Irish Standard
I.S. EN ISO 15004-1:2020

Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments (ISO 15004-1:2020)

I.S. EN ISO 15004-1:2020

Incorporating amendments/corrigenda/National Annexes issued since publication:

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National Foreword

I.S. EN ISO 15004-1:2020 is the adopted Irish version of the European Document EN ISO 15004-1:2020, Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments (ISO 15004-1:2020)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15004-1

November 2020

ICS 11.040.70

Supersedes EN ISO 15004-1:2009

English Version

Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments (ISO 15004-1:2020)

Instruments ophtalmiques - Exigences fondamentales et méthodes d'essai - Partie 1: Exigences générales applicables à tous les instruments ophtalmiques (ISO 15004-1:2020)

Ophthalmische Instrumente - Grundlegende Anforderungen und Prüfverfahren - Teil 1: Allgemeine Anforderungen an ophthalmische Instrumente (ISO 15004-1:2020)

This European Standard was approved by CEN on 5 September 2020.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 15004-1:2020 E

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European foreword

This document (EN ISO 15004-1:2020) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" in collaboration with Technical Committee CEN/TC 170 “Ophthalmic optics” 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 May 2021, and conflicting national standards shall be withdrawn at the latest by May 2021.

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 15004-1:2009.

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, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 15004-1:2020 has been approved by CEN as EN ISO 15004-1:2020 without any modification.

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INTERNATIONAL STANDARD

ISO 15004-1

Second edition
2020-05

Ophthalmic instruments — Fundamental requirements and test methods —

Part 1: General requirements applicable to all ophthalmic instruments

Instruments ophtalmiques — Exigences fondamentales et méthodes d'essai —

Partie 1: Exigences générales applicables à tous les instruments ophtalmiques

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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.

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).

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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 172 *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments* , in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 170, *Ophthalmic optics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 15004-1:2006), which has been technically revised.

The main changes compared to the previous edition are as follows:

— normative references have been updated;

— the definition of 3.4 manufacturer has been aligned with the corresponding definition in ISO 13485;

— particular requirements about environmental conditions have been replaced by a reference to IEC 60601-1:2005 + A1:2012;

— Annex A has been updated;

— some editorial changes have been made.

A list of all parts in the ISO 15004 series can be found on the ISO website.

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.

Ophthalmic instruments — Fundamental requirements and test methods —

Part 1: General requirements applicable to all ophthalmic instruments

1 Scope

This document specifies fundamental requirements for non-invasive, active and non-active ophthalmic instruments and to devices for enhancing low vision. This document is also applicable to tonometers, but not to other ophthalmic instruments which are used in contact with the globe of the eye.

This document is not applicable to operation microscopes, endoscopes and devices intended for laser investigation or laser treatment of the eye.

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 15004-2:2007, *Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection*

IEC 60601-1:2005 + A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60695-2-10, *Fire hazard testing — Part 2-10: Glowing/hot-wire based test methods — Glow-wire apparatus and common test procedure*

IEC 60695-2-11, *Fire hazard testing — Part 2-11: Glowing/hot-wire based test methods — Glow-wire flammability test method for end-products*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

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

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

3.1
ophthalmic instrument
device designed to have an application to the eye, and intended by its manufacturer to be used in the diagnosis, treatment, or monitoring of a patient, or for compensation or alleviation of disease, injury or disability