

# SVENSK STANDARD

## SS-EN ISO 17511:2021

**Medicintekniska produkter för in vitro-diagnostik – Krav för att fastställa metrologisk spårbarhet av värden som tilldelas kalibratorer, truenesskontrollmaterial och human prover (ISO 17511:2020)**

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



**sis** Svenska  
Institutet för  
Standarder

Language: engelska/English

Edition: 2

This preview is downloaded from [www.sis.se](http://www.sis.se). Buy the entire standard via <https://www.sis.se/std-80029633>

Den här standarden kan hjälpa dig att effektivisera och kvalitetssäkra ditt arbete. SIS har fler tjänster att erbjuda dig för att underlätta tillämpningen av standarder i din verksamhet.

#### **SIS Abonnemang**

Snabb och enkel åtkomst till gällande standard med SIS Abonnemang, en prenumerationstjänst genom vilken din organisation får tillgång till all världens standarder, senaste uppdateringarna och där hela din organisation kan ta del av innehållet i prenumerationen.

#### **Utbildning, event och publikationer**

Vi erbjuder även utbildningar, rådgivning och event kring våra mest sålda standarder och frågor kopplade till utveckling av standarder. Vi ger också ut handböcker som underlättar ditt arbete med att använda en specifik standard.

#### **Vill du delta i ett standardiseringsprojekt?**

Genom att delta som expert i någon av SIS 300 tekniska kommittéer inom CEN (europeisk standardisering) och/eller ISO (internationell standardisering) har du möjlighet att påverka standardiseringsarbetet i frågor som är viktiga för din organisation. Välkommen att kontakta SIS för att få veta mer!

#### **Kontakt**

Skriv till [kundservice@sis.se](mailto:kundservice@sis.se), besök [sis.se](https://www.sis.se) eller ring 08 - 555 523 10

---

© Copyright/Upphovsrätten till denna produkt tillhör Svenska institutet för standarder, Stockholm, Sverige. Upphovsrätten och användningen av denna produkt regleras i slutanvändarlicensen som återfinns på [sis.se/slutanvandarlicens](https://www.sis.se/slutanvandarlicens) och som du automatiskt blir bunden av när du använder produkten. För ordlista och förkortningar se [sis.se/ordlista](https://www.sis.se/ordlista).

© Copyright Svenska institutet för standarder, Stockholm, Sweden. All rights reserved. The copyright and use of this product is governed by the end-user licence agreement which you automatically will be bound to when using the product. You will find the licence at [sis.se/enduserlicenseagreement](https://www.sis.se/enduserlicenseagreement).

Upplysningar om sakinnehållet i standarden lämnas av Svenska institutet för standarder, telefon 08 - 555 520 00. Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.

Standarden är framtagen av kommittén för Laboratoriemedicin, SIS/TK 331.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på [www.sis.se](https://www.sis.se) - där hittar du mer information.

Europastandarden EN ISO 17511:2021 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 17511:2021.

Denna standard ersätter SS-EN ISO 17511:2004, utgåva 1

The European Standard EN ISO 17511:2021 has the status of a Swedish Standard. This document contains the official version of EN ISO 17511:2021.

This standard supersedes the SS-EN ISO 17511:2004, edition 1

## LÄSANVISNINGAR FÖR STANDARDER

I dessa anvisningar behandlas huvudprinciperna för hur regler och yttre begränsningar anges i standardiseringsprodukter.

### Krav

Ett krav är ett uttryck i ett dokumentets innehåll som anger objektivet verifierbara kriterier som ska uppfyllas och från vilka ingen avvikelse tillåts om efterlevnad av dokumentet ska kunna åberopas. Krav uttrycks med hjälpverbet ska (eller ska inte för förbud).

### Rekommendation

En rekommendation är ett uttryck i ett dokumentets innehåll som anger en valmöjlighet eller ett tillvägagångssätt som bedöms vara särskilt lämpligt utan att nödvändigtvis nämna eller utesluta andra. Rekommendationer uttrycks med hjälpverbet bör (eller bör inte för avrådanden).

### Instruktion

Instruktioner anges i imperativ form och används för att ange hur något görs eller utförs. De kan underordnas en annan regel, såsom ett krav eller en rekommendation. De kan även användas självständigt, och är då att betrakta som krav.

### Förklaring

En förklaring är ett uttryck i ett dokumentets innehåll som förmedlar information. En förklaring kan uttrycka tillåtelse, möjlighet eller förmåga. Tillåtelse uttrycks med hjälpverbet får (eller motsatsen behöver inte). Möjlighet och förmåga uttrycks med hjälpverbet kan (eller motsatsen kan inte).

## READING INSTRUCTIONS FOR STANDARDS

These instructions cover the main principles for the use of provisions and external constraints in standardization deliverables.

### Requirement

A requirement is an expression, in the content of a document, that conveys objectively verifiable criteria to be fulfilled, and from which no deviation is permitted if conformance with the document is to be claimed. Requirements are expressed by the auxiliary shall (or shall not for prohibition).

### Recommendation

A recommendation is an expression, in the content of a document, that conveys a suggested possible choice or course of action deemed to be particularly suitable, without necessarily mentioning or excluding others. Recommendations are expressed by the auxiliary should (or should not for dissuasion).

### Instruction

An instruction is expressed in the imperative mood and is used in order to convey an action to be performed. It can be subordinated to another provision, such as a requirement or a recommendation. It can also be used independently and is then to be regarded as a requirement.

### Statement

A statement is an expression, in the content of a document, that conveys information. A statement can express permission, possibility or capability. Permission is expressed by the auxiliary may (its opposite being need not). Possibility and capability are expressed by the auxiliary can (its opposite being cannot).

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: Avenue Marnix 17, B-1000 Brussels

# Contents

Page

Foreword .....	ix
European foreword .....	xi
Introduction .....	xiii
<b>1 Scope.....</b>	<b>1</b>
<b>2 Normative references .....</b>	<b>2</b>
<b>3 Terms and definitions, symbols and abbreviated terms.....</b>	<b>2</b>
<b>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 .....</b>	<b>19</b>
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
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	RM's other than end-user IVD MD calibrators .....	31
4.9.7	EQA and PT materials with claims of metrologically traceable target values .....	31
<b>5</b>	<b>Model calibration hierarchies for metrological traceability .....</b>	<b>31</b>
5.1	Elements of the description of a calibration hierarchy .....	31
5.2	Cases with RMPs and primary RM's .....	32
5.2.1	General considerations .....	32
5.2.2	Definition of the measurand .....	33
5.2.3	Selecting RMP's .....	34
5.2.4	Primary RMP's .....	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 RM's .....	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 RM's .....	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

SS-EN ISO 17511:2021 (E)

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
<b>6</b>	<b>Labelling information to be provided to end-users by the manufacturer .....</b>	<b>51</b>
<b>Annex ZA (informative) Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered.....</b>		<b>52</b>
<b>Bibliography .....</b>		<b>54</b>



## 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](http://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](http://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](http://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](http://www.iso.org/members.html).



## 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