 2016) [6]

I.1 Detail on changes:

- Better definition of Economic Operators (manufacturers, authorised representatives, importers and distributors) and their obligations
(Chapter 2 Arts. 8 to 11)
- Importers and distributors can become the manufacturer if they place an instrument on the market under their name or modify an instrument already placed on the market in such a way that compliance with the Directive may be affected
(Chapter 2 Art. 12)
- Improved traceability and co-operation with Market Surveillance authorities
(Chapter 2 Art. 13)
- Introduction of analysis and assessment of the risks
(Annex II Module B Technical documentation and Chapter 3 Art. 18)
- Description of structure and content of EU declaration of conformity
(Chapter 3 Art. 19 and Annex XIII)
- Manufacturer's (and importer's when applicable) full address must appear on the instrument
(Chapter 2 Art. 8.6 and Art. 10.3)

I.2 Implications:

I.2.1 Required actions for organizations with EC-Type Examination certificates issued by ITE (module B)

EC-type examination certificates issued under Directive 2004/22/EC for measuring instruments placed on the market before 20.04.2016 remain valid under Directive 2014/32/EU
(Chapter 7 Art. 50.1)

Regarding any modification over a meter type notified after 20.04.2016, it will be assessed accordingly the requirements on new Directive.
(Chapter 7 Art. 52)

For the purposes of the transition of certifications into new Directive manufacturer shall lodge to ITE a formal application attaching the following information as part of instrument technical documentation:

- Analysis and assessment of risks
- Meter type nameplate including manufacturer's full address, and importer's address is applicable

(Annex II Module B Technical documentation and Chapter 3 Art. 18, Chapter 2 Art. 8.6 and Art. 10.3)

I.2.2 Required actions for organizations with approved quality systems for production, final product inspection and testing of the measuring instrument (module D) issued by ITE:

Certificates of quality system for production, final product inspection and testing (module D) having been issued by ITE under directive 2004/22/EC remain valid until their expiry date, even after April 20th, 2016. During surveillance visits ITE will apply the criteria set out in the new Directive. However, the transition of declaration of conformity to a new directive will require updating of certification for which purpose; manufacturer shall lodge to ITE a formal application providing evidences of implementation of the corresponding changes (inclusive new elements in the quality management system) as follows:

- Implementation of provisions for adequately taken into account the 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
[Chapter 2 Art. 8 point 4]
- Implementation of the provisions to identify economic operators to whom they have supplied a measuring instrument and who have supplied them with a measuring instrument and store this information for the period of 10 years since the delivery of those instruments
[Chapter 2 Art. 13]
- A response to changes regarding the marking of measuring instruments under new Directive MID – indication of their name, registered trade name or registered trade mark and the postal address at they can be contacted
[Chapter 2 Art. 8 point 6 y Art. 10 point 3]
- Changing the EU declaration of conformity, according to the template set out in Annex XIII of Directive and ensuring that all relevant information to identify the Union harmonisation legislation according to which is issued, as well as the manufacturer, the authorised representative if applicable, the notified body, the product, and a reference to harmonised standards or other technical specifications
[Chapter 3 Art. 19 and Annex XIII]
- In cooperation with ITE to reflect the changes having been made in corresponding EU type examination certificates (module B) to module D certificates
[Annex II Module D Art. 3.2]

II.2.3 Required actions for organizations with conformity certificates with module F issued by ITE:

Conformity certificates with module F issued by ITE under Directive 2004/22/EC for measuring instruments placed on the market before 20.04.2016 remain valid until their expiry date

II. Main changes introduced by Royal Decree 244/2016 and implications:

New Royal Decree 244/2016, 3 June, develops the chapters II, III and V of Law 32/2014, 22 December, of Metrology, which regulates respectively, legal system of measurement units, State metrological control and metrology organization, and incorporates to Spanish legal order the Directive 2014/32/EU, repealing the Royal Decree 889/2006, 21 July. Royal Decree 244/2016, entered into force last 8 of June 2016.

II.1 Detail of changes:

- Clearer definition of Economic Operators (manufacturer, authorised representative, importer and distributor) and their obligations
(Chapter III, Section 6^a Arts. 25 to 28)
- Importers and distributors can become the manufacturer if they place an instrument on the market under their name or modify an instrument already placed on the market in such a way that compliance with the Royal Decree 244/2016
(Chapter III, Section 6th Arts. 29)
- Improved traceability and co-operation with Market Surveillance Authorities
(Chapter III, Section 6th Arts. 30)
- Introduction of analysis and assessment of the risks
(Annex I, Art. 5, point 3, letter c) and Chapter III Section 3rd Art. 13)
- Description of structure and content of national declaration of conformity
(Chapter 3 Section 3rd Art. 15 and Annex V)
- Manufacturer's (and importer's when applicable) full address must appear on the instrument
(Chapter III Section 6th Art. 25.6 and Art. 27.3)
- Legally relevant measurement associated software must meet the requirements of Royal Decree 244/2016
(Annex IV)

II.2 Implications:

II.2.1 Required actions for organizations with type examination certificates issued by ITE (module B)

Type examination certificates issued under ITC/3022/2007 for measuring instruments placed on the market before 08.06.2016 remain valid under Royal Decree 244/2016

[First transitional provision]

Regarding any modification over a meter type notified after 08.06.2016, it will be assessed accordingly the requirements on new Royal Decree 244/2016 and also with ITC/3022/2007.

