

SVENSK STANDARD

SS-EN ISO 15004-1:2020

Ögonoptik – Oftalmologiska instrument – Baskrav och provningsmetoder – Del 1: Allmänna krav tillämpbara på alla oftalmologiska instrument (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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Kontakt

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Standarden är framtagen av kommittén för Ögonoptik, SIS/TK 336.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

Europastandarden EN ISO 15004-1:2020 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 15004-1:2020.

Denna standard ersätter SS-EN ISO 15004-1:2009, utgåva 2

The European Standard EN ISO 15004-1:2020 has the status of a Swedish Standard. This document contains the official version of EN ISO 15004-1:2020.

This standard supersedes the SS-EN ISO 15004-1:2009, edition 2

LÄSANVISNINGAR FÖR STANDARDER

I dessa anvisningar behandlas huvudprinciperna för hur regler och yttre begränsningar anges i standardiseringsprodukter.

Krav

Ett krav är ett uttryck i ett dokumentets innehåll som anger objektivet verifierbara kriterier som ska uppfyllas och från vilka ingen avvikelse tillåts om efterlevnad av dokumentet ska kunna åberopas. Krav uttrycks med hjälpverbet ska (eller ska inte för förbud).

Rekommendation

En rekommendation är ett uttryck i ett dokumentets innehåll som anger en valmöjlighet eller ett tillvägagångssätt som bedöms vara särskilt lämpligt utan att nödvändigtvis nämna eller utesluta andra. Rekommendationer uttrycks med hjälpverbet bör (eller bör inte för avrådanden).

Instruktion

Instruktioner anges i imperativ form och används för att ange hur något görs eller utförs. De kan underordnas en annan regel, såsom ett krav eller en rekommendation. De kan även användas självständigt, och är då att betrakta som krav.

Förklaring

En förklaring är ett uttryck i ett dokumentets innehåll som förmedlar information. En förklaring kan uttrycka tillåtelse, möjlighet eller förmåga. Tillåtelse uttrycks med hjälpverbet får (eller motsatsen behöver inte). Möjlighet och förmåga uttrycks med hjälpverbet kan (eller motsatsen kan inte).

READING INSTRUCTIONS FOR STANDARDS

These instructions cover the main principles for the use of provisions and external constraints in standardization deliverables.

Requirement

A requirement is an expression, in the content of a document, that conveys objectively verifiable criteria to be fulfilled, and from which no deviation is permitted if conformance with the document is to be claimed. Requirements are expressed by the auxiliary shall (or shall not for prohibition).

Recommendation

A recommendation is an expression, in the content of a document, that conveys a suggested possible choice or course of action deemed to be particularly suitable, without necessarily mentioning or excluding others. Recommendations are expressed by the auxiliary should (or should not for dissuasion).

Instruction

An instruction is expressed in the imperative mood and is used in order to convey an action to be performed. It can be subordinated to another provision, such as a requirement or a recommendation. It can also be used independently and is then to be regarded as a requirement.

Statement

A statement is an expression, in the content of a document, that conveys information. A statement can express permission, possibility or capability. Permission is expressed by the auxiliary may (its opposite being need not). Possibility and capability are expressed by the auxiliary can (its opposite being cannot).

EUROPEAN STANDARD

EN ISO 15004-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

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.

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, Turkey and United Kingdom.



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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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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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.

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.

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Endorsement notice

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