

Information on the revocation of Section 28 para 3 of the Measures and Verification Act (as of 1 September 2021)

This information sheet is directed to economic operators (manufacturers, importers, traders and authorized representatives) who were entitled in the past to file an application with PTB about taking a decision as to the equivalence of measuring instruments according to Section 28 para 1 of the Measures and Verification Act (MessEG)¹

According to Section 28 para 1 of the Measures and Verification Act (MessEG), measuring instruments which cannot obtain the CE marking, the EC type approval or the EC initial verification and have been lawfully placed on the market in an EU Member State or in a Signatory State to the Agreement on the European Economic Area, or in Switzerland or in Turkey, may also be placed on the market in Germany if their measuring correctness, their durability and their verifiability are ensured in an equivalent way as in the case of measuring instruments which have been placed on the market in accordance with Section 6 of the Measures and Verification Act (MessEG).

This provision applies the European principle of mutual recognition. According to this principle, "Member States may not prohibit the sale on their territory of goods which are lawfully marketed in another Member State, even where those goods have been produced in accordance with different technical rules, ...". (See recital 4 of the Regulation (EU) 2019/515). Regulation (EU) 2019/515 stipulates that by submitting a voluntary declaration on the mutual recognition according to Section 4, para 1 of the Regulation, it is possible for manufacturers to demonstrate to the competent authorities of the Member State of destination that their measuring instruments are lawfully marketed in another Member State.

The regulation allows, however, that Member States can restrict the marketing of goods where such restrictions are justified on the basis of legitimate public interest grounds. If market access is restricted or denied, the provisions of Regulation (EU) 2019/515 must be observed.

In Germany, the authorities which are competent according to federal state law (verification authorities) may thus assess the equivalence of measuring instruments which have already been placed lawfully on the market abroad and are also marketed in Germany by applying Regulation (EU) 2019/515.

In the past, PTB took decisions upon request on the equivalence of measuring instruments according to Section 28 para 3 of the Measures and Verification Act (MessEG) and issued the respective notifications.

By virtue of the Second Act on the Amendment of the Measures and Verification Act of 9 June 2021 (Federal Law Gazette I, page 1663), the provision of Section 28 para 3 of the Measures and Verification Act (MessEG) was revoked. Thus, the legal basis for the task of PTB to take decisions on the equivalence of measuring instruments has, since 15 June 2021, no longer been applicable.

However, the further provisions of Section 28 (paras 1 and 2) of the Measures and Verification Act (MessEG) continue to apply, together with a revision of the European Regulation referred to in para 2 which is the Regulation (EU) 2019/515 now. (The old and the

¹ <http://www.gesetze-im-internet.de/messeg/> (available in German only)

new wording of Section 28 of the Measures and Verification Act (MessEG) is to be found in Annex 1).

As Section 28 of the Measures and Verification Act (MessEG) continues to apply, it remains possible to place measuring instruments on the market in Germany according to Section 28 para 1 of the Measures and Verification Act (MessEG).

Details on the mutual recognition of goods which have been lawfully placed on the market in another Member State are laid down in Regulation (EU) 2019/515.

In the case of measuring instruments for which there would be the possibility of mutual recognition but for which the manufacturer does not want to make use of this possibility, there is the option to place measuring instruments on the market in Germany on the basis of a conformity assessment procedure according to German measures and verification legislation. Further information on this is to be found in Annex 2.

PTB Working Group 9.21 “Legal Metrology“

Annex 1: Old and new wording in Section 28 para 3 of the Measures and Verification Act (MessEG)

Old wording:

Section 28 Measuring instruments which have been lawfully placed on the market abroad

(1) Measuring instruments which

1. cannot obtain the CE marking, the EC type approval or the EC initial verification, and
 2. have been lawfully placed on the market in an EU Member State or in a Signatory State to the Agreement on the European Economic Area, or in Switzerland or in Turkey,
- may also be placed on the market within the scope of this Act if their measuring correctness, their durability and their verifiability are ensured in an equivalent way as in the case of measuring instruments which have been placed on the market in accordance with this Act.

(2) In the case of an equivalence assessment performed on measuring instruments within the meaning of para 1, the authorities competent under federal state law have to observe the provisions of Chapter 2 of Regulation (EC) No. 764/2008 of the European Parliament and of the Council of 9 July 2008 (Official Journal L 218 of 13 August 2008, page 21).

