

STN	Diagnostické zdravotnícke pomôcky in vitro Požiadavky na zavedenie metrologickej nadväznosti hodnôt priradených kalibračným, skutočným kontrolným materiálom a ľudským vzorkám (ISO 17511: 2020)	STN EN ISO 17511 85 1017
------------	---	--

In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/21

Obsahuje: EN ISO 17511:2021, ISO 17511:2020

Oznámením tejto normy sa od 30.06.2024 ruší
STN EN ISO 17511 (85 1017) z mája 2004

133456

EUROPEAN STANDARD

EN ISO 17511

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2021

ICS 11.100.10

Supersedes EN ISO 17511:2003

English Version

In vitro diagnostic medical devices - Requirements for
establishing metrological traceability of values assigned to
calibrators, trueness control materials and human samples
(ISO 17511:2020)

Dispositifs médicaux de diagnostic in vitro - Exigences
pour l'établissement d'une traçabilité métrologique
des valeurs attribuées aux étalons, aux matériaux de
contrôle de la justesse et aux échantillons humains
(ISO 17511:2020)

In-vitro-Diagnostika - Anforderungen an die
Ermittlung metrologischer Rückführbarkeit von
Werten, die Kalibratoren,
Richtigkeitskontrollmaterialien und Humanproben
zugeordnet sind (ISO 17511:2020)

This European Standard was approved by CEN on 4 February 2020.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents	Page
European foreword.....	3
Annex ZA (informative) Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered.....	5

European foreword

This document (EN ISO 17511:2021) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 "In vitro diagnostic medical devices" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2021, and conflicting national standards shall be withdrawn at the latest by June 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 17511:2003.

This document has been prepared under a standardization request/mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

NOTE In this European Standard the concept "accuracy of measurement" is not equivalent to "trueness of measurement" (see 3.47) nor to the "precision of measurement" (see 3.34) alone. Instead, accuracy is commonly used as a combination of trueness and precision, which is also used as a concept in the Regulation 2017/746/EU on in-vitro diagnostic medical devices.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard 'within the meaning of Annex ZA', the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this should be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table – Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 18113-2:2009	EN ISO 18113-2:2011	ISO 18113-2:2009
ISO 15193	EN ISO 15193:2009	ISO 15193:2009
ISO 15194	EN ISO 15194:2009	ISO 15194:2009

EN ISO 17511:2021 (E)

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 17511:2020 has been approved by CEN as EN ISO 17511:2021 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered

This European standard has been prepared under a Commission's standardisation request to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/746 of 5 April 2017 concerning in vitro diagnostic medical devices [O] L 117].

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/746. This means that risks have to be 'reduced as far as possible', 'reduced to a level as low as reasonably practicable', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'prevented' or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 10, 11, 13, 15, 16, 17, 18 and 19 of the Regulation.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European Foreword, replacing the references in the core text.

NOTE 4 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/746 [O] L 117]

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
9.1 (a)	4.3, 4.6.2	Covered with respect to analytical performance requirements resulting from a calibration hierarchy, and related uncertainty
9.3	4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 5	Covered
10.1	4.2, 4.5.4, 4.5.5	Covered with respect to definition of the measurand, corresponding performance characteristics and commutability during design and manufacturing processes
13.4	4.7, 4.8	Covered with respect to effectiveness and reliability of calibration

EN ISO 17511:2021 (E)

