



**SLOVENSKI STANDARD**  
**SIST EN ISO 10942:2006**

**01-september-2006**

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**SIST EN ISO 10942:2000**  
**SIST EN ISO 10942:2000/AC:2003**

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Ophthalmic instruments - Direct ophthalmoscopes (ISO 10942:2006)

**iTeh STANDARD PREVIEW**

Ophthalmische Instrumente - Direkte Ophthalmoskope (ISO 10942:2006)

Instruments ophtalmiques - Ophtalmoscopes directs (ISO 10942:2006)

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**Ta slovenski standard je istoveten z: EN ISO 10942:2006**

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**ICS:**

11.040.70      Oftalmološka oprema      Ophthalmic equipment

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 10942**

June 2006

ICS 11.040.70

Supersedes EN ISO 10942:1998

English Version

**Ophthalmic instruments - Direct ophthalmoscopes (ISO  
10942:2006)**

Instruments ophtalmiques - Ophthalmoscopes directs (ISO  
10942:2006)

Ophthalmische Instrumente - Direkte Ophthalmoskope  
(ISO 10942:2006)

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.

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

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**EN ISO 10942:2006 (E)****Foreword**

This document (EN ISO 10942:2006) 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 10942:1998.

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 10942:2006 has been approved by CEN as EN ISO 10942:2006 without any modifications.

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INTERNATIONAL  
STANDARD

ISO  
10942

Second edition  
2006-06-01

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**Ophthalmic instruments — Direct  
ophthalmoscopes**

*Instruments ophtalmiques — Ophtalmoscopes directs*

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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 10942 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 10942:1998 and ISO 10942:1998/Cor.1:1998), which has been technically revised.

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# Ophthalmic instruments — Direct ophthalmoscopes

## 1 Scope

This International Standard, together with ISO 15004-1 and ISO 15004-2, specifies minimum requirements and test methods for hand-held direct ophthalmoscopes designed for directly observing the eye fundus.

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

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

ISO 15004-2:—<sup>1)</sup>, *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

### 3.2

#### **direct ophthalmoscope**

ophthalmoscope which provides an illuminating system, an observation system and viewing lenses which allow the observer to visualize the patient's eye directly, that is without the formation of an intermediate image

### 3.3

#### **viewing lens**

lens which is positioned between the observer's eye(s) and the eye to be examined in order to achieve optimum focus, i.e. to correct for patient's and/or observer's refractive error and/or accommodation

**NOTE** In direct ophthalmoscopes when a selection of such lenses is required, these are integrated with or mounted in a disc or other mechanical means by which the user may easily position the lens of choice centrally in the visual path.

1) To be published.