

Information Sheet
on the omission of the
"Regulation on companies which merely place a product on the market but have not produced the product themselves"
in the case of type examinations according to the
Measures and Verification Ordinance (MessEV) Module B

A. Until now, the following regulation applied to type approvals according to the previous Verification Act which was valid until 31 December 2014:

According to the previous Verification Act which was valid until 31 December 2014, it was possible for the holder of a certificate to have also companies entered into the national type approval certificate *which merely placed the product on the market but had not produced the product themselves*, and which were then allowed to place measuring instruments of that certain type on the market under their own name and to mark them with the same approval mark (see previous Verification Ordinance dated 12 August 1988, General Requirements, Section 19 para 2). The responsibility for compliance of the respective measuring instruments with the provisions in the type approval was up to the holder of the certificate.

With the introduction of the conformity assessment procedure according to the Measures and Verification Act (MessEG), this possibility has been omitted as of 1 January 2015.

B. New definition of the term "manufacturer" according to the *"Act concerning the placement and provision of measuring instruments on the market, their use and verification, and also on prepackages"* (Measures and Verification Act [Mess- und Eichgesetz – MessEG] dated 25 July 2013, BGBl. I [Official Law Gazette] I, p. 2722)

Measures and Verification Act (MessEG), Section 2, sub-paragraph 6. :

"manufacturer" means a natural or legal person who manufactures a product, or who arranges the development or manufacture of a product, and places it on the market under his/her own name or his/her own label, or who commissions it for his/her own purposes; any party which modifies a measuring instrument found on the market in such a way that conformity with the essential requirements as per Section 6, sub-paragraph 2 can be compromised is classed as a measuring instrument manufacturer.

According to the above definition, *companies which merely place a product on the market but have not produced the product themselves* are, in the sense of the new Measures and Verification Act (MessEG), also to be regarded as manufacturers.

They must thus fulfil the entire duties of a manufacturer according to the Measures and Verification Act (MessEG) Section 23. These duties also include the carrying out of the

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conformity assessment procedure. Like any other manufacturer, such a manufacturer, too, (i.e. a manufacturer who merely places the products on the market but does not produce them himself) has the possibility to choose the appropriate conformity assessment modules such as, e.g., B+F or B+D.

PTB's Conformity Assessment Body has – in accordance with paragraph 5.1.5 of the Blue Guide 2014 issued by the European Commission – laid down the regulations described below (under paragraphs C and D) for the conformity assessment procedures offered by it according to the modules B and D.

C. Regulations of PTB's Conformity Assessment Body for type examinations according to the Measures and Verification Ordinance (MessEV) Module B

Due to the new definition of the term "manufacturer", *companies which merely place a product on the market but have not produced the product themselves* are no longer entered into type examination certificates according to the Measures and Verification Ordinance (MessEV) Module B. Additional manufacturers in the sense of the Measures and Verification Act (MessEG) (i.e. also manufacturers who merely place the instruments on the market under their own name but have not produced them themselves) can, however, obtain a type examination certificate of their own for the measuring instruments which are to be placed on the market under their own name by means of a facilitated procedure (this is called "parallel certificate"). Already existing documents and test reports pertaining to the original type examination certificate can be used for this purpose if the holder of the original type examination certificate has given his written consent.

Under the preconditions specified under D below, it is, however, possible to use also the original type examination certificate (of the producer) for the conformity assessment modules below.

D. Regulations of PTB's Conformity Assessment Body for QS approval procedures according to the Measures and Verification Ordinance (MessEV) Module D

Every manufacturer in the sense of the Measures and Verification Act (MessEG) who has decided to apply the module combination B+D needs a QS approval of his own according to Module D. The QS approval is based on an audit and monitoring of those production sites in which the relevant activities are carried out to ensure compliance of the instruments with the requirements of the Measures and Verification Ordinance (MessEV) and with the provisions of the type examination certificate. In the case of manufacturers who merely place the instruments on the market under their own name but do not produce them themselves, these sites are – usually – the headquarters of that manufacturer who is responsible for the placing of the instrument on the market and the production site of the measuring instrument producer. Already existing audit reports made out by the production surveillance of the measuring instrument producer (as far as same has a QS approval himself) may, however, be used if the measuring instrument producer has given his consent and if the audit reports include also special statements on the quality assurance for the products of the company which merely places the product on the market but has not produced the product itself.

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For each measuring instrument type covered by the QS approval, a valid type examination certificate must be available. This type examination certificate does not necessarily have to be issued to the manufacturer himself (i.e. to the manufacturer in the sense of the Measures and Verification Act [MessEG]). In the case of manufacturers who merely place the instruments on the market under their own name but do not produce them themselves, also the original type examination certificate of the producer is acceptable if same also contains the specific provisions for the respective instruments*.

* From 1 January 2015 onwards, this regulation will also be applied in the case of QM approvals according to MID Module D.

Within the scope of the transitional provisions according to the Measures and Verification Act (MessEG), Section 62, para 2, instead of submitting one's own type examination certificate, it is also acceptable to submit a type examination certificate which has been issued to a producer before 31 December 2014 and in which the *company* is stated *which merely places the product on the market but has not produced the product itself*. This regulation will apply until the end of the validity of the type examination certificate which, at the latest, will be on 31 December 2024. Any deviations of the measuring instruments from the provisions in the type approval certificate which might be required (for example, new markings, inscriptions, documents to be enclosed with the product) will be assessed within the scope of the QS approval procedure.

Each manufacturer in the sense of the Measures and Verification Act (MessEG) is, however, in each case responsible himself for the conformity of the products which are placed on the market under his own name. Manufacturers who merely place instruments on the market under their own name but do not produce them themselves must therefore have special agreements with the producer in order to be able to entirely assume the duties of the manufacturer mentioned in the Measures and Verification Act (MessEG)(in particular: the submission of the required documents) and, if required, to be able to render the necessary proof.

On behalf of PTB
signed
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