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Ögonoptik – Oftalmologiska instrument – Baskrav och provningsmetoder – Del 1: Allmänna krav tillämpbara på alla oftalmologiska instrument (ISO 15004-1:2006)

Ophthalmic instruments – Fundamental requirements and test methods – Part 1: General requirements applicable to all ophthalmic instruments (ISO 15004-1:2006)

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Europastandarden EN ISO 15004-1:2009 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 15004-1:2009.

Denna standard ersätter SS-EN ISO 15004-1:2006, utgåva 1.

The European Standard EN ISO 15004-1:2009 has the status of a Swedish Standard. This document contains the official English version of EN ISO 15004-1:2009.

This standard supersedes the Swedish Standard SS-EN ISO 15004-1:2006, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00.
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15004-1

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ICS 11.040.70

Supersedes EN ISO 15004-1:2006

English Version

Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments (ISO 15004-1:2006)

Instruments ophtalmiques - Exigences fondamentales et méthodes d'essai - Partie 1: Exigences générales applicables à tous les instruments ophtalmiques (ISO 15004-1:2006)

Ophthalmische Instrumente - Grundlegende Anforderungen und Prüfverfahren - Teil 1: Allgemeine Anforderungen an ophthalmische Instrumente (ISO 15004-1:2006)

This European Standard was approved by CEN on 7 March 2009.

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 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 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

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Foreword

The text of ISO 15004-1:2006 has been prepared by Technical Committee ISO/TC 172 “Optics and optical instruments” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 15004-1:2009 by 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 October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 supersedes EN ISO 15004-1:2006.

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 93/42/EEC, as amended by Directive 2007/47/EC.

For relationship with EU Directive 93/42/EEC as amended by Directive 2007/47/EC, 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.

Endorsement notice

The text of ISO 15004-1:2006 has been approved by CEN as a EN ISO 15004-1:2009 without any modification.

Ophthalmic instruments — Fundamental requirements and test methods —

Part 1:
General requirements applicable to all ophthalmic instruments

1 Scope

This part of ISO 15004 specifies fundamental requirements for non-invasive, active and non-active ophthalmic instruments. This part of ISO 15004 is also applicable to low-vision aids and tonometers, but not to other ophthalmic instruments which are used in contact with the globe of the eye.

This part of ISO 15004 is not applicable to operation microscopes, endoscopes and devices intended for laser investigation or laser treatment of the eye.

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 9022-2:2002, *Optics and optical instruments — Environmental test methods — Part 2: Cold, heat and humidity*

ISO 9022-3:1998, *Optics and optical instruments — Environmental test methods — Part 3: Mechanical stress*

ISO 15004-2:—[1)], *Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection*

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

IEC 60601-1-1:1992, *Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems*

IEC 60695-2-10:2000, *Fire hazard testing — Part 2-10: Glowing/hot-wire based test methods — Glow-wire apparatus and common test procedure*

IEC 60695-2-11:2000, *Fire hazard testing — Part 2-11: Glowing/hot-wire based test methods — Glow-wire flammability test method for end-products*

1) To be published. (Revision of ISO 15004:1997)

3 Terms and definitions

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

3.1
ophthalmic instrument
device designed to have an application to the eye

3.2
non-invasive ophthalmic instrument
ophthalmic instrument which does not in whole or in part penetrate inside the body, either through a body orifice or through the surface of the body

3.3
active ophthalmic instrument
any ophthalmic instrument that depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and that acts by converting this energy

NOTE Ophthalmic devices intended to transmit energy, substances or other elements between an active ophthalmic instrument and the patient, without any significant change, are not considered to be an active ophthalmic instrument.

3.4
manufacturer
〈ophthalmic instrument〉 natural or legal person who places the ophthalmic instrument on the market

4 Fundamental requirements (for non-active and active ophthalmic instruments)

4.1 General

This part of ISO 15004 takes precedence over the corresponding requirements of IEC 60601-1:2005 and IEC 60601-1-1:1992, if differences exist.

The general requirements specified in this part of ISO 15004 for ophthalmic instruments shall be applied in conjunction with those of the relevant product-related International Standard, if it exists. Annex A provides for information the list of relevant product-related International Standards.

4.2 Design

Ophthalmic instruments shall be so designed that, when used for the performance of the intended function(s) in accordance with instructions provided by the manufacturer, the risks associated with such use are reduced to a level compatible with the generally acknowledged state of the art.

4.3 Performance

The ophthalmic instrument shall achieve the performance stipulated by the manufacturer for the intended function(s) under the intended conditions of use.

4.4 Combination of different devices

If another device is intended for use in combination with an ophthalmic instrument, the connecting system shall not impair the specified performance of either instrument.

For coupling with active ophthalmic instruments, the provisions of IEC 60601-1-1 shall apply.

4.5 Materials

4.5.1 Components of the ophthalmic instrument which are designed to come into direct contact with the skin of the patient or operator shall be made of materials which are neither toxic nor known to create significant allergic reactions, when used as intended by the manufacturer.

4.5.2 Materials used shall not ignite. When tested as described in 7.1, combustion shall not continue after withdrawal of the glow-wire.

4.6 Protection against contaminants

Parts of the ophthalmic instrument which are designed to come into contact with the patient or the operator shall either be capable of easy disinfection or be protected by a disposable cover.

4.7 Scales and displays

Scales and displays of ophthalmic instruments shall be designed and placed in accordance with ergonomic principles, taking into account the intended purpose of the instrument.

4.8 Thermal hazards

The temperature of parts of the ophthalmic instrument held by the operator or accessible to the patient shall not exceed the allowable maximum temperatures given in Tables 22, 23 and 24 of IEC 60601-1:2005, 11.1.

4.9 Mechanical hazards

The ophthalmic instrument shall be designed so that, when used to perform the intended function(s) in conformance with the user's instructions, the risk of physical injury when using this instrument is reduced as much as is practicable.

5 Environmental conditions (for non-active and active ophthalmic instruments)

NOTE The requirements specified in 5.1, 5.2 and 5.3 are verified as described in 7.3.

5.1 Environmental conditions of use

The ophthalmic instrument shall conform to all safety, optical, mechanical and accuracy requirements under the environmental conditions given in Table 1.

Table 1 — Environmental conditions of use

Criterion	Environmental conditions
Temperature	+ 10 °C to + 35 °C
Relative humidity	30 % to 90 %
Atmospheric pressure	800 hPa to 1 060 hPa
Shock (without packing)[a]	10 g, duration 6 ms
a Applicable to hand-held instruments only.	