

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

MODULE B

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 20th 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 of conformity assessment under current European Directive 2004/22/EC to the new one 2014/32/EU (MID) in relation to module B (EU- type examination) and is intended for the manufacturers whose measuring instruments were approved by SLM NB or for new clients.

TRANSITIONAL PROVISIONS

The old directive 2004/22/EC is in force until 19th April 2016. The new directive 2014/32/EU will come into force from 20th April 2016 onwards. It means, that all instruments placed on the market after 20th April 2016 shall comply with the requirements in the new directive 2014/32/EU. The consequence of this is, in particular, that declarations of conformity for measuring instruments which are placed on the market until 19th April 2016 shall still relate to the old directive, and declarations of conformity for measuring instruments which are placed on the market from 20th April 2016 onwards must relate to the new directive 2014/32/EU.

No changes have been made to the scope or the essential requirements and therefore this alignment measure does not affect the presumption of conformity on which harmonised standards and normative documents are based.

EC-type examination certificates 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 of the measuring instrument is made, it is not necessary to rewrite EC-type examination certificate on 20th April 2016 according to the new directive 2014/32/EU.

APPROACH AND PRINCIPLES

- a) The new directive 2014/32/EU implements the requirements of EU Regulation (EC) 765/2008 for accreditation and market surveillance and of EU Decision 768/2008/EC on a common legal framework for the marketing of products. In the new directive 2014/32/EU, in principle, the following amendments which are important for manufacturers have been made:
- Specification of the roles and obligations of economic operators - manufacturers, authorized representatives, importers and distributors;
 - Accredited in-house bodies may be used for conformity assessment modules A2 and C2;
 - Structure and content of the Declaration of Conformity now described in specific Articles and Annex;
 - Requirement for manufacturers and, if applicable, importers 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 they can be contacted;
 - Introduction of a risk analysis and a risk assessment;
 - Improved traceability and co-operation with Market Surveillance authorities.
- b) Certification procedures and activities of SLM NB already started pursuant to the old directive 2004/22/EC and not finished by April 19th 2016 will be reviewed and finalized in accordance with new directive 2014/32/EU. The consequence of this is that SLM NB will require the manufacturers to submit additional documentation to lodged application in accordance with requirements of new directive 2014/32/EU, if needed.
- c) **Starting on April 20th 2016 measuring instruments being made available on the market have to be in compliance with the requirements of new directive 2014/32/EU.**

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>

Should you have any questions please contact slmcb@slm.sk.

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