

## Information sheet on the use of type examination certificates of other legal entities

This information sheet describes the specifications of the conformity assessment body of PTB on the possibilities of using type examination certificates according to the Ordinance on Weights and Measures (MessEV), the Measuring Instruments Directive (MID, 2014/32/EU) and the Directive on Non-Automatic Weighing Instruments (NAWID, 2014/31/EU) which are not issued for the manufacturer himself, and the obligations which the manufacturer has to fulfil in this case.

### A. Definition of manufacturer according to the Act on the Placing and Making Available of Measuring Instruments on the Market, their Use and Verification and on Prepackages (Measurement and Verification Act - MessEG) of 25 July 2013 BGBl. I p. 2722

MessEG § 2 No. 6.:

*A manufacturer is any natural or legal person who manufactures a product or has a product developed or manufactured and markets this product under his own name or trademark or puts it into operation for his own purposes; a person who modifies a measuring instrument that is on the market in such a way that conformity with the essential requirements pursuant to § 6 paragraph 2 may be impaired is deemed to be a manufacturer of a measuring instrument.*

According to this definition, a person who places a product on the market but does not necessarily produce it himself is also a manufacturer. Sentence 1 is identical to the specifications in the MID and the content is consistent with the specifications in NAWID. A manufacturer who does not produce the products himself must therefore thus fulfil the complete manufacturer's obligations according to MessEG § 23. These obligations also include the performance of the conformity assessment procedure. Like any manufacturer, such a manufacturer has the possibility to choose the appropriate conformity assessment modules, e.g. B+F or B+D.

In accordance to the "Blue Guide" (2016) published by the European Commission, para. 5.1.5, the conformity assessment body of PTB has made the following specifications regarding the use of type examination certificates of other legal entities for the conformity assessment procedures it offers according to modules B and D, respectively, as described below under sections B and C, respectively.

### B. Specifications of the conformity assessment body of PTB for type examinations according to module B of the MessEV, MID and NAWID

Parallel certification procedure:

Manufacturers in the sense of the Metrology Act who do not produce instruments themselves, but only market them under their own name, can obtain their own type

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examination certificate for the measuring instruments to be marketed under their name according to a simplified procedure (parallel certification). The already existing documents and test reports of the original type examination certificate (of the manufacturer) can be used, provided that the holder of the original type examination certificate has given his written consent.

Direct use of the manufacturer's type examination certificate:

However, under the conditions stated in C, the original type examination certificate (of the producer) issued according to MessEV, 2014/31/EU, 2014/32/EU, 2009/23/EC or 2004/22/EC may also be used for the subsequent conformity assessment modules.

**C. Specifications of the PTB conformity assessment body for QA recognition procedures according to Module D of the MessEV, MID (2014/32/EU) and NAWID (2014/31/EU)**

Every manufacturer in the sense of the Metrology Act who has decided to apply the module combination B+D requires its own QA recognition according to module D. The QA recognition is based on auditing and monitoring of the production sites where the relevant activities are carried out to ensure the conformity of the devices with the type described in the type examination certificate and the requirements of the Metrology Act and the Metrology Ordinance. In the case of manufacturers who only place the devices on the market under their own name, these are normally the company headquarters of the manufacturer responsible for placing the devices on the market and the production site of the measuring device manufacturer. However, already existing audit reports of the manufacturing surveillance of the measuring instrument producer (if he himself has a QA recognition) can be used if the measuring instrument producer has given his consent. In any case, however, the quality assurance of the manufacturer's products must also be demonstrated and monitored.

A valid type examination certificate must be available for each type of measuring instrument covered by QS recognition. In the case of manufacturers who only place the devices on the market under their own name, the original type examination certificate of the manufacturer is also acceptable instead of a parallel certificate, provided that the measuring devices comply with the device-specific specifications of the type examination certificate and the technical documents referenced therein and the manufacturer fulfills the conditions listed in the Blue Guide (2016), section 5.1.5.

The CAB of PTB is of the opinion that these conditions are fulfilled,

- if the manufacturer who places the product on the market and the holder of the type examination certificate are located in a joint group of companies and have a kind of subsidiary-parent relationship,
- or if the manufacturer who places the product on the market and the holder of the type examination certificate have a contractual agreement.

In both cases, the following aspects must be ensured:

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1. conformity of the components supplied to the manufacturer with the provisions of the type examination certificate and the technical documentation referenced therein.
2. right of surveillance with the holder of the type examination certificate (producer) for the conformity assessment body of the manufacturer.
3. access to the technical documentation of the certified type for market surveillance authorities and the conformity assessment body of the manufacturer.
4. clearly defined procedure for informing the manufacturer by the holder of the type examination certificate of any changes to the certified type and of any non-conformities found in the certified type, including the measures to be taken to remedy them.

Each manufacturer in the sense of the Metrology Act is in any case responsible for the conformity of the products marketed under his name. Manufacturers who only place devices on the market under their own name must therefore have corresponding agreements with the producer in order to be able to fully comply with the manufacturer's obligations specified in the Measurement Act (in particular, submission of the necessary documents) and, if necessary, to provide evidence thereof.

#### **D. Transitional provisions for national type approvals issued under the old verification law**

The Measuring Act came into effect on 01.01.2015. A transitional provision applies to type approvals issued before this date (MessEG § 62 para. 2). Instead of the own type examination certificate, the submission of a type approval already issued for a producer by 31.12.2014, in which the manufacturer is listed as co-distributor, is acceptable. This applies until the end of the validity of the type approval, at the latest until 31 December 2024.

Any necessary deviations of the measuring instruments from the specifications in the type approval (e.g. new markings, inscriptions, documents to be supplied) are assessed within the framework of the QA recognition procedure.

On behalf of PTB

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