

Legal Metrology in Slovak Republic

<p>1. Organizational structure in LM</p>	<p>The Slovak Office of Standards, Metrology and Testing, is the central government authority in the area of metrology for ensuring measurement accuracy and uniformity</p> <p>1. Government authorities for the area of metrology are:</p> <ul style="list-style-type: none">a) the Slovak Office of Standards, Metrology and Testingb) the Slovak Metrological Inspectorate <p style="text-align: center;">The Slovak Office of Standards, Metrology and Testing</p> <p>The Slovak Office of Standards, Metrology and Testing, as the central government authority in the area of metrology for ensuring measurement accuracy and uniformity,</p> <ul style="list-style-type: none">a) represents the Slovak Republic in international metrological organisations, ensures the performance of tasks ensuing from this membership, and coordinates participation by government authorities, corporate subjects and natural persons in the fulfilment of these tasks, as well as tasks ensuing from international agreements for the area of metrology by which the Slovak Republic is bound;b) declares national reference standards, changes their declaration, and repeals their declaration;c) specifies types of specified measuring instruments, technical requirements, and metrological requirements for individual types of specified measuring instruments, and the manner of their metrological inspection;d) decides on the authorisation of exercise of verification of specified measuring instruments or the exercise of official measurement, and keeps a list of authorised subjects;e) decides on registration where the activity in question is repair or installation of specified measuring instruments or packaging of marked consumer packages or import of marked consumer packages, and keeps a list of registered subjects;f) regulates activity in the area of metrology;g) publishes in the Journal of the Slovak Office of Standards, Metrology and Testing:<ul style="list-style-type: none">1. declares a national reference standard, changes its declaration, and repeals its declaration;2. specified measuring instrument type approval, suspension of type-approval decisions, and revocation of type-approval decisions;3. notifications regarding a decision on authorisation, a decision to change authorisation, or a decision to repeal authorisation;4. notifications of expiry of authorisation, if the Office has learned of the expiry;5. recognition of initial verification of a new specified measuring instrument;6. permission for the temporary use of a different unit of measurement as a legal unit of measurement;7. a requirement for the maximum permissible measuring instrument error, if not stipulated by special legislation;h) publishes the following lists on the Office's website and on the Central Government Portal:<ul style="list-style-type: none">1. national reference standards;2. approved types;3. authorised subjects;4. authorisation suspension decisions;5. registered subjects;6. registration suspension decisions;7. laboratories that performed initial verification;8. permission for the temporary use of a different unit of measurement as a legal unit of measurement;9. notifications regarding extension of the time of use of a specified measuring instrument from completion of its repair until its subsequent verification;i) creates conditions for activities in the area of metrology;j) is the appellate body against decisions of the Slovak Metrological Institute and the Inspectorate;k) assigns verification marks, partial verifications marks, security marks, repair security marks, temporary repair security marks, or installation security marks;l) checks compliance with authorisation requirements in cooperation with the Institute or
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with a specified organisation, and checks compliance with registration requirements in cooperation with the Institute or with a specified organisation.

The Slovak Metrological Inspectorate

The Slovak Metrological Inspectorate is a budgetary organisation.

- a) The Inspectorate is a metrological supervision authority.
- b) The Inspectorate supervises fulfilment of obligations by a public authority, operator, a different corporate entity, or a different natural person pursuant to this Act.
- c) The Inspectorate also performs the function of an oversight authority for the area of measuring instruments.
- d) The Inspectorate is managed by its director, who is responsible for its activity and is appointed and dismissed by the president of the Slovak Office of Standards, Metrology and Testing.

