

STN	Diagnostické zdravotnícke pomôcky <i>in vitro</i> Požiadavky na certifikované referenčné materiály a obsah sprievodnej dokumentácie (ISO 15194: 2026)	STN EN ISO 15194 85 1011
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In vitro diagnostic medical devices - Requirements for certified reference materials and the content of supporting documentation (ISO 15194: 2026)

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. 09/26

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 15194

July 2026

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Supersedes EN ISO 15194:2009

English Version

**In vitro diagnostic medical devices - Requirements for
certified reference materials and the content of supporting
documentation (ISO 15194:2026)**

Dispositifs médicaux de diagnostic in vitro - Exigences
relatives aux matériaux de référence certifiés et au
contenu de la documentation associée (ISO
15194:2026)

In-vitro-Diagnostika - Anforderungen an zertifizierte
Referenzmaterialien und an den Inhalt der
Begleitdokumentation (ISO 15194:2026)

This European Standard was approved by CEN on 21 June 2026.

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.

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EN ISO 15194:2026 (E)

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European foreword

This document (EN ISO 15194:2026) has been prepared by Technical Committee ISO/TC 212 "Medical laboratories and in vitro diagnostic 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 January 2027, and conflicting national standards shall be withdrawn at the latest by July 2029.

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 15194:2009.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 15194:2026 has been approved by CEN as EN ISO 15194:2026 without any modification.

EN ISO 15194:2026 (E)**Annex ZA**
(informative)**Relationship between this European Standard the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered**

This European standard has been prepared under M/575 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 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, performance studies, clinical evidence or post-market performance follow-up.

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 Tables ZA.1, ZA.3, ZA.4 and application of the edition of the normatively referenced standards as given in Table ZA.2 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.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/746, the differences shall be indicated in the Annex ZA. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/746, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the In vitro Diagnostic Regulation (EU) 2017/746).

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 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 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
9.3	4, 5	Covered with respect to — properties and characterization of a certified reference material — identification of a suitable certified reference material through its supporting documentation that describes its fitness for the intended application
20.4.1. (u)	5.3	Covered with respect to the information in the reference material certificate that identifies the applied reference material and reference measurement procedure to be provided in the instructions for use of the IVD
20.4.1. (w)	5.3	Covered with respect to the information in the reference material certificate that describes the intended use of the applied reference material and reference measurement procedure to be provided in the instructions for use of the IVD

Table ZA.2 — Normative references from Clause 2 of this document and their corresponding European publications

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 17034	ISO 17034:2016	General requirements for the competence of reference material producers	EN ISO 17034:2016
ISO 17511	ISO 17511:2020	In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples.	EN ISO 17511:2021
ISO/IEC Guide 99	ISO/IEC Guide 99:2007	International vocabulary of metrology — Basic and general concepts and associated terms (VIM)	None

EN ISO 15194:2026 (E)**Table ZA.3 — Correspondence between this European standard and Annex II of Regulation (EU) 2017/746 [OJ L 117] and to requirements to the technical documentation**

Annex II of (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
6.1.2.1. a)	5.4.9 b)	Covered with respect to information about the intended use of the certified reference material as trueness control material

Table ZA.4 — Correspondence between this European standard and Annex XIII of Regulation (EU) 2017/746 [OJ L 117] and to requirements for the performance evaluation, performance studies and post-market performance follow-up

Annex XIII of (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1.1. 5 th bullet point	4, 5	Covered with respect to
		properties and characterization of a certified reference material to show metrological traceability identification of a suitable (i.e. allowing metrological traceability) certified reference material through its supporting documentation

Table ZA.5 — Differences in definitions between this European standard and Regulation (EU) 2017/746 [OJ L 117]

Defined term used this EN	Defined in this EN	Defined or legally relevant term used in (EU) 2017/746	Legally relevant Yes/No	Differences
in vitro diagnostic medical device	Yes, clause no 3.11	legally relevant by Art. 2 no. 2 of IVDR	Yes	IVDR refers to "in vitro diagnostic medical devices" also as systems and reagent products.

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document and are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

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 15194

In vitro diagnostic medical devices — Requirements for certified reference materials and the content of supporting documentation

*Dispositifs médicaux de diagnostic in vitro — Exigences
relatives aux matériaux de référence certifiés et au contenu de la
documentation associée*

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ISO 15194:2026(en)**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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Medical laboratories and in vitro diagnostic systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *In vitro diagnostic medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 15194:2009), which has been technically revised.

