BSI Standards Publication

In vitro diagnostic medical devices — Requirements for reference measurement procedures

National foreword

This British Standard is the UK implementation of EN ISO 15193:2026. It is identical to ISO 15193:2026. It supersedes BS EN ISO 15193:2009, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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UK Government is responsible for legislation. For information on legislation and policies relating to that legislation, consult the relevant pages of www.gov.uk.

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Date	Text affected

EUROPEAN STANDARD **EN ISO 15193**

NORME EUROPÉENNE

EUROPÄISCHE NORM July 2026

ICS 11.100.10 Supersedes EN ISO 15193:2009

English Version

In vitro diagnostic medical devices - Requirements for reference measurement procedures (ISO 15193:2026)

Dispositifs médicaux de diagnostic in vitro - Exigences relatives aux procédures de mesure de référence (ISO 15193:2026)

In-vitro-Diagnostika - Anforderungen an Referenzmessverfahren (ISO 15193:2026)

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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European foreword

This document (EN ISO 15193:2026) 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 15193:2009.

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 15193:2026 has been approved by CEN as EN ISO 15193:2026 without any modification.

(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	4.1, 4.12.3, 4.15	Covered with respect to
		The description of suitable reference measurement procedures. The use of calibrators. The requirements of suitable reference measurement procedures and their validation.
		NOTE: The expression of uncertainty in measurements is not covered by this standard.

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/IEC Guide 98-3:2008	ISO/IEC Guide 98-3:2008	Guide to the expression of uncertainty in measurement (GUM:1995)	None
ISO/IEC Guide 99:2007	ISO/IEC Guide 99:2007	International vocabulary of metrology — Basic and general concepts and associated terms (VIM)	None
ISO 15194	ISO 15194:2026	In vitro diagnostic medical devices — Requirements for certified reference materials and the content of supporting documentation	EN ISO 15194:2026
ISO 17511:2020	ISO 17511:2020	In vitro diagnostic medical devices — Requirements for establishing metrological traceability	EN ISO 17511:2021

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
		of values assigned to calibrators, trueness control materials and human samples	

Table ZA.3— Correspondence between this European standard and the requirements of Article 100 of Regulation (EU) 2017/746 [OJ L 117]

Requirements of Article 100 of (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
2. (h)	4.15	Covered with respect to the determination of the performance criteria (validation) to define the suitability of a reference measurement procedure to the intended use.

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	4.2	Covered with respect to information to identify the applied reference measurement procedure.

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.

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 15193:2009), which has been technically revised.

The main changes are as follows:

— incorporated requirements, concepts and definitions for consistency with ISO 17511, ISO 15194, and ISO 15195;

— adapted content to make the document applicable to all types of measurands;

— revised Clause 4 to present requirements more transparently;

— added 4.1 added to emphasize quality requirements for a reference measurement procedure (MP);

— updated and summarized aspects of validation in 4.15.

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.

Reference measurement systems are needed to enable the results produced by end user measurement procedures (MPs) to be metrologically traceable to either measurement standards, or measurement procedures, or both 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, traceability to the highest metrological level reduces the risk of harm to patients by avoiding inconsistent results from different measuring systems.

Reference measurement procedures play a crucial role in this metrological traceability system, because they can be used for the following:

a) assessing performance properties of measuring systems – comprising measuring instruments, auxiliary equipment as well as reagents,

b) assessing whether there is a functional interchangeability of different end user measurement procedures purporting to measure the same quantity,

c) assigning quantity values to reference materials that are then used for purposes of calibration or measurement trueness control of measurement procedures, and

d) detecting analytical influence quantities in biological samples measured using end user measurement procedures.

For medical laboratory measurements, in particular, it is important to both patient care and health screening that the measurement results reported by different end user measuring systems be equivalent, comparable over time, reproducible and accurate. Establishing metrological traceability of an end user measuring system to a reference measurement procedure enables equivalent results to be reported. A reference measurement procedure should be specified, especially when

— it is required by e.g. standards, technical specifications, or technical regulations,

— quantity values are to be stated by the manufacturer, and

— technical requirements have a direct relationship to the performance of a product or process.

In vitro diagnostic medical devices — Requirements for reference measurement procedures

1 Scope

This document specifies requirements for reference measurement procedures (RMP) for measurands used in laboratory medicine.

This document applies to:

a) RMPs providing values of differential or rational quantities where each quantity value is a numerical value multiplied by a measurement unit. Annex A provides information on ordinal quantities and nominal properties;

b) any person, body or institution developing RMPs for measurands used in laboratory medicine.

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/IEC Guide 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

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

ISO 15194, *In vitro diagnostic medical devices — Requirements for certified reference materials and the content of supporting documentation*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99, ISO 15194, and ISO 17511 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
analyte
component represented in the name of a measurable *quantity* (3.31)

EXAMPLE In the type of quantity “mass of protein in 24-hour urine”, “protein” is the analyte. In “amount of substance of glucose in plasma”, “glucose” is the analyte. In both cases the full phrase describes the *measurand* (3.18).

[SOURCE: ISO 17511:2020, 3.1]