2. The other authorities in metrology.

The Slovak Metrological Institute

The Institute is a contributory organisation

The Institute, as a national metrological institution,

- a) develops metrology development policy;
- b) engages in research and development in the area of metrology;
- c) represents the Slovak Republic in international metrological organisations to which it belongs and ensures the performance of tasks ensuing from this membership;
- d) arranges international recognition of national reference standards and certified reference materials;
- e) nominates a national reference standard for declaration, changes to the declaration, or repeal of the declaration;
- f) oversees the development, maintenance, and use of national reference standards maintained by the designated organisation;
- g) oversees the designated organisation's compliance with requirements;
- h) ensures the creation, maintenance, development, and international comparison of national reference standards and the transfer of quantity values to measuring instruments;
- i) coordinates the approval process for national reference standards;
- j) certifies reference materials;
- k) performs type approval for specified measuring instruments, verifies specified measuring instruments, calibrates measuring instruments subject to mandatory calibration and other measuring instruments, and performs official measurements;
- l) authorises a specified organisation to perform specified activities in the type approval of measuring instruments;
- m) verifies qualifications of natural persons in the area of metrology through testing;
- n) issues natural persons proof of qualifications in the area of metrology;
- o) sends the Slovak Office of Standards, Metrology and Testing type-approval decisions within 30 days of their issue;
- p) sends the Slovak Office of Standards, Metrology and Testing a list of certificates in the area of metrology with at least the certificate number, the date of issue and its expiry date, within five workdays of the date of their issue;
- q) checks compliance with authorisation requirements and checks compliance with registration requirements;
- r) provides specialised services in the area of metrology;
- s) can perform inter-laboratory comparison measurements;
- t) can, to the extent stipulated, perform tests on sources of ionising radiation, certification of persons, equipment, and work procedures in the area of ionising radiation;
- u) can perform activity pursuant to special legislation.

	<p style="text-align: center;">Specified organisation</p> <p>Slovak Legal Metrology, n. o., is the organization specified by a decision of the Slovak Office of Standards, Metrology and Testing for the metrological control - verification of the measuring instruments and for other activities in compliance with Act on metrology.</p> <p style="text-align: center;">Authorised subject</p> <p>An operator or other corporate entity whose has the right to verify a specified measuring instrument or to perform official measurement. The Slovak Office of Standards, Metrology and Testing grants authorisation based on a written application by the applicant for authorisation. The applicant for authorization to perform the verification of a specified meter must be accredited.</p> <p style="text-align: center;">Registered subject</p> <p>An operator or other corporate entity whose line of business is repair or installation of a specified measuring instrument or packaging of a specified measuring instrument or import of a specified measuring instrument.</p> <p style="text-align: center;">Accredited calibration laboratory</p> <p>is performing calibration of measuring instruments subject to mandatory calibration.</p> <p style="text-align: center;">Notified body (activity according to EU Directives)</p> <p>A conformity assessment body is a third-party body independent of the organisation or the measuring instrument it assesses.</p>
<p>2. Units</p>	<p>The units of the International System of Units (SI) are applied in the Slovak Republic.</p>
<p>3. Law on metrology</p>	<p>Two basic metrological legislative systems have been introduced in Slovakia, namely Metrological control (old approach) and Conformity assessment (new approach).</p> <p>Metrological control</p> <p>Act No. 158/2018 Coll. on metrology and on amendments to certain acts.</p> <p>Decree of the Slovak Office of Standards, Metrology and Testing No 161/2019 Coll. on measuring instruments and metrological control.</p> <p>Decree of the Slovak Office of Standards, Metrology and Testing No. 173/2018 Coll. on legal units of measurement.</p> <p>Decree of the Slovak Office of Standards, Metrology and Testing No. 188/2018 Coll. on consumer packaging, on a bottle as a measuring container, on requirements for checking the quantity of a product in a consumer packaging and on requirements for checking the actual volume of a bottle as a measuring container.</p> <p>Conformity assessment</p> <p>Government Ordinance of the Slovak Republic No. 145/2016 Coll. Relating to the making available on the market of measuring instruments as amended by Government Ordinance of the Slovak Republic No. 328/2019 Coll., which implemented the Directive 2014/32/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments.</p> <p>Government Ordinance of the Slovak Republic No. 126/2016 Coll. Relating to the making available on the market of non-automatic weighing instruments as amended by Government Ordinance of the Slovak Republic No. 330/2019 Coll., which implemented the Directive 2014/31/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments.</p> <p>Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.</p>

