

Instruction sheet for manufacturers regarding the placing of measuring instruments on the market in accordance with the German Measures and Verification Act

On 1.1.2015, the "Act concerning the placement and provision of measuring instruments on the market, their use and verification, and also on prepackages" (Measures and Verification Act¹) came fully into force (Federal Law Gazette 2013, part I, p. 2722). Together with this Act, the new Measures and Verification Ordinance¹ was adopted. This overall package replaced the previous Verification Act² as well as the Verification Ordinance³ (with its 23 annexes for special measuring instrument categories). Now that the German Measures and Verification Act has been newly regulated, the requirements are identical for both European as well as nationally regulated measuring instruments that are placed on the market. In this way, it becomes possible to account for technological developments promptly and in an adequate way. The subsequent verification of measuring instruments remains the task and responsibility of the verification authorities of the German federal states and of the state-approved test centres to the same extent as before.

The aim of this instruction sheet is to inform manufacturers about the regulations for placing measuring instruments on the market and to point out special modifications that have been introduced by the German Measures and Verification Act and by the German Measures and Verification Ordinance.

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¹ Ordinance concerning the placement and provision of measuring instruments on the market, their use and verification" (Measures and Verification Ordinance – MessEV) dated 11 December 2014 (Federal Law Gazette I p. 2010).

² Verification Act in the version as promulgated on 23 March 1992 (Federal Law Gazette. I p. 711), last amended by Article 1 of the Act of 7 March 2011 (Federal Law Gazette I p. 338)

³ Verification Ordinance of 12.08.1988 (Federal Law Gazette. I p. 1657), last amended Ordinance of 6 June 2011 (Federal Law Gazette I p. 1035).

1. Scope of application

The German Measures and Verification Act and the Measures and Verification Ordinance are intended to protect industry and the consumers when buying measurable goods or services, to protect them in commercial and official transactions, and to protect them in measurements which are performed in the public interest, by ensuring metrological reliability and stability of measuring instruments.

The scope of application of the measuring instruments covered by law is laid down in the Measures and Verification Ordinance. The term "measuring instruments" refers to all those devices (or systems of devices) that are provided with a measurement function, and it also refers to material measures. The regulations for measuring instruments apply equally to the ancillary equipment of measuring instruments as well as to sub-assemblies. Covered are measuring instruments which are intended for measuring purposes and services that are determined in the Measures and Verification Ordinance (determination of measurands). Exempted from this scope of application are measuring instruments (or the concrete use of measuring instruments and measurement values) if the need for protection of the parties concerned does not require the application of the Measures and Verification Act. The extent of this scope of application is basically geared to the so far existing provisions of the Verification Act and the Verification Ordinance.

2. Prerequisites for placing measuring instruments on the market

2.1 Introduction

Measuring instruments are "placed on the market" when they are made available on the market of the European Union for the first time, i.e. when they are delivered for distribution, consumption or use in the course of a commercial activity, whether in return for payment or free of charge⁴. Measuring instruments which are subject to the German Measures and Verification Act (formerly: "measuring instruments subject to mandatory verification") may be placed on the market only if they fulfil certain requirements. Hereby, a distinction is no longer made between instruments which are covered by European harmonisation directives according to the "New Approach" and nationally regulated measuring instruments. National type approval and initial verification, which have been applied to date, are omitted and are also replaced by conformity assessment and a declaration of conformity provided by the manufacturer. An exception to this are the measuring instruments covered by the individual directives of the EEC, for which the regulations of Directive 2009/34/EC (common provisions for both measuring instruments and methods of metrological control) continue to be valid.

The following prerequisites must be met when measuring instruments are placed on the market⁵:

- The measuring instruments must comply with the essential requirements.
- To demonstrate conformity with the essential requirements, a suitable conformity assessment procedure must have been carried out.
- Proof of conformity must be furnished by a declaration of conformity provided by the manufacturer and by the application of conformity marks to the measuring instrument.
- For its further identification, the measuring instrument must be provided with specified inscriptions.

Measuring instruments which have been placed on the market under these conditions may be used immediately within the scope of application of the Measures and Verification Act. For the

⁴ See Section 2 No. 7 in connection with No. 1 Measures and Verification Act

⁵ See Section 6 Measures and Verification Act

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duration of the respective verification period, the measuring instruments correspond to verified measuring instruments.