[Sixth final provision]

For the purposes of the transition of certifications into new Royal Decree, manufacturer shall lodge to ITE a formal application attaching the following information as part of instrument technical documentation:

- Analysis and assessment of risks
(Annex I, Art. 5, point 3, letter c) and Chapter III Section 3rd Art. 13)
- Meter type nameplate including manufacturer's full address, and importer's address is applicable
(Annex I, Art. 5, point 3, letter c) and Chapter III Section 3rd Art. 13 & Chapter III Section 6th Art. 25.6 and Art. 27.3)
- Additional information related legally relevant measurement associated software:
 - o Must provide a signed statement on software compliance with the applicable essential requirements [7]
 - o Must provide instructions and tools needed to perform an external download of legally relevant software
 - o Solutions adopted to fulfil the requirement concerning the filling of event log concerning history of software updates, and instrument disqualification to perform legally relevant metrological functions

(Annex IV)

II.2.2 Required actions for organizations with approved quality system for production, final product inspection and testing of measuring instruments (module D)

Certificates of quality system for production, final product inspection and testing (module D) issued by ITE under the ITC/3022/2007 will remain valid until its expiration date, even after 08.06.2016. During surveillance visits ITE will apply the criteria set out in the new Royal Decree. However, the transition of declaration of conformity to a new Royal Decree will require updating of certification for which purpose; manufacturer shall lodge to ITE a formal application providing evidences of implementation of the corresponding changes (inclusive new elements in the quality management system) as follows

- Implementation of provisions for adequately taken into account the 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.
[Chapter III Section 6th Art. 25 point 4]
- Implementation of the provisions to identify economic operators to whom they have supplied a measuring instrument and who have supplied them with a measuring instrument and store this information for the period of 10 years since the delivery of those instruments

[Chapter III Section 6th Art. 30]

- A response to changes regarding the marking of measuring instruments under new Royal Decree – indication of their name, registered trade name or registered trade mark and the postal address at they can be contacted
[Chapter III Section 6th Art. 25 point 6 and Art. 27 point 3]
- Changing the national declaration of conformity, according to the template set out in Annex V of Royal Decree and ensuring that all relevant information to identify the Spanish legislation according to which is issued, as well as the manufacturer, the authorised representative if applicable, the notified body, the product, and a reference to harmonised standards or other technical specifications
[Chapter 3 Section 3rd Art. 15 and Annex V]
- In cooperation with ITE to reflect the changes having been made in corresponding type examination certificates (module B) to module D
[Annex I Art. 9 Paragraph 3.2]

II.2.3 Required actions for organizations with module F conformity certificates issued by ITE

Conformity certificates with module F issued by ITE under ITC/3022/2007 for measuring instruments placed on the market before 08.06.2016 remain valid until their expiry date

Should you have any questions, please contact ocp@ite.es

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Anabel Soria Esteve
Certification Entity Technical Director

References/Links:

- ¹ DIRECTIVE 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast)
http://eur-lex.europa.eu/legal-content/ES/TXT/?uri=uriserv:OJ.L_.2014.096.01.0149.01.SPA&toc=OJ:L:2014:096:TOC
- ² References of harmonized standards which have been published in the EU OJ
http://ec.europa.eu/growth/single-market/goods/building-blocks/legal-metrology/measuring-instruments/index_en.htm
- ³ ROYAL DECREE 244/2016, 3 June, by which develops the Law 32/2014, 22 December, of Metrology.
http://www.boe.es/diario_boe/txt.php?id=BOE-A-2016-5530
- ⁴ REGULATION (EC) No 765/2008 of the European Parliament and the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
http://eur-lex.europa.eu/legal-content/ES/TXT/?uri=uriserv:OJ.L_.2008.218.01.0030.01.SPA&toc=OJ:L:2008:218:TOC
- ⁵ DECISION No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC
http://eur-lex.europa.eu/legal-content/ES/TXT/?uri=uriserv:OJ.L_.2008.218.01.0082.01.SPA&toc=OJ:L:2008:218:TOC
- ⁶ BLUE GUIDE – Guide on the implementation of EU product rules
<http://ec.europa.eu/DocsRoom/documents/16210?locale=es>
- ⁷ Template of statement of software according to RD 244/2016
<http://www.ite.es/organismos-de-control/documentos-organismos-de-control/>