

I n f o r m a t i o n as regards:

modul **B**

Transition of conformity assessment under the EU Directives 2004/22/EC and 2009/23/EC to the new Directives 2014/32/EU (MID) and 2014/31/EU (NAWID)

Based on consultations with the European Commission DG Grow and national notifying authority CMI, as Notified Body no. 1383 (further referred to as CMI NB) for the above mentioned directives, has adopted the following principles (where appropriate, the corresponding provisions of the directives as an original source of the information are given in square brackets) of a unified and correct approach to the transition of conformity assessment under current directives 2004/22/EC and 2009/23/EC to the new ones 2014/32/EU (MID) and 2014/31/EU (NAWID):

- 1) Certification activities of CMI NB which will not be finished by April 19th, 2016 at the latest will have to be reviewed and finalized in accordance with 2014/31/EU, resp. 2014/32/EU (it applies especially to the conformity assessment modules B and G but to the module F as well) inclusive the consequences arising from the harmonized standard EN 45501:2015 applicable to NAWIs.
[\[MID art. 51 par. 1, art 52, art. 50; NAWID art. 44 par. 1, art. 45, art. 43, art. 12, art. 6 par. 4, art. 3 par. 1\]](#)
- 2) When placing instruments on the market related, by a documentary evidence and in reality, to the date of April 20th, 2016 or to later dates manufacturers and importers should refer to the new directives, inclusive the declaration of conformity which has to be adapted.
[\[MID art. 19 par. 2, art. 51 par. 1, art. 52, art. 50; NAWID art. 14 par. 2, art. 44 par. 1, art. 45, art. 43, art. 3 par. 1\]](#)
- 3) Since April 20th, 2016 inclusive making measuring instruments conforming to the "old" directives (2009/23/ES and 2004/22/ES) available on the market (e.g. stock in the distribution chain) and into use is permitted provided that they had been put on the market before April 20th, 2016 (so that there was at least documentary evidence that they had been supplied by the manufacturer or importer down the distribution chain to another body - to a distributor or a user).
[\[MID art. 50, art. 4 par. 5 and 6, art. 51 par. 1, art. 52, point 61 of the preamble; NAWID art. 43, art. 2 par. 3 and 4, art. 44 par. 1, art. 45, point 46 of the preamble\]](#)
- 4) Since April 20th, 2016 all the measuring instruments being put on the market have to comply with the provisions of the Directives 2014/31/EU, resp. 2014/32/EU as far as indication on the measuring instrument of the contact postal address of the manufacturer or importer, in case of NAWIs also the form of the supplementary metrology marking, are concerned.
[\[MID art. 8 par. 6, art. 10 par. 3, art. 51 par. 1, art. 52, art. 50; NAWID art. 6 par. 6, art. 8 par. 3, art. 44 par. 1, art. 45, art. 3 par. 1\]](#)
- 5) Starting on April 20th, 2016 economic operators (manufacturers, their authorized representatives, importers, distributors) have to make records of economic operators to whom they have supplied measuring instruments and records of operators having supplied measuring instruments to them if such documentation has not already been made before the above mentioned date. This information has to be kept on records for the period of 10 years after the supply of measuring instruments was made.
[\[MID art. 13, art. 51 par. 1, art. 52, art. 50; NAWID art. 11, art. 44 par. 1, art. 45\]](#)

- 6) Certificates of the EC examination of type (or design examination in case of MID) having been issued under current directives remain officially valid for the period of its validity even after the date of April 20th, 2016; however, when the reality of the transition to conformity declaration to a new directive results in some sort of a departure from such a certificate this has to be reflected in the certificate (a change of any data with the exception of the number of the directive being used in the certificate inclusive annexes, e.g. also in relation to point 4 of this information) – the holder of the certificate has to contact, without delay, the NB having issued the certificate with a request to make the change in it. The approvals (certificates) of quality management systems (module D) remain valid as well.

[MID art. 50 par. 1, art. 51 par. 1, art. 52; NAWID art. 43, art. 44 par. 1, art. 45]

- 7) Manufacturers and importers of NAWIs who intend to keep using EC type examination certificates issued under the Directive 2009/23/EC on the basis of the older version of the harmonized standard EN 45501:1992 after the date of April 20th, 2016 will be called upon by NB CMI starting with April 2016 to initiate a process to review conformity of their NAWIs with requirements of the harmonized standard EN 45501:2015 (the date when the presumption of conformity based on the old version is terminated is April 19th, 2016) if they have not already done that by themselves; in the framework of this process, compliance or non-compliance of all the manufactured types with the requirements of the new standard is established by the holder of the certificate(s) in cooperation with the NB – in the positive case, the statement of the demonstration of conformity will be reflected in the certificate(s); on the other hand, if it is found out in the process that a certain type does not comply with the new requirements given in EN 45501:2015 or the holder of the certificate has failed to finalize the review process within an appropriate time period since April 20th, 2016 the legitimacy of the reference to the certification, when such instruments are to be put on the market, will cease to exist and the NB will initiate the process of suspension or withdrawal of the certificate(s), as appropriate, as stipulated by the Directive; apart from that when an existing EC type approval certificate is to be revised the NB will proceed in line with the Directive in force and with the harmonized standard.

[NAWID art. 6 par. 4, art. 12, art. 3 par. 1, art. 31, point 4, art. 43, art. 44 par. 1, art. 45; Official Journal EU2015/C/300 – notice no. 2015/C 300/02]

In Brno dated February 23rd, 2016



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