



The legislative framework of Europe with the elements for

- > conformity assessment,
- > standardization,
- > accreditation,
- > market surveillance and
- > the control of products from outside the European Union

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European regulations

- > REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 setting out the requirements for accreditation and market surveillance
- > REGULATION (EU) No 1025/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2012 on European standardization

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European directives

- > DIRECTIVE 2014/32/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments
- ➤ DIRECTIVE 2014/31/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments

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Essential product requirements

- > Essential requirements are designed to provide and ensure a high level of protection.
- > Essential requirements define the results to be attained, or the hazards to be dealt with, but do not specify the technical solutions for doing so.
- > The precise technical solution may be provided by a standard or by other technical specifications.

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Harmonised Standards

- > Harmonised standards are European standards adopted, upon a request made by the European Commission for the application of Union harmonisation legislation.
- > Harmonised standards provide a presumption of conformity with the essential requirements they aim to cover.
- > Standards are of voluntary application.

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Normative Documents

➤ Measuring instruments which are in conformity with parts of normative documents (for example an OIML-Recommendation), the list of which has been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the essential requirements.

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CE Marking

- > The CE marking indicates the conformity of the product with the Union legislation applying to the product and providing for CE marking.
- > The product fulfill all essential requirements.

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The legislative framework:

- Measures and Verification Act (Mess- und Eichgesetz)
- ➤ Measures and Verification Ordinance (Mess- und Eichverordnung)
- More than 150 types of measuring instruments
- · Over 130 million measuring instruments in use

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The legislative framework:

- > Duties of the economic operators (manufacturer, authorised representative of manufacturer, importer and dealer),
- > placement of measuring instruments on the market,
- > recognition and notification of conformity assessment bodies,
- > use of measuring instruments and measured values,
- > pre-packages and other sales units,
- > market surveillance and
- > monitoring the use of measuring instruments

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Placement of measuring instruments on the market

- > Measuring instruments must satisfy the essential requirements.
- > A conformity assessment must have been carried out successfully.
- > A declaration of conformity (by a manufacturer) must be available.
- > The conformity of a measuring instrument must be validated by means of a label (CE or DE marking).
- > The measuring instrument must be furnished with the inscriptions indicated.

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Rule Determination Committee

- ➤ The Rule Determination Committee ("Regelermittlungsausschuss") determines rules, findings and technical specifications for measuring instruments, for conformity assessment procedures, and for the users of measuring instruments or of measured values.
- > The Committee is composed of the PTB, the respective authorities of the federal states, conformity assessment bodies, state-accredited test centers, trade associations and consumer associations.
- > The Rule Determination Committee is located at the PTB, which presides over it and houses its executive office.

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Verification tests of measuring instruments

- > official inspection, assessment and labelling of a measuring instrument
- > permission to use the measuring instrument for a further verification period
- verification tests are carried out by the responsible authorities of the Federal States

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Thank you for your attention

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