<p>4. List of MIs within the field of Legal Metrology or scope of state regulation</p>	<p>1. Specified measuring instrument - a measuring instrument specified for mandatory metrological inspection or for conformance assessment</p> <p>1.1 Classification of a measuring instrument into specified measuring instrument group depends on its purpose and use</p> <ul style="list-style-type: none"> - for payment-related measurement; - for the protection of health, safety, property or the environment; - to prepare consumer packaging; - in another area of public life where conflicting interests in the result of measurement may arise or where an incorrect measurement result may harm the interests of a natural person, a corporate entity, or the public; - for measurement, if so stipulated by special legislation. <p>1.2 Payment-related measurement is primarily measurement</p> <ul style="list-style-type: none"> - in business relations; - for determining price during a direct sale to the consumer; or - for the purposes of calculating prices, fees, tariffs, customs charges, taxes, discounts, fines, compensation, damages insurance or similar payments. <p>1.3 Without the performance of a metrological inspection or assessment, a specified measuring instrument must not be placed on the market and used.</p> <p>2. Metrological inspection (control)</p> <p>2.1 Metrological inspection takes place</p> <ul style="list-style-type: none"> - prior to placing a specified measuring instrument on the market; - during the use of a specified measuring instrument. <p>2.2 Metrological inspection prior to placing a specified measuring instrument on the market is</p> <ul style="list-style-type: none"> - type approval, which is a national-type approval or an EC type approval; - initial verification of a specified measuring instrument that is a national initial verification or an EC initial verification. <p>2.3 Metrological inspection during the use of a specified measuring instrument is subsequent verification of a specified measuring instrument.</p> <p>2.4 Verification of a specified measuring instruments may be performed by the Slovak Metrology Institute, Specified organisation and Authorised subjects.</p> <p>3. Conformance assessment</p> <p>3.1 Conformity assessment takes place prior to placing a specified measuring instrument on the market. Conformity assessment is performed by Notified bodies.</p> <p>3.2 Subsequent verification of a specified measuring instrument may be performed by the Slovak Metrology Institute, Specified organisation and Authorised subjects.</p>
<p>5. Type approval</p>	<p>5.1 Legal and technical requirements for type approval</p> <p>Requirements for type approval are set in act No. 157/2018 Coll. on metrology and on amendments to certain acts.</p> <ul style="list-style-type: none"> - Type approval confirms that the specified measuring instrument type meets requirements for the kind of specified measuring instrument as regards its technical characteristics, metrological characteristics, and design/build. - Type approval is performed by the Slovak Metrology Institution. For an application-specific specified measuring instrument, if the economics or technical feasibility of type approval are not commensurate with the importance of type approval, the Slovak Metrology Institute may decide that this type is not subject to type approval. - A written application for type approval is submitted to the Slovak Metrology Institute by a specified measuring instrument manufacturer from a Member State or his designated importer or a specified measuring instrument importer authorised by a manufacturer from a country that is not a Member State. <p>5.2 Bodies, responsible for type approval</p> <p>Slovak Metrology Institute is responsible for type approval according to Act No. 157/2018 Coll. on metrology and on amendments to certain acts.</p>

	<p>5.3 Bodies, responsible for testing for type approval Slovak Metrology Institute perform or arrange the performance of tests on the samples of the specified measuring instrument in order to determine if the specified measuring instrument meets technical and metrological requirements, and matches the manufacturer's declared metrological characteristics; it shall perform the tests in its own laboratories, in selected laboratories, or on the premises of the manufacturer or importer, or at the location where the specified measuring instrument is installed.</p> <p>Foreign relations: The Slovak Metrology Institute may, based on a written request from a type approval applicant, issue a decision on the national-type approval based on the results of tests of a measuring instrument performed in a Member State other than the Slovak Republic for purposes of domestic-type approval. Test results are recognised if the measuring instrument is manufactured in this Member State or placed on the market pursuant to this Member State's legislation if these results guarantee that its technical and metrological characteristics comply with the technical and metrological characteristics required by Slovak legislation. Performance of technical tests on a sample measuring instrument is not required.</p>
	<p>5.4 Recognition of OIML certificates Slovakia is a full OIML member.</p>
<p>6. Verification</p>	<p>6.1 Legal and technical requirements for initial and periodic verification</p> <p>1. Verification of a specified measuring instrument consists of a test of the specified measuring instrument, and confirmation that it complies with the approved type and with technical and metrological requirements for the kind of specified measuring instrument being verified. If this kind of specified measuring instrument is not subject to type approval, verification of the specified measuring instrument consists of a test of the specified measuring instrument and confirmation that it complies with technical and metrological requirements for the kind of specified measuring instrument being verified.</p> <p>During verification of a specified measuring instrument, testing primarily establishes the following:</p> <ul style="list-style-type: none"> - technical and metrological characteristics; - maximum permissible error; - in the case of initial verification, design/build that guarantees that under prescribed operating conditions, the specified measuring instrument's metrological characteristics will not deteriorate significantly; - in the case of subsequent verification, the specified measuring instrument's technical condition; and - that prescribed inscriptions are complete and correct and that the verification mark has been placed pursuant to special legislation. <p>2. Initial verification is the verification of a new specified measuring instrument.</p> <p>Initial verification of a specified measuring instrument is also considered to be a specified measuring instrument placed on the market or into operation following conformity assessment. The manufacturer (or importer) of a specified measuring instrument must ensure initial verification</p> <p>3. Subsequent verification is every verification that follows initial verification or after repairs on a specified measuring instrument</p> <p>The user of a specified measuring instrument must arrange subsequent verification</p> <p>6.2 Bodies for verification</p> <p>1. Initial verification is performed by Slovak Metrology Institute, specified organisation or authorised subject. Initial verification during multiple phases or initial verification of a specified measuring instrument that is not subject to type approval may be performed only by the Institute or a specified organisation.</p> <p>2. Subsequent verification is performed by Slovak Metrology Institute, specified organisation or authorised subject.</p> <p>3. Initial verification according conformity assessment legislation and relevant conformity assessment modules is performed by Notified body or producer of the measuring instrument.</p>

	<p>6.3 Categories of sorts of specified measuring instruments Slovak Office of Standards, Metrology and Testing specifies sorts of specified measuring instruments, technical requirements, and metrological requirements for individual types of specified measuring instruments, and the manner of their metrological inspection. Types of specified measuring instruments, areas of their use, details of their metrological method checks or conformity assessments and the period of validity of the verification of each type of specified instrument are listed in Annexes no. 1 and from 3 to 65 of the Decree of the Slovak Office of Standards, Metrology and Testing No 161/2019 Coll. on measuring instruments and metrological control. In the Slovak Republic are currently valid the 62 sorts of specified measuring instruments.</p> <p>6.4 Other national requirements for verification 1. Initial verification of a new specified measuring instrument performed in a Member State other than the Slovak Republic is recognised as national initial verification based on a written request submitted to the Institute or a specified organisation. 2. A verification mark is - a national verification mark; - an EC initial verification mark; - a national partial verification mark; and - a partial EC verification mark The Slovak Metrology Institute, a specified organisation, or an authorised subject may place a verification mark on a specified measuring instrument only if the specified measuring instrument complies with requirements pursuant to Act.</p>
<p>7.Conformity assessment for MIs</p>	<p>7.1 Brief description of the system 1. The conformity assessment shall be the determination of whether the characteristics of a specified product conform to the established technical and metrological requirements for a specified product according by the relevant conformity assessment procedure. The conformity of a measuring instrument with metrological Directive shall be indicated by the presence on it of the CE marking and the supplementary metrology marking. The European Union Member States should not impede the placing on the market and/or putting into use of measuring instruments that carry the CE marking and supplementary metrology marking in accordance with the provisions of relevant Directive.</p> <p>2. EU Directives and Regulation for metrology. Directive 2014/32/EU of the European Parliament and of the Council 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 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.</p> <p>7.2 Bodies for assessment of conformity Slovak Metrology Institute Registration number of the notified body: 1781 Directive 2014/31/EU Directive 2014/32/EU Slovak Legal Metrology, n. o., Registration number of the notified body: 1432 Directive 2014/31/EU Directive 2014/32/EU</p>