(3) At the request of an economic operator or of the authority competent under federal state law, the Physikalisch-Technische Bundesanstalt shall take a decision on equivalence in accordance with para 1. This decision shall be binding for the authorities competent under federal state law.

New wording:

Section 28 Measuring instruments which have been lawfully placed on the market abroad

(1) Measuring instruments which

1. cannot obtain the CE marking, the EC type approval or the EC initial verification, and
 2. have been lawfully placed on the market in an EU Member State or in a Signatory State to the Agreement on the European Economic Area, or in Switzerland or in Turkey,
- may also be placed on the market within the scope of this Act if their measuring correctness, their durability and their verifiability are ensured in an equivalent way as in the case of measuring instruments which have been placed on the market in accordance with this Act.

(2) In the case of an equivalence assessment performed on measuring instruments within the meaning of para 1, the authorities competent under federal state law have to observe the provisions of Regulation (EC) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No. 764/2008 (Official Journal L 91 of 29 March 2019, page 1).

(3) (revoked)

Annex 2: Placing non-EU-harmonised measuring instruments on the market in Germany on the basis of a conformity assessment procedure carried out according to the German measures and verification legislation

The prerequisites for placing measuring instruments on the market are as follows (see Section 6 of the Measures and Verification Act (MessEG)):

- Measuring instruments must fulfil the essential requirements.
- As a proof of conformity with the essential requirements, a suitable conformity assessment procedure must have been carried out.
- The conformity of a measuring instrument must be confirmed by a declaration of conformity of the manufacturer and by affixing conformity markings to the measuring instrument.
- The measuring instrument must be provided with prescribed inscriptions for identification purposes.

The essential requirements are laid down in Annex 2 of the Measures and Verification Ordinance (MessEV)². The contents of this annex essentially correspond to those in Annex I of the European Measuring Instruments Directive 2014/32/EU (“MID” in short). Among other things, the measuring instruments must not exceed maximum permissible errors (MPEs), they must be suitable for the intended purpose, must be reliable, durable and protected against the corruption of measurement results, must display the measurement results in a suitable way and must be verifiable.

To specify the essential requirements, the so-called Rule Determination Committee has been established according to German measures and verification legislation. This committee publishes a document³ which stipulates rules for such a specification. In addition, the document includes information as to which modules of conformity assessment procedures are applicable for a certain type of measuring instrument. Details of the individual modules are to be found in Annex 4 Part B of the Measures and Verification Ordinance (MessEV). Part A includes general provisions for conformity assessment procedures.

After the conformity assessment procedure has been successfully completed, the manufacturer has to declare the conformity with the requirements of German measures and verification legislation and in this way also assumes responsibility for the conformity of his/her instruments. Annex 5 of the Measures and Verification Ordinance (MessEV) provides a model structure for the declaration of conformity. If a measuring instrument underlies several legal provisions, then only one such declaration has to be drawn up (Section 8 MessEG, Section 11 MessEV). Further obligations of the manufacturer are to be found in Section 23 of the Measures and Verification Act (MessEG).

German measures and verification legislation also stipulates provisions for inscriptions on measuring instruments. These must be clearly visible, legible and indelibly affixed to the measuring instrument (Section 13 MessEV). The markings and inscriptions to be borne by the measuring instrument when being placed on the market are outlined in Sections 14 and 15 of the Measures and Verification Ordinance (MessEV).

Further information on the conformity assessment bodies (CABs) which operate according to German measures and verification legislation:

- CAB of PTB (Modules B and D):
<https://www.ptb.de/cms/en/metrological-services/kbs/kbs4.html> (Module B)
<https://www.ptb.de/cms/en/metrological-services/kbs/kbs3.html> (Module D)
- List of the conformity assessment procedures offered by the CABs of the German verification authorities (Modules F, F1):

² <http://www.gesetze-im-internet.de/messev/index.html> (available in German only)

³ The currently valid document can be downloaded here (see “Fundstellen”):

<https://www.ptb.de/cms/de/metrologische-dienstleistungen/rea/dokumente-fundstellen.html>

- www.agme.de >> Fachinformationen >> Allgemeine Fachinformationen
- List according to Section 18 para 1 of the Measures and Verification Act (MessEG) of the designated conformity assessment bodies for nationally regulated measuring instruments:
<https://www.bmwi.de/Redaktion/DE/Downloads/V/verzeichnis-anerkannte-konformitaetsbewertungsstellen-national-geregelte-messgeraete.html>