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I.S. EN ISO 15193:2009 (AUG 09)

In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO 15193:2009)

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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 content and presentation of reference measurement procedures (ISO 15193:2009)

Dispositifs médicaux de diagnostic in vitro - Mesurage des grandeurs dans des échantillons d'origine biologique - Exigences relatives au contenu et à la présentation des procédures de mesure de référence (ISO 15193:2009)

In-vitro-Diagnostika - Messung von Größen in Proben biologischen Ursprungs - Anforderungen an den Inhalt und die Darstellung von Referenzmessverfahren (ISO 15193:2009)

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

EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 15193:2009) 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of an identical text or by endorsement, at the latest by November 2009, and conflicting national standards shall be withdrawn at the latest by November 2009.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 12286:1998.

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 15193:2009

INTERNATIONAL STANDARD

ISO 15193

Second edition
2009-05-01

In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for content and presentation of reference measurement procedures

Dispositifs médicaux de diagnostic in vitro — Mesurage des grandeurs dans des échantillons d'origine biologique — Exigences relatives au contenu et à la présentation des procédures de mesure de référence

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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 15193 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 15193:2002), 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 units and/or measurement standards and/or measurement procedures of the highest metrological level. Reference measurement procedures play a crucial role in this metrological system because they can be used for the following:

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

b) in demonstrating if there is a functional interchangeability of different routine measurement procedures purporting to measure the same quantity,

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

d) in detecting analytical influence quantities in patient samples.

For medical laboratory measurements, in particular, it is vitally important to both patient care and health screening that the measurement results reported to the physicians and patients are adequately comparable, reproducible and accurate. In some cases, it is advisable that a reference measurement procedure be given in the form of a standard, namely when it is related to technical requirements:

— that are specified in standards, technical specifications, or technical regulations, etc.,

— for which quantity values are to be stated by the supplier, and

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

The advantages of having such a standard 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 content and presentation of reference measurement procedures

1 Scope

This International Standard specifies requirements for the content of a reference measurement procedure for *in vitro* diagnostic medical devices and medical laboratories.

NOTE 1 It is intended that an experienced laboratory worker who follows a measurement procedure written in accordance with this International Standard can be expected to produce measurement results with a measurement uncertainty not exceeding the stipulated interval.

This International Standard applies to reference measurement procedures providing values of differential or rational quantities. Annex A provides information on nominal properties and ordinal quantities.

This International Standard is valid for any person, body or institution involved in one of the various branches of laboratory medicine whose intention is to write a document to serve as a reference measurement procedure.

Full descriptions of measurement methods are usually published in scientific literature, in which methods are described in sufficient detail that they can be used as the basis of a documented measurement procedure.

NOTE 2 In this International Standard, “international measurement standard” designates a material standard. The term “international standard” is used by WHO for reference materials.

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 15194, 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/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)*