13.5	4.5.4, 4.5.5, 4.8	Covered with respect to commutability and traceability of end-user calibrator
14.1	4.3, 4.6.2	Covered with respect to analytical performance requirements resulting from a calibration hierarchy, and related uncertainty
20.1 (g)	4.3, 4.7.1	Covered with respect to uncertainty as a limitation and information to be provided by the manufacturer
20.4.1 (g)	4.7.1	Covered with respect to uncertainty of assigned values for end-user calibrator and information to be provided by the manufacturer
20.4.1 (u)	4.7.1, 4.9.1, 4.9.3	Partly covered with respect to uncertainty and assigned values of end-user calibrators and their associated metrological traceability as the kind of information to be provided by the manufacturer, but the requirement to provide this information in the IFU is not addressed by this European standard.
20.4.1 (w)	4.6.2, 4.7.1, 4.9.1	Partly covered with respect to analytical performance requirements resulting from a calibration hierarchy, assigned values for end-user calibrators and their associated metrological traceability as the kind of information to be provided by the manufacturer, but the requirement to provide this information in the IFU is not addressed by this European standard.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO
17511

Second edition
2020-04

In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples

*Dispositifs médicaux de diagnostic in vitro — Exigences pour
l'établissement d'une traçabilité métrologique des valeurs attribuées
aux étalons, aux matériaux de contrôle de la justesse et aux
échantillons humains*



Reference number
ISO 17511:2020(E)

© ISO 2020

**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword.....	vi
Introduction.....	viii
1 Scope.....	1
2 Normative references.....	2
3 Terms and definitions, symbols and abbreviated terms.....	2
4 General requirements to be fulfilled by a manufacturer for establishing, validating and documenting metrological traceability of human sample values determined with a specified IVD MD.....	19
4.1 Requirements for documenting metrological traceability of measured quantity values.....	19
4.2 Definition of the measurand.....	19
4.3 Specifications for maximum allowable expanded measurement uncertainty, $U_{max}(y)$	20
4.3.1 General requirements.....	20
4.3.2 Scope of the specification.....	20
4.4 Defining the calibration hierarchy.....	20
4.4.1 General requirements.....	20
4.4.2 Measured quantity.....	21
4.4.3 Highest level of metrological traceability.....	21
4.4.4 Traceability to SI.....	21
4.4.5 Non-SI traceable IVD MDs.....	21
4.4.6 Number of levels in the specified hierarchy.....	21
4.5 Selection and requirements for RMs and calibrators.....	21
4.5.1 General requirements.....	21
4.5.2 Characteristics to be documented.....	21
4.5.3 Higher order RMs that conform with ISO 15194.....	22
4.5.4 RMs not conforming to ISO 15194.....	22
4.5.5 Commutability of RMs.....	22
4.5.6 Exception to commutability assessment requirements.....	23
4.5.7 Application of a non-commutable CRM.....	23
4.5.8 Alternative RMs.....	23
4.5.9 Augmentation of alternative RMs.....	23
4.5.10 Non-commutable end-user IVD MD calibrators.....	24
4.6 Selection and requirements for MPs.....	24
4.6.1 Rationale for selection of MPs and documentation responsibility.....	24
4.6.2 Metrological status of MPs.....	24
4.6.3 Reference measurement laboratories.....	24
4.6.4 Impact of influence quantities.....	25
4.6.5 Changes in the measured quantity within a calibration hierarchy.....	25
4.7 Estimating uncertainty of assigned values for end-user IVD MD calibrators.....	25
4.7.1 General requirements.....	25
4.7.2 Documentation for method of estimating u_{cal}	26
4.7.3 Statistical considerations and scope of u_{cal} estimates.....	26
4.7.4 Expression of u_{cal}	26
4.7.5 Product modifications.....	27
4.7.6 Information to be provided to the end-user.....	28
4.8 Validation of metrological traceability of values assigned to an IVD MD calibrator.....	28
4.8.1 General validation requirements.....	28
4.8.2 Validation strategies.....	28
4.8.3 Test design considerations and acceptance criteria.....	29
4.8.4 Calibration hierarchies with an available RMP.....	29
4.8.5 Calibration hierarchies with no available RMP.....	29
4.8.6 Calibration hierarchies with no RMPs and no CRMs.....	29
4.8.7 Validation of design changes to an end-user IVD MD calibrator.....	30
4.9 Additional calibration hierarchy documentation responsibilities.....	30

