SLOVENSKI STANDARD
SIST EN ISO 15194:2026

01-september-2026

Nadomešča:
SIST EN ISO 15194:2009

Diagnostični medicinski pripomočki in vitro - Zahteve za certificirane referenčne materiale in vsebino podporne dokumentacije (ISO 15194:2026)

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

In-vitro-Diagnostika - Messung von Größen in Proben biologischen Ursprungs - Anforderungen an zertifizierte Referenzmaterialien und an den Inhalt der Begleitdokumentation (ISO 15194:2026)

Dispositifs médicaux de diagnostic in vitro Mesurage des grandeurs dans les échantillons d'origine biologique Exigences relatives aux matériaux de référence certifiés et au contenu de la documentation associée (ISO 15194:2026)

Ta slovenski standard je istoveten z: **EN ISO 15194:2026**

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

SIST EN ISO 15194:2026 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15194

July 2026

ICS 11.100.10

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.

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, Türkiye and United Kingdom.

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

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Ref. No. EN ISO 15194:2026 E

Contents

Page

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.

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

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. 5th 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

Third edition
2026-06

Reference number
ISO 15194:2026(en)