

**Oftalmilised instrumendid. Põhinõuded ja
katsemeetodid. Osa 1: Üldnõuded kõigile oftalmilistele
instrumentidele**

Ophthalmic instruments - Fundamental requirements and
test methods - Part 1: General requirements applicable to all
ophthalmic instruments

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 15004-1:2009 sisaldab Euroopa standardi EN ISO 15004-1:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 29.05.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 08.04.2009.

Standard on kättesaadav Eesti standardiorganisatsioonist.

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EUROPEAN STANDARD

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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.

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COMITÉ EUROPÉEN DE NORMALISATION
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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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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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.

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Endorsement notice

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

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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)