ISO 17511:2020(E)

4.9.1	Obligation to end-users.....	30
4.9.2	Maintaining documentation.....	30
4.9.3	Third party manufacturers of IVD MD calibrators.....	30
4.9.4	Modifications introduced by independent entities.....	30
4.9.5	Calibration hierarchies supporting IVD MDs developed by a single entity for its own use.....	31
4.9.6	RMs other than end-user IVD MD calibrators.....	31
4.9.7	EQA and PT materials with claims of metrologically traceable target values.....	31
5	Model calibration hierarchies for metrological traceability.....	31
5.1	Elements of the description of a calibration hierarchy.....	31
5.2	Cases with RMPs and primary RMs.....	32
5.2.1	General considerations.....	32
5.2.2	Definition of the measurand.....	33
5.2.3	Selecting RMPs.....	34
5.2.4	Primary RMPs.....	34
5.2.5	Primary calibrators.....	35
5.2.6	Assigning a value to a secondary RM or calibrator.....	35
5.2.7	Commutability of secondary RMs.....	35
5.2.8	Manufacturer's Selected MP.....	35
5.2.9	Working calibrators.....	35
5.2.10	Manufacturer's standing MP.....	36
5.2.11	Manufacturer's end-user calibrator.....	36
5.2.12	u_{cal} of the assigned value of the end-user calibrator.....	36
5.2.13	End-user IVD MD.....	36
5.3	Cases with a primary RMP that defines the measurand.....	36
5.3.1	General Considerations.....	36
5.3.2	Definition of the measurand.....	38
5.3.3	Higher order RMP that defines the measurand.....	38
5.3.4	The primary RMP and definition of the measurand.....	38
5.3.5	Documentation of the primary RMP.....	38
5.3.6	Assignment of values to secondary RMs.....	39
5.3.7	Manufacturer's selected MP.....	39
5.3.8	Manufacturer's working calibrator.....	39
5.3.9	Manufacturer's standing MP.....	40
5.3.10	Manufacturer's end-user calibrator.....	40
5.3.11	End-user IVD MD.....	40
5.4	Cases for measurands defined by a RMP calibrated with a particular primary calibrator.....	40
5.4.1	General considerations.....	40
5.4.2	Definition of the measurand.....	41
5.4.3	Value assignment of the primary RM.....	42
5.4.4	Value assignment of the primary calibrator.....	42
5.4.5	Selection and intended use of the RMP in the calibration hierarchy.....	42
5.4.6	Manufacturer's selected MP.....	42
5.4.7	Manufacturer's working calibrator.....	42
5.4.8	Manufacturer's standing MP.....	43
5.4.9	End-user IVD MD calibrator.....	43
5.4.10	End-user IVD MD.....	43
5.5	Cases with an international conventional calibrator that defines the measurand.....	43
5.5.1	General considerations.....	43
5.5.2	The international conventional calibrator — Material description.....	45
5.5.3	Value assignment of an international conventional calibrator.....	45
5.5.4	Commutability of an international conventional calibrator.....	45
5.5.5	Calibration and selection of the manufacturer's selected MP.....	46
5.5.6	Characteristics and value assignment of the manufacturer's working calibrator.....	46
5.5.7	Manufacturer's standing MP.....	46
5.5.8	End-user IVD MD calibrator.....	46
5.5.9	End-user IVD MD.....	46

5.6	Cases with metrological traceability supported by an international harmonisation protocol.....	46
5.6.1	General Considerations.....	46
5.6.2	International harmonisation protocol.....	47
5.6.3	Assignment of values to harmonisation RMs.....	48
5.6.4	Application of harmonisation RMs.....	48
5.6.5	End-user IVD MD.....	48
5.7	Cases for measurands with metrological traceability only to manufacturer's internal arbitrarily defined RM(s).....	48
5.7.1	General considerations.....	48
5.7.2	Selection of RMs.....	49
5.7.3	Manufacturer's Selected MP.....	50
5.7.4	Manufacturer's Standing MP.....	50
5.7.5	End-user IVD MD calibrators.....	50
5.7.6	End-user IVD MD.....	50
5.7.7	Documentation of the calibration hierarchy.....	50
6	Labelling information to be provided to end-users by the manufacturer.....	51
	Bibliography.....	52

