# Oftalmilised instrumendid. Põhinõuded ja katsemeetodid

Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection

**EESTI STANDARDI EESSÕNA** **NATIONAL FOREWORD**

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| Käesolev Eesti standard EVS-EN ISO 15004-2:2007 sisaldab Euroopa standardi EN ISO 15004-2:2007 ingliskeelset teksti.<br><br>Käesolev dokument on jõustatud 30.03.2007 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.<br><br>Standard on kättesaadav Eesti standardiorganisatsioonist. | This Estonian standard EVS-EN ISO 15004-2:2007 consists of the English text of the European standard EN ISO 15004-2:2007.<br><br>This document is endorsed on 30.03.2007 with the notification being published in the official publication of the Estonian national standardisation organisation.<br><br>The standard is available from Estonian standardisation organisation. |

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| **Käsitlusala:**<br>Käesolev rahvusvaheline standard esitab põhinõuded mitteinvasiivsetele aktiivsetele ja mitteaktiivsetele oftalmilistele instrumentidele. Käesolev rahvusvaheline standard on rakendatav ka abivahenditele, mis on ette nähtud kasutamiseks nõrga nägemise puhul, ning tonomeetritele, kuid mitte teiste oftalmiliste instrumentide puhul, mida kasutatakse otseses kokkupuutes silmamunaga. | **Scope:**<br>This part of ISO 15004 specifies fundamental requirements for optical radiation safety for ophthalmic instruments and is applicable to all ophthalmic instruments that direct optical radiation into or at the eye and for which there is a specific light hazards requirement section within their respective International Standards, i.e. all ophthalmic instruments listed in Annex B. It is also applicable to all new and emerging ophthalmic instruments that direct optical radiation into or at the eye. Where differences exist between this part of ISO 15004 and the light hazard requirements section of the respective vertical International Standard, then the vertical International Standard shall take precedence. |

**ICS** 11.040.70

**Võtmesõnad:** klassifikatsioon, märgistus, optika, optiline instrumentaarium, tehnilised andmed, testimine, tüüptestimine (-testid)

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 15004-2

February 2007

ICS 11.040.70

Supersedes EN ISO 15004:1997

English Version

# Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection (ISO 15004-2:2007)

Instruments ophtalmiques - Exigences fondamentales et méthodes d'essai - Partie 2: Protection contre les dangers de la lumière (ISO 15004-2:2007)

Ophthalmische Instrumente - Grundlegende Anforderungen und Prüfverfahren - Teil 2: Schutz gegen Gefährdung durch Licht (ISO 15004-2:2007)

This European Standard was approved by CEN on 10 February 2007.

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.

CEN members are the national standards bodies of 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 United Kingdom.



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

**Management Centre: rue de Stassart, 36 B-1050 Brussels**



Ref. No. EN ISO 15004-2:2007: E

## Foreword

This document (EN ISO 15004-2:2007) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" 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 August 2007, and conflicting national standards shall be withdrawn at the latest by August 2007.

This document supersedes EN ISO 15004:1997.

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 United Kingdom.

### Endorsement notice

The text of ISO 15004-2:2007 has been approved by CEN as EN ISO 15004-2:2007 without any modifications.

INTERNATIONAL STANDARD

**ISO 15004-2**

First edition
2007-02-15



# Ophthalmic instruments — Fundamental requirements and test methods —

## Part 2: Light hazard protection

*Instruments ophtalmiques — Exigences fondamentales et méthodes d'essai —*

*Partie 2: Protection contre les dangers de la lumière*

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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 15004-2 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This first edition, together with ISO 15004-1, cancels and replaces ISO 15004:1997. All reference to light hazard (definitions 3.4 to 3.9, subclause 6.3, subclause 7.5, Annexes A, C and D of ISO 15004:1997) has essentially been moved to the present part of ISO 15004 and has been technically revised.

ISO 15004 consists of the following parts, under the general title *Ophthalmic instruments — Fundamental requirements and test methods*:

— *Part 1: General requirements applicable to all ophthalmic instruments*

— *Part 2: Light hazard protection*



 

# Ophthalmic instruments — Fundamental requirements and test methods —

# Part 2: Light hazard protection



## 1 Scope

This part of ISO 15004 specifies fundamental requirements for optical radiation safety for ophthalmic instruments and is applicable to all ophthalmic instruments that direct optical radiation into or at the eye and for which there is a specific light hazards requirement section within their respective International Standards, i.e. all ophthalmic instruments listed in Annex B. It is also applicable to all new and emerging ophthalmic instruments that direct optical radiation into or at the eye. Where differences exist between this part of ISO 15004 and the light hazard requirements section of the respective vertical International Standard, then the vertical International Standard shall take precedence.

NOTE The emission limits are based on the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines for human exposure to optical radiation. See Bibliography [1].

This part of ISO 15004 does not apply to radiation that is in excess of limits specified in ISO 15004 and that is intended for treatment of the eye.

This part of ISO 15004 classifies ophthalmic instruments into either Group 1 or Group 2 in order to distinguish instruments that are non-hazardous from those that are potentially hazardous.

## 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.

IEC 60825-1:2001, *Safety of laser products — Part 1: Equipment classification, requirements and user's guide*

## 3 Terms, definitions and symbols

### 3.1 Terms and definitions

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

**3.1.1**
**aperture**
**aperture stop**
opening that defines the area over which average optical emission is measured

NOTE For spectral irradiance measurements this opening is usually the entrance of a small sphere placed in front of the radiometer/spectroradiometer entrance slit.