<p>8. Prepackages</p>	<p>8.1 Legal requirements for controlling prepackages State regulation applies to measurements, made in determining the quantity of prepackages. Slovak Office of Standards, Metrology and Testing sets the requirements for determining the quantity of prepackages, inter alia for the rules of its indication on the package during the production (prepackaging) and (or) sale of prepackages.</p> <p>8.2 Documents, setting requirements for prepackages Act No. 158/2018 Coll. on metrology and on amendments to certain acts.</p> Decree of the Slovak Office of Standards, Metrology and Testing No 188/2018 Coll. on consumer packaging, on a bottle as a measuring container, on requirements for checking the quantity of a product in a consumer packaging and on requirements for checking the actual volume of a bottle as a measuring container. <p>8.3 Bodies, involved in control of prepackages The Slovak Metrology Inspection is performing state metrological supervision of compliance with requirements for prepackages.</p> <p>8.4 Other national requirements for prepackages -</p>
<p>9. Metrological supervision</p>	<p>1. The Slovak Metrological Inspectorate is a metrological supervision authority. The Inspectorate supervises fulfilment of obligations by a public authority, operator, a different corporate entity, or a different natural person pursuant to this Act. The Inspectorate also performs the function of an oversight authority for the area of measuring instruments. The Inspectorate is managed by its director, who is responsible for its activity and is appointed and dismissed by the president of the Slovak Office of Standards, Metrology and Testing.</p> <p>2. The Inspectorate checks that the supervised subject complies with the following:</p> <ul style="list-style-type: none"> - use of a legal unit of measurement and unit of measurement and their symbols; - the obligations of a user of a specified measuring instrument or the obligations of the user of a measuring instrument subject to mandatory calibration; - the obligations of a manufacturer or importer of a specified measuring instrument prior to placing it on the market; - requirements, obligations, scope and standard of metrological activities performed by the Institute, a specified organisation, or an authorised subject; - requirements, obligations, scope, and standard of metrological activities performed by a registered subject within the scope of the activity subject to registration; - technical and metrological requirements for a specified measuring instrument pursuant to the approved type, if the specified measuring instrument is subject to type approval and for a specified product pursuant to special legislation; - the obligations of consumer packaging plant operators and importers of consumer packaging; - the obligations of manufacturers or importers of flasks as measuring containers; - requirements for consumer packages and flasks as measuring containers. <p>3. Rights of inspectors. An inspector has the right to:</p> <ul style="list-style-type: none"> - enter manufacturing areas, sales areas, and storage areas and other buildings of the supervised subject; - request relevant information, documents, and data; - request the creation of adequate conditions for the performance of metrological supervision; - take away a specified measuring instrument, consumer package, or flask as a measuring container; - check the identity of the supervised subject, its employees, or those acting in the name of supervised subjects; - impose a fine on the spot; - perform a test purchase. <p>4. Obligations of inspectors. An inspector must:</p> <ul style="list-style-type: none"> - show the supervised subject an inspector's badge and no later than the start of metrological supervision, inform it of the subject and purpose of the metrological supervision; - comply with requirements for entering the supervised subject's premises and proceed during metrological supervision in a manner that does not threaten the supervised subject's operations; - keep confidential any information that he or she has obtained during the course of metrological supervision;

	<ul style="list-style-type: none"> – make out a record of the result of the metrological supervision, which is a public document, and give the supervised subject a copy.
10. Legal metrology practitioners	<ol style="list-style-type: none"> 1. The qualifications in the area of metrology means the sum total of expert knowledge, practical abilities, and knowledge of regulations in an area that is subject to authorisation (for the performance of verification of a specified measuring instrument or for the performance of official measurement) or registration (object of activity is the repair or installation of a specified measuring instrument or packaging labelled consumer packaging, or the import of a labelled consumer packaging). 2. The Slovak Metrology Institute verifies qualifications in the area of metrology through an examination and certifies it by the issuance of a certificate in the area of metrology within. The Slovak Metrology Institute verifies qualifications in the area of metrology every five years after it issues a certificate of competence in the area of metrology.
11. Sanctions	<ol style="list-style-type: none"> 1. The Inspectorate will impose a fine from EUR 200 to EUR 10 000 on someone who breaches the provisions of this Act by: <ul style="list-style-type: none"> –failing to use legal units of measurement, units of measurement and their symbols in the Slovak Republic; –uses a measuring instrument or neglects to use a measuring instrument without metrological inspection or without conformity assessment for a purpose for which this kind of measuring instrument is classified into the group of specified measuring instruments; –damages, illegally changes or removes a type-approval mark, verification marks, partial verifications mark, security mark, repair security mark, temporary repair security mark, or installation security mark; –repairs or installs a specified measuring instrument without registration, etc. 2. The Inspectorate will impose a fine from EUR 500 to EUR 50 000 on someone who breaches the provisions of this Act by: <ul style="list-style-type: none"> – placing a measuring instrument on the market without metrological supervision, that has not been type-approved, though subject to approval, or that does not comply with the approved type, or placing a measuring instrument on the market that has not been verified, though subject to verification; – places a marked consumer package on the market without registration, etc. 3. An inspector may impose a spot fine up to EUR 300 on anyone if the supervised subject breaches only one obligation pursuant to this Act, the breach of obligation has been determined reliably, and the supervised subject pays the fine on the spot at the time of metrological supervision.