The main changes are as follows:

- incorporated requirements, concepts and definitions for consistency with ISO 17511:2020;
- removed [Clause 4](#) of the second edition;
- expanded and clarified the Scope to specify requirements for higher order certified reference materials (CRMs) whose intended use is to underpin routine measurements in laboratory medicine;
- added requirements regarding description of the intended use and commutability of the CRM;
- strengthened the documentation requirements for both the certificate and the certification report accompanying a CRM.

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 15194:2026(en)

Introduction

Reference measuring systems are needed to enable the results produced by end user measurement procedures (MPs) to be metrologically traceable to either measurement standards or MPs of the highest metrological level. Such systems exist within a metrological traceability chain/calibration hierarchy as described in ISO 17511. In the context of in vitro diagnostic (IVD) medical devices, metrological traceability to the highest metrological level mitigates the risk of harm to patients by avoiding inconsistent results from different measuring systems.

Reference materials (RMs) are used to establish and maintain metrological traceability of measurement results over time within one location, between different physical locations or with the application of different measurement procedures. Certified reference materials (CRMs) are a category of RMs required at the higher metrological levels of a calibration hierarchy or that underpin the metrological traceability of measurement results.

A given CRM is supported by documentation describing the sources of the material, its processing and production, measurement results, metrological traceability, instructions for use, homogeneity and stability data, commutability data when applicable, and storage conditions, as well as health and safety warnings. When the intended application of the CRM is as a secondary calibrator in the calibration hierarchy of IVD devices, the commutability of the CRM is a critical property to be reported.

This document specifies the quality requirements for such materials and the recommended content of their supporting documentation.

CRMs are used for one of three main purposes:

- a) calibration of quantity values indicated by a measuring system or assigned to another RM;
- b) assessment of measurement trueness of quantity values obtained in a given laboratory, or in a group of laboratories;
- c) assessment of measurement trueness of quantity values obtained using a new MP.

NOTE 1 “Measurement trueness” (ISO 17511:2020, 3.47) is the closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value. It is inversely related to systematic measurement error but is not related to random measurement error.

NOTE 2 “Measurement precision” (ISO 17511:2020, 3.34) is the closeness of agreement between measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions. It is usually expressed numerically by measures of imprecision, such as standard deviation, variance, or coefficient of variation under the conditions of measurement. “Measurement precision” is a measure of random measurement error.

The combined measurement uncertainty of the assigned value of a CRM is the combined measurement uncertainty of the steps above the CRM in the calibration hierarchy and the CRM uncertainties associated with its homogeneity and stability. Suitability of its measurement uncertainty is determined by its intended use in the calibration hierarchy.

Since the proper use of a CRM depends on the provision of detailed information on its production, characterization and intended use, it is important to apply rules for the documentation of CRMs.

[Annex A](#) provides information on CRMs for qualitative nominal properties and ordinal quantities, to provide guidance on important quality attributes for such CRMs, whilst recognizing that they are not within the metrological traceability schemes described in ISO 17511:2020.

In vitro diagnostic medical devices — Requirements for certified reference materials and the content of supporting documentation

1 Scope

This document specifies requirements for certified reference materials (CRMs) of higher metrological order and the content of the supporting documentation and the calibration hierarchies as described in ISO 17511:2020, 5.2.1, 5.3.1, 5.4.1, 5.5.1, 5.6.1, 5.7.1. It is applicable to CRMs intended for use as either primary reference materials (PRMs), secondary calibrators or international conventional calibrators within calibration hierarchies appropriate for measurands used in laboratory medicine, or for applications as trueness controls. It also specifies requirements for determining the certified value of a CRM, including evaluation, and reporting of the assigned uncertainty.

This document is applicable primarily to CRMs with assigned property values where the property has a magnitude that can be expressed as a quantitative scalar number or ratio to a reference or refers to a counting scale as also described in ISO 17511:2020, Clause 1.

When a CRM includes multiple measurands, this document is applied to each of the certified quantity values present in the CRM.

Although intended to be applicable to producers of CRMs, this document is also useful for reference materials (RMs) that are not in conformity with the full metrological requirements of CRMs. For example, this document does not apply to an RM created by an in vitro diagnostic medical device (IVD MD) manufacturer for use as working calibrator or end-user calibrator within a calibration hierarchy traceable to a CRM, although some content can be useful in assessing its performance.

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 17034, *General requirements for the competence of reference material producers*

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

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN