



**SLOVENSKI STANDARD**  
**SIST EN ISO 10943:2000**  
**01-januar-2000**

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Ophthalmic instruments - Indirect ophthalmoscopes (ISO 10943:1998)

Ophthalmische Instrumente - Indirekte Ophthalmoskope (ISO 10943:1998)

Instruments ophtalmiques - Ophtalmoscopes indirects (ISO 10943:1998)

**Ta slovenski standard je istoveten z: EN ISO 10943:1998**

[SIST EN ISO 10943:2000](https://standards.iteh.ai/catalog/standards/sist/d437eee0-e747-46fb-80fb-7ee08649ca94/sist-en-iso-10943-2000)

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**ICS:**

11.040.70      Oftalmološka oprema      Ophthalmic equipment

**SIST EN ISO 10943:2000**

**en**

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

EN ISO 10943

May 1998

ICS 11.040.70

Descriptors: see ISO document

English version

## Ophthalmic instruments - Indirect ophthalmoscopes (ISO 10943:1998)

Instruments ophtalmiques - Ophthalmoscopes indirects (ISO 10943:1998)

Ophthalmische Instrumente - Indirekte Ophthalmoskope (ISO 10943:1998)

This European Standard was approved by CEN on 9 March 1998.

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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

## Foreword

The text of the International Standard ISO 10943:1998 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 November 1998, and conflicting national standards shall be withdrawn at the latest by November 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

## Endorsement notice

The text of the International Standard ISO 10943:1998 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative). A-deviations are given in Annex ZB (informative).

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REPUBLIKA SLOVENIJA  
AGENCIJA REPUBLIKE SLOVENIJE  
ZA KVALITETO IN VARNOST  
PROJEKTA ZA UVEDENJE  
AVTORITATIVNEGA

.....  
1/2000 10943:2000 EN ISO 10943:1998



**Annex ZA (normative)**  
**Normative references to international publications**  
**with their relevant European publications**

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 15004	1997	Ophthalmic instruments - Fundamental requirements and test methods	EN ISO 15004	1997

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## ANNEX ZB (informative)

### A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN/CENELEC member.

This European Standard does not fall under any Directive of the EC. In the relevant CEN/CENELEC countries these A-deviations are valid instead of the provisions of the European Standard until they have been removed.

The legislative situation in Germany requires the unit "dioptré" be designated by the symbol "dpt" instead of "D".

This is to avoid conflict with the rules of ISO 1000 being the basic International Standard on symbols and units and with the respective basic resolution of the CGPM (International Conference on Weights and Measures).

Identification of the regulation:

Gesetz über die Einheiten im Meßwesen vom 02.07.1969 in der Fassung der Bekanntmachung vom 22.04.1985; and

Ausführungsverordnung zum Gesetz über Einheiten im Meßwesen (Einheitenverordnung - EinhV) vom 13.12.1985, § 1 und Anlage 1, Nr. 9

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# INTERNATIONAL STANDARD

**ISO**  
**10943**

First edition  
1998-05-01

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## Ophthalmic instruments — Indirect ophthalmoscopes

*Instruments ophtalmiques — Ophtalmoscopes indirects*

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Reference number  
ISO 10943:1998(E)

**ISO 10943:1998(E)****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.

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.

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

Annex A forms an integral part of this International Standard. Annexes B and C are for information only.

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# Ophthalmic instruments — Indirect ophthalmoscopes

## 1 Scope

This International Standard, together with ISO 15004, 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, 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.

## 2 Normative references

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The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 15004:1997, *Ophthalmic instruments — Fundamental requirements and test methods*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*

## 3 Définitions

For the purposes of this International Standard, the following definitions apply.

### 3.1

#### **indirect ophthalmoscope**

optical instrument used with a condensing lens (hand-held or integral) to examine the eye, particularly the media and the fundus, by producing a real intermediate image which is viewed by the observer

### 3.2

#### **monocular indirect ophthalmoscope**

monocular ophthalmoscope which provides an illumination system and which is used with a condensing lens (hand-held or integral) in order to direct appropriately focused light into the patient's eye

NOTE - Such instruments may include corrective lenses or eyepieces to aid focusing by the observer of the real intermediate image produced by the condensing lens.