2.2 Essential requirements

The following information does not apply to non-automatic weighing instruments⁶ as the essential requirements are ultimately regulated in Directives 2009/23/EC or 2014/31/EU.

Measuring instruments must comply with the maximum permissible errors. For measuring instruments falling under Directive 2004/22/EC or 2014/32/EU, the maximum permissible errors are laid down in the instrument-specific Annexes of the Directives. For nationally regulated measuring instruments, the maximum permissible errors must comply with the state of the art. Thereby, the intended duration of use and the measurement task to be fulfilled, as well as the environmental conditions intended for their use must be taken into account. Maximum permissible errors are, for example, laid down in DIN standards or in other regulations which represent the state of the art.

The Rule Determination Committee⁷ specifies the essential requirements for measuring instruments. For this purpose, it determines – on the basis of the state of the art – the corresponding rules and technical specifications for the respective measuring instrument category. An exception to this are measurement instruments which fall under Directive 2004/22/EC or (from 20.04.2016) under Directive 2014/32/EU (Measuring Instruments Directive), and non-automatic weighing instruments according to Directive 2009/23/EC or (from 20.04.2016) Directive 2014/31/EU. For these measuring instruments, the essential requirements are specified by the harmonized standards adopted for the directives and/or by normative documents⁸ (see No. 2.3).

In addition, measuring instruments must be suitable for their intended use, they must be reliable and stable and they must be protected against falsification of the measurement results. Also, they must display these results in a suitable form, process them in such a way that they are protected against falsification, and it must be possible to verify these results.

Details of these general essential requirements are laid down in Annex 2 of the Measures and Verification Ordinance. Annex 2 basically corresponds to Annex I of the Measuring Instruments Directive. Thus, the basic requirements of the Measuring Instruments Directive have been introduced also for nationally regulated measuring instruments.⁹

2.3 Presumption of conformity

The determination of the essential requirements is based on the "New Approach" of European law which – together with the above directives for measuring instruments and for non-automatic weighing instruments – has been transposed into the Measures and Verification Act. For the instruments falling under the European directives, the presumption of conformity is triggered by harmonised standards and normative documents – as far as these (or part of them) are published as such in the Official Journal of the EU.

This principle is now also being used for the nationally regulated measuring instruments. The essential requirements are no longer specified by Annexes to the Verification Ordinance for measuring instrument categories (as has been the case so far), but by suitable technical rules or specifications. Whether a rule or specification is suitable to specify, supplement or verify the essential requirements, is determined by the Rule Determination Committee.¹⁰ Manufacturers

⁶ This instruction sheet only deals with non-automatic weighing instruments for use in accordance with Article 1 para. 2 letters a) to f) of Directives 2009/23/EC and 2014/31/EU.

⁷ With regard to the tasks of the Rule Determination Committee at PTB, see Section 46 of the Measures and Verification Act.

⁸ Normative documents can only be published for instruments of the Measuring Instruments Directive.

⁹ See Section 7 Measures and Verification Ordinance

¹⁰ See Section 6 of the Measures and Verification Act

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can assume that a measuring instrument which agrees with this rule or with this specification complies with the essential requirements of the Measures and Verification Ordinance which are covered by this rule or specification.¹¹

If the Rule Determination Committee has not yet determined any rules or specifications for nationally regulated measuring instruments, the conditions which are contained in Annexes 1 to 23 of the Verification Ordinance in the version valid on 31 December 2014 apply with regard to the presumption of conformity until 31.12.2017.¹²

The reference of the current *rule document* of the Rule Determination Committee is published in the Federal Gazette. You can also find the document under <http://www.ptb.de/cms/en/metrological-services/rea.html> under "Rules, decisions, documents".

2.4 Conformity assessment procedures

The manufacturer must carry out a suitable conformity assessment procedure to demonstrate the conformity of a measuring instrument with the essential requirements of the Measures and Verification Ordinance.

For measuring instruments of Directives 2004/22/EC (or 2014/32/EU) and 2009/23/EC (or 2014/31/EU), the manufacturer may select one of the conformity assessment procedures laid down in the directives for the respective instrument type.

For nationally regulated measuring instruments, the Measures and Verification Ordinance lays down the conformity assessment procedures from modules B and D or B and F as suitable procedures.¹³ The Rule Determination Committee can stipulate additional conformity assessment procedures as suitable procedures. How to carry out these procedures is laid down in Annex 4 of the Measures and Verification Ordinance. The respective procedures of Directive 2014/32/EU have been adopted. Additional information about conformity assessment procedures can be found in the "Guide on the implementation of directives based on the New Approach and the Global Approach" (<http://ec.europa.eu/DocsRoom/documents/12661> "Blue Guide").

2.5 Declaration of Conformity

Up to now, a manufacturer's declaration of conformity had only been required for European-regulated measuring instruments which have obtained a CE marking. Now, a declaration of conformity will also be required for nationally regulated measuring instruments. For the instruments of the Measuring Instruments Directive, the declaration must be issued in accordance with the form shown in Directive 2014/32/EU (Annex XIII) and for non-automatic weighing instrument according to the form shown in Directive 2014/31/EU (Annex IV). The declaration of conformity will be issued for all EU Directives to which the measuring instrument is subjected (e.g. also for EMC Directive 2014/30/EU).

For nationally regulated measuring instruments, the form shown in Annex 5 of the Measures and Verification Ordinance must be used. The declaration of conformity will be issued for all other (national) legal regulations if the measuring instrument is subject to other legal regulations (in addition to the Measures and Verification Act) which require a manufacturer's declaration of conformity.¹⁴

2.6 Marking

The devices which fall under the Measuring Instruments Directive, as well as non-automatic weighing instruments will, also in future, be marked with the CE marking, the metrology

¹¹ See Section 7 of the Measures and Verification Act

¹² See Section 7(4) of the Measures and Verification Ordinance

¹³ Section 9 of the Measures and Verification Ordinance

¹⁴ See Section 8 of the Measures and Verification Act and Section 11 of the Measures and Verification Ordinance

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marking, the year, and the identification number of the notified body, in accordance with the provisions of the respective directive. When the new European directives become effective on 20 April 2016, non-automatic weighing instruments will be marked in the same way as the instruments falling under the Measuring Instruments Directive.

For nationally regulated measuring instruments, a new marking will be introduced. The approval mark used so far does no longer entitle to place a measuring instrument on the market, to verify it and to use it. The new marking consists of the sequence of characters "DE-M" (surrounded by a rectangle with a height of at least 5 millimetres), the last two digits of the year in which the marking has been applied, and the identification number of the conformity assessment body which has been involved in the production phase.¹⁵

2.7 Inscriptions

Inscriptions must be applied to the measuring instrument in a way that they are clearly visible, readable and indelible. Roman letters and Arabic numerals must be used. For measuring instruments which are too small or too sensitive, there is still the possibility to apply the required inscriptions to the packaging and to the information that is to be enclosed.

Measuring instruments must be provided with the symbol or with the name or trade mark of the manufacturer and, from 20.04.2016, with a valid postal address as well as with information on the measurement accuracy. Other information may be required in addition if such information is necessary for the proper operation or monitoring of the measuring instrument. This information concerns the conditions of use, the measuring capacity, the measurement range, the identity marking, the number of the type-examination certificate or of the design-examination certificate¹⁶ as well as information on whether ancillary devices which have been supplied together with the instrument and which indicate, store or print measurement results comply with the Measures and Verification Act.

For instruments which fall under the Measuring Instruments Directive, additional details are laid down in the instrument-specific requirements (Annexes MI-001 to MI-010). Additional information is also required for non-automatic weighing instruments.

For nationally regulated measuring instruments, concrete additional information can be taken from the regulations concerning the presumption of conformity for the respective measuring instruments (where necessary, the Conformity Assessment Body decides).¹⁷

¹⁵ See Section 14 of the Measures and Verification Ordinance

¹⁶ If the granted national type approval is used according to Section 62 of the Measures and Verification Act, the approval mark that has been used so far in the sense of an inscription can remain on the measuring instrument.

¹⁷ Section 15 of the Measures and Verification Ordinance

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3. Obligations of the manufacturer

According to Section 2, number 6 of the Measures and Verification Act, “manufacturer” means any 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 (2) can be compromised, is classed as a measuring instrument manufacturer.

The obligations of the manufacturer are laid down in Section 23 of the Measures and Verification Act. According to this section, the manufacturer bears the responsibility for the fact that only measuring instruments are placed on the market which comply with the essential requirements laid down in the Measures and Verification Act. Changes to the design of a measuring instrument or to the technical rules on which the declaration of conformity is based, must be taken into account to a suitable extent.

The manufacturer draws up the technical documentation which is required for the performance of the conformity assessment procedure. He must arrange the performance of the conformity assessment and issue the declaration of conformity. The technical documentation and the declaration of conformity must be kept for a period of ten years, starting with the date on which the measuring instrument is placed on the market. With the issuing of the declaration of conformity, the manufacturer assumes responsibility for the conformity of the measuring instrument with the relevant legal regulations.

The manufacturer has to apply the required markings and inscriptions to the measuring instruments. When the measuring instrument is placed on the German market, the manufacturer must enclose the required information on how to use the measuring instrument (**in German**). If necessary, this must be made in the form of an instruction manual, so that the full range of functions of the measuring instruments can be properly used, maintained and tested by anyone.¹⁸

The manufacturer must check measuring instruments which are available on the market by taking samples if this is purposeful for the assessment of the functionality of a measuring instrument. If quality defects are identified, the measuring instruments which have proved to be non-conforming, and the respective recalls must be recorded in a register of complaints, and the distributors must be informed about the current situation.

If the manufacturer has information and knowledge of the fact that a measuring instrument which has been placed on the market by him does not meet the legal requirements, he must immediately take measures to restore the conformity of the measuring instrument. If this is not possible, he must withdraw the measuring instruments from the market or recall them. Where a measuring instrument represents a risk due to its metrological characteristics, he will immediately inform the authority in charge under federal state law about the non-conformity and about the measures already taken.

Manufacturers may also appoint authorised representatives and delegate (in writing) certain tasks to them. It is, however, not permitted to delegate the responsibility for the conformity of the measuring instruments which are placed on the market by the manufacturer with the essential requirements. Also, it is not permitted to delegate the preparation of the technical documentation.

The Measures and Verification Act also lays down requirements for importers and distributors. Importers and distributors as well as any legal or natural person who places measuring instruments on the market under his/her own name or who uses the measuring instruments himself/herself or who modifies measuring instruments which are on the market in such an

¹⁸ See Section 17 of the Measures and Verification Ordinance

essential way that their conformity may be compromised, are considered as manufacturers in the sense of the Measures and Verification Act.

4. Conformity assessment bodies

According to the Measures and Verification Act, conformity assessment bodies can be established at authorities and at private bodies.

Conformity assessment bodies at authorities have been set up at PTB and at the verification authorities.

PTB has demonstrated to the BMWi compliance with the requirements of the Measures and Verification Act for conformity assessment bodies.

PTB's Conformity Assessment Body acts on behalf of the manufacturers in the case of conformity assessment procedures for measuring instruments which are subject to the Measures and Verification Act and to the Measures and Verification Ordinance. These are the procedures according to the modules B, D, D1 and G for all instruments falling under the Measuring Instruments Directive, as well as for non-automatic weighing instruments and for nationally regulated measuring instruments if these modules are feasible for the respective measuring instruments.

Detailed information can be found in our service offer under <http://www.ptb.de/cms/en/metrological-services/kbs.html>.

The verification authorities which have so far been responsible for the initial verification of the measuring instruments usually offer the modules F and F1 via the conformity assessment bodies affiliated to them. A survey, as well as the links to the conformity assessment bodies of the verification authorities, can be found on the web page of the "Arbeitsgemeinschaft Mess- und Eichwesen" (AGME) under www.agme.de → *Fachinformation* (technical information) → *Allgemeine Fachinformationen* (general technical information) → *Liste der von den deutschen Behörden ab 1. Januar 2015 angebotenen Konformitätsbewertungsverfahren* (List of the conformity assessment procedures offered by the German verification authorities from 1 January 2015).

In addition, three bodies are at present working in Germany as Notified Bodies according to the Measuring Instruments Directive¹⁹.

It is planned to provide a survey of all conformity assessment bodies which are working in accordance with the Measures and Verification Act, as well as a survey of their tasks, on the web page of the "Committee of Conformity Assessment Bodies" (www.adkbs.ptb.de).

¹⁹ See <http://ec.europa.eu/growth/tools-databases/hando>

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5. Verification

Measuring instruments which are used within the scope of the German Measures and Verification Act must be verified. The measuring instruments placed on the market by the manufacturer in accordance with the Measures and Verification Act are regarded as having been verified.²⁰ The verification period of the measuring instruments begins with their placing on the market. Until the end of this period, no verification is required. After that date, or if the period ends prematurely, the measuring instruments must be verified.