ISO 17511:2020(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This second edition cancels and replaces the first edition (ISO 17511:2003), which has been technically revised. The main changes compared to the previous edition are as follows:

- incorporation of the special requirements for metrologically traceable calibration hierarchies for measurement of catalytic concentration of enzymes (previously covered in ISO 18153:2003);
- to clarify that final reported values on human samples shall be metrologically traceable to the highest order available reference, the title and scope were modified to include metrological traceability of values assigned to human samples;
- updated normative references to remove International Vocabulary of Basic and General Terms in Metrology, 2nd edition, ISO, Geneva (1993) and ISO Guide 35:1989, Certification of reference materials — General and statistical principles;
- revision of [Clause 4](#) to clearly define requirements of a manufacturer of an in vitro diagnostic medical device in establishing and documenting metrological traceability of assigned values (for calibrators, trueness controls and human samples), while incorporating requirements previously addressed in [Clauses 6](#), 7 and 8 (thus eliminating those sections);
- revision of [Clause 5](#) to incorporate additional models of metrologically traceable calibration hierarchies, especially [5.3](#) for measurement of catalytic concentration of enzymes (where the measurand is defined by a primary RMP; previously addressed in ISO 18153:2003), and [5.6](#) for an overview of the concept of assigned values of materials for measurands with metrological traceability to international harmonisation protocols (addressed in detail in ISO 21151).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

ISO 17511:2020(E)**Introduction**

In laboratory medicine, the objective of examining a measurand in a human sample is to produce laboratory results that will enable a clinician to assess the risk of a disease, or to diagnose and make treatment decisions for a medical condition. To be clinically useful, the results obtained from a given human sample examined by different laboratories or among different in vitro diagnostic medical devices (IVD MDs) within a single laboratory should be equivalent, regardless of the measurement procedure employed. Equivalent results allow uniform application of medical decision limits and reference intervals, which can reduce the risk of harm caused by medical decisions based on non-equivalent examination results. Equivalence of results among different IVD MDs for the same measurand is also important for the analysis of results in medical records for the purpose of supporting clinical decisions and for conducting epidemiological investigations.

Equivalent results for human samples for a measurand can be achieved by establishing metrological traceability of the values assigned to the calibrators for a measurement procedure (MP) to the highest available reference system component for the measurand. Metrological traceability describes the calibration hierarchy and the sequence of value assignments, demonstrating an unbroken linkage between the measurement result for a human sample up to the highest available reference system component in the calibration hierarchy. The point at which metrological traceability begins (i.e. the highest level of metrological traceability in the calibration hierarchy) depends on the availability of higher order reference measurement procedures (RMPs), reference materials (RMs) or harmonisation protocols for the stated measurand.

Limitations in implementing metrologically traceable calibrations occur when different IVD MDs intended for the same measurand do not measure the same or very closely related measurable quantities. Some measurands of medical interest may be well-defined elements or molecules. An increasing number of medical decisions depend on measurands that consist of complex and variable mixtures of chemical structures, molecular species and molecular complexes in varying proportions, e.g. glycoproteins with multiple isoforms, variant amino acid sequences, nucleic acid sequences, and other complex molecular forms. When the selectivity of an IVD MD is not fit-for-purpose, sample-specific influence quantities in human samples due to factors including disease, drugs or other pathological conditions may lead to erroneous values for the intended measured quantity. Even with metrological traceability to higher order reference system components, the selectivity of MPs at all levels in the calibration hierarchy for a given IVD MD can influence its ability to achieve results for human samples that are equivalent to the results obtained with other IVD MDs for the same measurand.

This document presents requirements for manufacturers of IVD MDs in documenting the calibration hierarchy for a measured quantity in human samples using a specified IVD MD. The document includes various model calibration hierarchies offering potential technical solutions for different kinds of measurands in establishing metrological traceability of assigned values for human samples, calibrators and trueness control materials. Use of this document as part of a broadly-based risk management program for manufacturers of IVD MDs is consistent with the requirements of ISO 14971 and is expected to assist in the reduction of the risk of harm to patients due to non-equivalence of results among different IVD MDs.

In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples

1 Scope

This document specifies technical requirements and documentation necessary to establish metrological traceability of values assigned to calibrators, trueness control materials and human samples for quantities measured by IVD MDs. The human samples are those intended to be measured, as specified for each IVD MD. Metrological traceability of values for quantities in human samples extends to the highest available reference system component, ideally to RMPs and certified reference materials (CRMs).

All parties having a role in any of the steps described in a calibration hierarchy for an IVD MD are subject to the requirements described. These parties include but are not limited to manufacturers (of IVD MDs), RMP developers (see ISO 15193), RM producers (see ISO 15194), and reference/calibration laboratories (see ISO 15195) supporting calibration hierarchies for IVD MDs.

NOTE 1 Producers of RMs intended for use in standardization or calibration of IVD MDs include commercial and non-commercial organizations producing RMs for use by many end-users of IVD MDs and/or calibration laboratories, or for use by a single end-user medical laboratory, as in the case of a measurement standard (calibrator) intended to be used exclusively for calibration of a laboratory-developed MP.

This document is applicable to:

- a) all IVD MDs that provide measurement results in the form of numeric values, i.e. rational (ratio) and/or differential (interval) scales, and counting scales.
- b) IVD MDs where the measurement result is reported as a qualitative value established with a ratio of two measurements (i.e. the signal from a specimen being tested and the signal from a RM with a specified concentration or activity at the cut-off), or a counting scale, with corresponding decision threshold(s). This also includes IVD MDs where results are categorized among ordinal categories based on pre-established quantitative intervals for a quantity.
- c) RMs intended for use as trueness control materials for verification or assessment of calibration of IVD MDs, i.e. some commutable CRMs and some external quality assessment (EQA) materials (if so indicated in the RM's intended use statement).
- d) IVD MD-specific calibrators and trueness control materials with assigned values, intended to be used together with a specified IVD MD.
- e) IVD MDs as described in a) and b), where no end-user performed calibration is required (i.e. when the manufacturer performs a factory calibration of the IVD MD).

This document is not applicable to:

- a) calibrators and trueness control materials for IVD MDs which, due to their formulation, are known to have zero amount of measurand;
- b) control materials that are used only for internal quality control purposes in medical laboratories to assess the imprecision of an IVD MD, either its repeatability or reproducibility, and/or for assessing changes in IVD MD results compared to a previously established calibration condition;
- c) control materials that are used only for internal quality control purposes in medical laboratories and which are supplied with intervals of suggested acceptable values that are not metrologically traceable to higher order reference system components;

ISO 17511:2020(E)

d) properties reported as nominal scales and ordinal scales, where no magnitude is involved.

NOTE 2 Nominal scales are typically used to report e.g. identity of blood cell types, microorganism types, identity of nucleic acid sequences, identity of urine particles.

NOTE 3 Ordinal scales are often applied to results differentiated into dichotomous groupings (e.g. 'sick' vs. 'healthy'), and occasionally to results differentiated into non-dichotomous categories where the result categories are rank-ordered but the rank-ordered categories cannot be differentiated in terms of relative degree of difference, e.g. negative, +1, +2, +3 for grading of presence of haemoglobin in urine specimens by visual observation.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 18113-2, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use*

ISO 15193, *In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for content and presentation of reference measurement procedures*

ISO 15194, *In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN