ČESKÝ
METROLOGICKÝ
INSTITUT

Czech Metrology Institute
Notified Body no. 1383
Okružní 31, 638 00 Brno, CR

Notification

for: producers of measuring instruments being holders of certification performed by Notified Body No. 1383 CMI

Transition of conformity assessment procedure of Capacity serving measures (MID, MI-008, Chapter II) according to directive 2004/22/ES to directive 2014/32/EU (MID)

modules A1/A2

Dear producers of capacity serving measures,

The directive No. 2014/32/EU which replaces the directive 2044/22/ES in terms of the requirements for these measuring instruments, procedures of placing these products on the market and rights and obligations of producers and other stakeholders and authorities of the EU Member States comes into force on April 20th, 2016. Hereby certain changes entry into force in terms of some obligations of producers and some aspects of the conformity assessment procedures.

We consider it necessary to provide you with this information and notification for practical realization of trouble-free transition to new directive given the fact that as producers of capacity serving measures you used to use module A1 to place them on the market. (The source provisions of new directive are shown in bracket where it is appropriate).

1) The module of conformity assessment A1 is no more included in directive 2014/32/EU. One of the most conceptually similar module is module A2 which is among of the authorized and applicable modules for capacity serving measures (CSMs) since April 20th, 2016. Therefore, your initial applications for performing of repetitive inspections of CSMs by Notified Body CMI under the procedure A1 will become unacceptable since April 20th, 2016 and it will be necessary to submit a new application in terms of paragraph 5 of this notification.

   [MID article. 51 paragraph 1 of directive; Annex X, chapter II]

2) Measuring instruments placed on the market shall conform to the requirements of directive 2014/32/EU since April 20th, 2016. Producers and importers have to refer to new directive when placing their measuring instruments on the market after April 20th, 2016.

   [MID article. 51 paragraph 1, article. 52, article. 50, article. 19 paragraph 2]

3) Since April 20th, 2016 it is permitted to supply (distribute) and put in use such measuring instruments which meet the requirements of the old directive (2004/22/ES) if these instruments have been placed on the market (which means that at least there is evidence in documentation that they have been supplied by the producer or importer to another subject = to a distributor or a user) before April 20th, 2016.

   [MID article. 50, article. 4 paragraph 5 and 6, article. 51 paragraph 1, article. 52, paragraph 61 preamble]

4) With the new directive becoming effective it is necessary to implement the following changes:

   - Producers are obliged to take steps for the series production (measuring instrument design, respectively) to remain (continuously) in compliance with the provisions of the directive even in the case of changes in the technical requirements (including changes in the harmonized standards);

     [MID article 8 paragraph 4, article 7 paragraph 2]

- Producers (importers, authorized representatives, distributors) are obliged to keep records of economic operators to whom they have supplied measuring instruments and to store this information for a period of 10 years since the instrument delivery;

  [MID article 13, article 51 paragraph 1, article 52, article 50]

- Producers are obliged to indicate their name, registered trade name or registered trade mark and the postal address at which they can be contacted concerning the measuring instrument or, where that is not possible, in a document accompanying the measuring instrument and on the packaging if any (the address has to indicate a single point at which the producer can be contacted);

  [MID article 8 paragraph 6, article 10 paragraph 3, article 51 paragraph 1, article 52, article 50]

- Producers shall revise the EU Declaration of conformity both in relation to directive 2014/32/EU (in relation to the national transposition legislation, respectively) and in structure corresponding to a the compulsory form given in the directive;

  [MID article 19 paragraph 2, article 51 paragraph 1, article 52, article 50]

5) The description of module A2 (unlike the preceding A1) also expressly stipulates that Notified Body itself has to select adequate samples of the final product on spot, before they are placed on the market. These samples must be examined and appropriately tested. This procedure prevents the previous practice of taking samples by the responsible department of the producer and sending them to Notified Body for examination. Under these circumstances we call on you to make a decision which conformity assessment module for placing your capacity serving measures on the market you want to apply since April 20th, 2016. Out of 7 available modules we recommend you to choose one from the following selection of modules and their combinations which are according to our opinion financially less expensive for producers (we present also selected pieces of information as regards the corresponding activities of a producer and of Notified Body). It is reasonable to assume that a producer being a holder a quality system management certificate under standard EN ISO/IEC 9001 has developed a system suitable for modules D1 or E1 and this certification can be taken into account during the certification of quality system management under directive 2014/32/EU:

   <u>module A2</u>

   - The producer shall establish technical documentation and take such necessary measures to secure that manufacturing process and its monitoring will ensure conformity of manufactured capacity serving measures with technical documentation and with the requirements of the directive;
   - The producer is subject to regular checks (metrological testing of samples) carried out by the Notified Body;
   - An authorized employee of Notified Body (CMI) would take specified number of samples of manufactured capacity serving measures for the purpose of the control at a suitable and reasonably accessible place having been agreed between the producer and the Notified Body where these capacity serving measures are intermittently stored before being placed on the market (e.g. storage facilities, transportation device, etc.);
   - Notified Body would carry out these checks at an interval specified by him, usually when introducing new types of CSMs on the market and subsequently once a year (once every two years in specific cases) on all currently produced types of CSMs;
   - Notified Body would issue the certificate of conformity (in relation to the given types of CSMs and for the corresponding period of validity) of performed certifications (the initial control of given types, subsequent annual or biannual inspections of given types);
   - While the producer fulfills his other duties given by directive 2014/32/EU for the module A2 he continuously places produced capacity serving measures on the market with conformity markings and other required indications including the number of Notified Body and issues the Declaration of conformity with the directive.

module D1

- The producer shall prepare the required technical documentation;
- The producer has an approved quality management system for the production process, final product inspection and testing of the given types of capacity serving measures;
- An evaluation of quality management system is carried out by Notified Body (e.g. CMI), as chosen by the producer, and in case of a positive evaluation the Notified Body issues the certificate (with an unlimited validity period);
- Regular planned audits of quality management system with a frequency of once per year are carried out by Notified Body which has approved this quality management system (under the approved quality system and in the framework of regular audits tests on randomly chosen CSMs before their placement on the market can be made);
- The assessment of the producer´s management system and subsequent audits are carried out by Notified Body at the place of production, final production inspection and testing of CSMs concerned;
- While the producer fulfills his other duties given by directive 2014/32/EU for the module D1 he continuously places produced capacity serving measures on the market with conformity markings and other required indications including the number of Notified Body and issues the Declaration of conformity with the directive.

module E1

- The producer shall prepare the required technical documentation;
- The producer has an approved quality management system for final product inspection and testing of the given types of capacity serving measures;
- An evaluation of quality management system is carried out by Notified Body (e.g. CMI), as chosen by the producer, and in case of a positive evaluation the Notified Body issues the certificate (with an unlimited validity period);
- Regular planned audits of quality management system with a frequency of once per year are carried out by Notified Body which has approved this quality management system (under the approved quality system and in the framework of regular audits tests on randomly chosen CSMs before their placement on the market can be made);
- The assessment of the producer´s management system and subsequent audits are carried out by Notified Body at the place of production and final inspection and testing of CSMs concerned;
- While the producer fulfills his other duties given by directive 2014/32/EU for the module D1 he continuously places produced capacity serving measures on the market with conformity markings and other required indications including the number of Notified Body and issues the Declaration of conformity with the directive.

Note:

According to Directive 2014/32/EU the placing on the market means the first supply of CSMs on the EU Single Market. Delivery of measures on the market means supply or supply for distribution or using on the EU Single Market as a part of business activities (whether in return for payment or free of charge).

Following particularly paragraph 5 of this notification we ask you to give us information which conformity assessment module for placing of CSMs on the market are you going to apply and in the case of module A2 your proposal of the logistics for taking samples. We will gladly accept your application for conformity assessment and certification and we will initiate further steps if you select any module (A2, D1, E1). Thank you for your timely response.

Brno, March 7th, 2016

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