Measuring instruments which had already been verified in accordance with the provisions of the previous Verification Ordinance before 01.01.2015, can still be used. After expiry of their verification period, they must be verified again (formerly, this was the “subsequent verification”).

The verification will – also in future – be performed by the verification authorities. Measuring instruments for electricity, gas, water and heat can, also in future, be verified by state-approved test centres. During the verification, the conformity marks of the manufacturer (when placing measuring instruments on the market) will be maintained.

In the case of a verified measuring instrument, the bodies responsible for the verification can check whether the instrument continues to comply with the requirements which had been met during verification (inspection testing) if there is a justified interest in this. During its use, the measuring instrument must comply with the maximum permissible errors in service.

6. Market surveillance

By means of market surveillance, it shall be checked whether the measuring instruments which have been placed on the market comply with the requirements of the Measures and Verification Act. In addition to the measuring instruments which are subject to the EU directives, the new German Measures and Verification Act also subjects nationally regulated measuring instruments to market surveillance. Usually, the verification authorities are in charge of this. The measures which will possibly be taken are addressed to the responsible economic operator concerned, i.e. to the manufacturer, to the importer or to the distributor. Within the scope of market surveillance, manufacturers are obligated to support the market surveillance bodies in the execution of their tasks and in the measures taken and to provide the required information.²¹

7. Monitoring of the correct use of measuring instruments and measurement values

Measures which are taken to monitor whether the measuring instruments and measurement values are used in the correct way are geared to the user. The verification authorities combine this task of monitoring the correct use of measuring instruments and measurement values as far as possible with the performance of verifications.

²⁰ See Section 37 of the Measures and Verification Act

²¹ See Section 52 of the Measures and Verification Act

8. Transitional provisions

Measuring instruments for which initial verification has already been performed before 01.01.2015 may be placed on the market or may continue to be used without a new conformity assessment becoming necessary.

Measuring instruments which have not yet been verified must, since 01.01.2015, no longer be subjected to (initial) verification. They must be placed on the market in accordance with the provisions of Section 6 of the Measures and Verification Act, i.e. the manufacturer must carry out a conformity assessment procedure (as a rule, the modules B and F or B and D are to be executed), involving thereby a conformity assessment body.

For the conformity assessment, a national type approval – which has been granted before 31.12.2014 and which is still valid – can be used to prove the conformity of the instrument type. Until 31.12.2024²², these type approvals will be covered by the right of continuance with regard to the proof of compliance with the essential requirements. It is, thus, assumed that the measuring instrument categories which comply with these approvals meet the essential requirements of the Measures and Verification Act and of the Measures and Verification Ordinance. It is, therefore, not required to carry out a conformity assessment of the type (module B) for such measuring instruments.

The right of continuance does not cover the assessment of the individual measuring instruments; the subsequent modules F or D have to be executed.

The other requirements for the placing on the market of measuring instruments must also be complied with. The measuring instruments obtain the new conformity marking, the manufacturer's declaration of conformity and the required inscriptions.

Since 01.01.2016, modifications of national type approvals have no longer been possible. In such cases, you should apply for a type-examination certificate for the modified type.

Until 30.11.2015 it was possible to issue EC type-approval certificates (formerly: EEC type-approval certificates) for measuring instruments falling under a valid EEC individual directive. These EEC individual directives were abolished taking effect on 01.12.2015.²³ The granted EEC type approvals remain, however, valid until the date of their expiry (not later than 30.11.2025). For measuring instruments in accordance with these approvals, EEC initial verification can still be carried out until the end of the period of validity of the approval. An amendment of the approved types as well as prolongations or transfers of type approvals will, however, no longer be possible.

9. Costs

PTB raises charges²⁴ (fees and outlay) for carrying out a conformity assessment of measuring instruments. These services are invoiced according to the *Regulations Governing Charges for Services Supplied by PTB* in their respectively current version. In general, the fees are calculated according to the amount of work actually arising. The services of PTB are subject to value-added tax (VAT).

Deviating from this, conformity assessments of the types of measuring instruments which determine the dose of ionising radiation are invoiced according to the *Regulations Governing Charges for Approvals Granted by PTB*.

²² Transitional provisions, see Section 62 of the Measures and Verification Act

²³ Directive 2011/17/EU of 09.03.2011

²⁴ See <http://www.ptb.de/cms/de/ptb/fachabteilungen/abt/z14/gebuehren.html>