

# Transition of conformity assessment under the Directive 2004/22/EC to the new Directive 2014/32/EU (MID)

## MODULE D

Within the scope of the introduction of the new legal framework of the European Union, the current European Directive 2004/22/EC for measuring instruments will be replaced on 20<sup>th</sup> April 2016 by the new European Directive 2014/32/EU (MID).

This information sheet prescribes the approach and principles of Notified Body no. 1432 (further referred to as SLM NB) to the transition to directive 2014/32/EU in relation to module D (Conformity to type based on quality assurance of the production process) and is intended mainly for the manufacturers whose quality assurance of the production process was approved by SLM NB.

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### TRANSITIONAL PROVISIONS

The old directive 2004/22/EC is in force until 19<sup>th</sup> April 2016. The new directive 2014/32/EU will come into force from 20<sup>th</sup> April 2016 onwards. It means, that all instruments placed on the market after 20<sup>th</sup> April 2016 will have to comply with the requirements in the new Directive 2014/32/EU.

The declarations of conformity for measuring instruments which are placed on the market until 19<sup>th</sup> April 2016 shall still relate to the old directive 2004/22/EC, and **declarations of conformity for measuring instruments which are placed on the market from 20<sup>th</sup> April 2016 onwards shall relate to the new directive 2014/32/EU.**

**Approvals** on quality management system of production process (module D) **which have been issued according to the old directive 2004/22/EC remain valid within the scope of the respective new directive 2014/32/EU.** The consequence of this is that, **provided that no other modification is made, it is not necessary to rewrite Approvals on 20<sup>th</sup> April 2016 according to the new directive 2014/32/EU.**

### APPROACH AND PRINCIPLES

- a) Certification procedures and activities of SLM NB already started pursuant to the old directive 2004/22/EC and not finished by April 19<sup>th</sup> 2016 will be reviewed and finalized in accordance with new directive 2014/32/EU.
- b) Starting on April 20<sup>th</sup>, 2016 measuring instruments being made available on the market have to be in compliance with the requirements of new directive 2014/32/EU.**
- c) Approvals on quality management system of production process (module D) having been issued under current old directive 2004/22/EC remain valid until their expiry, even after April 20<sup>th</sup>, 2016. However, **starting on April 20<sup>th</sup>, 2016 the transition of declaration of conformity to a new directive 2014/32/EU requires from the manufacturers mainly an implementation of the corresponding changes in the quality management system of production process as follows:**
  - implementation of the provision to take measures for the production of the measuring instrument to be in conformity with the new directive 2014/32/EU;
  - **implementation of the provision to indicate on the measuring instrument their name, registered trade name or registered trade mark and the postal address** at which they can be contacted or, where that is not possible, in a document accompanying the measuring instrument and on the packaging. The address shall indicate a single point at which the manufacturer can be contacted.
  - implementation of the provision to change the **EU Declaration of conformity to be in line with the directive 2014/32/EU and with a structure given by the mandatory template in the directive 2014/32/EU;**
  - implementation of the provision to identify economic operators to whom they have supplied a measuring instrument and who have supplied them with a measuring instrument and to store this information for the period of 10 years since the delivery of those instruments;

To achieve a continuous validity of the Approvals on quality management system of production process (module D) having been issued under the current old directive 2004/22/EC even after the date of April 20<sup>th</sup>, 2016 manufacturers shall send SLM NB following:

- 1) a written confirmation that the quality management system of production process has been transitioned to the new requirements of directive 2014/32/EU, and
- 2) a description of changes made to the quality management system of production process which have been made to achieve this goal including supporting evidence regarding these changes (form of the declaration of conformity in line with new MID directive 2014/32/EU, indication of the contact postal address on the instrument etc.).

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### REFERENCES/LINKS

1. DIRECTIVE 2004/22/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on measuring instruments (OJ L 135, 30.4.2004, pp. 1-80)  
<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004L0022&from=en>
2. 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) (OJ L 96, 29.3.2014, pp. 149–250)  
<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0032&from=EN>
3. REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF 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 (OJ L 218, 13.8.2008, pp. 30–47)  
<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0765&from=EN>
4. 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 (OJ L 218, 13.8.2008, pp. 82–128)  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0082:0128:en:PDF>
5. COMMISSION DELEGATED DIRECTIVE (EU) 2015/13 of 31 October 2014 amending Annex III to Directive 2014/32/EU of the European Parliament and of the Council, as regards the flowrate of water meters) (OJ L 96, 29.3.2014, pp. 149–250)  
<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015L0013&from=EN>
6. COMMISSION NOTICE of 5.4.2016 The 'Blue Guide' on the implementation of EU product rules 2016  
<http://ec.europa.eu/DocsRoom/documents/16210>

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