Irish Standard
I.S. EN ISO 15194:2009 (AUG 09)

In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)

I.S. EN ISO 15194:2009 (Aug 09)

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EUROPEAN STANDARD

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English Version

In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)

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 15194:2009)

In-Vitro-Diagnostika - Messung von Größen in Proben biologischen Ursprungs - Anforderungen an zertifizierte Referenzmaterialien und an den Inhalt der Begleitdokumentation (ISO 15194:2009)

This European Standard was approved by CEN on 16 April 2009.

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

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Foreword

This document (EN ISO 15194:2009) has been prepared by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems".

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of an identical text or by endorsement, at the latest by November 2009, and conflicting national standards shall be withdrawn at the latest by November 2009.

This document supersedes EN 12287:1999.

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

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

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

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 98/79

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 98/79.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

I.S. EN ISO 15194:2009

INTERNATIONAL STANDARD

ISO 15194

Second edition
2009-05-01

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

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

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 15194 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, In vitro *diagnostic medical devices*, in collaboration with Technical Committee ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 15194:2002), which has been technically revised.

Introduction

Reference measurement systems are needed to produce useful and reliable measurement results, whether in science, technology or routine service, so as to be comparable and ultimately metrologically traceable to measurement standards and/or measurement procedures of the highest metrological level.

Substances or devices that are used to obtain this metrological traceability, through time, distances and different measurement procedures, are reference materials. Certified reference materials are needed at the higher metrological levels of a calibration hierarchy.

A given certified reference material is supported by documentation containing sources of material, descriptions, measurement results, metrological traceability, instructions for use, stability data and storage conditions, as well as health and safety warnings. This International Standard specifies the quality requirements for such materials and the content of their supporting documentation.

Reference materials are used for one of three main purposes:

a) calibration of quantity values indicated by a measuring system or assigned to another reference material;

b) validation or control of trueness of measured values in a given laboratory, or in a group of laboratories;

NOTE In ISO terminology “trueness” is related to “bias”, “systematic effect” and “systematic error”, whereas “accuracy” is related both to “trueness” (with its relations) and “precision”, where the latter is related to “standard deviation”, “coefficient of variation ”, “random effect” and “random error”.

c) evaluation of the performance of a new measurement procedure.

The maximum acceptable measurement uncertainty of the assigned value of a reference material depends on the requirements of the measured quantity values obtained by a measurement procedure involving the reference material.

As the proper use of a reference material depends on its description, it is important to apply rules for the documentation of reference materials.

The advantages of having standards available are listed in ISO/IEC Guide 15.

In Clause 3 of this International Standard, concepts are indicated by *italicized text*.

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

1 Scope

This International Standard specifies requirements for certified reference materials and the content of their supporting documentation, in order for them to be considered of higher metrological order in accordance with ISO 17511. It is applicable to certified reference materials classifiable as primary measurement standards, secondary measurement standards and international conventional calibrators that function either as calibrators or trueness control materials. This International Standard also provides requirements on how to collect data for value determination and how to present the assigned value and its measurement uncertainty.

This International Standard applies to certified reference materials with assigned values of differential or rational quantities. Annex A provides information on nominal properties and ordinal quantities.

This International Standard does not apply to reference materials that are parts of an *in vitro* diagnostic measuring system, although it is possible that many elements are helpful.

2 Normative references

The following referenced documents are indispensable for the application 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 31 (all parts)[1)], *Quantities and units*

ISO 5725-2*, Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method*

ISO 17511:2003, In vitro *diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials*

ISO 18153, In vitro *diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials*

ISO Guide 31, *Reference materials — Contents of certificates and labels*

ISO Guide 34, *General requirements for the competence of reference material producers*

ISO Guide 35, *Reference materials — General and statistical principles for certification*

ISO/IEC Guide 98-3:2008, *Guide to the expression of uncertainty in measurement (GUM:1995)*

ISO/IEC Guide 99:2007, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

1) The ISO 31 series is currently being replaced progressively by the ISO 80000 series and the IEC 80000 series.