



SLOVENSKI STANDARD
SIST EN ISO 10943:2006

01-september-2006

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SIST EN ISO 10943:2000

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Ophthalmic instruments - Indirect ophthalmoscopes (ISO 10943:2006)

Ophthalmische Instrumente - Indirekte Ophthalmoskope (ISO 10943:2006)

Instruments ophtalmiques - Ophtalmoscopes indirects (ISO 10943:2006)

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Ta slovenski standard je istoveten z: EN ISO 10943:2006

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10943

June 2006

ICS 11.040.70

Supersedes EN ISO 10943:1998

English Version

**Ophthalmic instruments - Indirect ophthalmoscopes (ISO
10943:2006)**

Instruments ophtalmiques - Ophthalmoscopes indirects (ISO
10943:2006)

Ophthalmische Instrumente - Indirekte Ophthalmoskope
(ISO 10943:2006)

This European Standard was approved by CEN on 9 March 2006.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, 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.

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

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

EN ISO 10943:2006 (E)**Foreword**

This document (EN ISO 10943:2006) 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 December 2006, and conflicting national standards shall be withdrawn at the latest by December 2006.

This document supersedes EN ISO 10943:1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, 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 10943:2006 has been approved by CEN as EN ISO 10943:2006 without any modifications.

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INTERNATIONAL
STANDARD

ISO
10943

Second edition
2006-06-01

**Ophthalmic instruments — Indirect
ophthalmoscopes**

Instruments ophtalmiques — Ophtalmoscopes indirects

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Reference number
ISO 10943:2006(E)

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Published in Switzerland

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 10943 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 10943:1998) which has been technically revised.

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Ophthalmic instruments — Indirect ophthalmoscopes

1 Scope

This International Standard, together with ISO 15004-1 and ISO 15004-2 specifies minimum requirements and test methods for hand-held, spectacle-type, and head-worn indirect ophthalmoscopes for observing indirect images of the eye fundus.

This International Standard takes precedence over ISO 15004-1 and ISO 15004-2, if differences exist.

This International Standard is not applicable to condensing lenses used for indirect ophthalmoscopy or to accessories.

This International Standard is not applicable to table-mounted instruments such as Gullstrand ophthalmoscopes and their derivatives, nor to ophthalmoscopes primarily intended for image capture and/or processing such as those based on scanning laser techniques.

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2 Normative references (standards.iteh.ai)

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 15004-1, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

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*

3 Terms and definitions

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

3.1

ophthalmoscope

optical instrument used to examine the external and internal parts of the eye, particularly the media and the fundus

1) To be published.