

SLOVENSKI STANDARD SIST EN ISO 10939:2007

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Ophthalmic instruments - Slit-lamp microscopes (ISO 10939:2007)

Ophthalmische Instrumente - Spaltleuchten (ISO 10939:2007)

Instruments ophtalmiques - Microscopes avec lampe a fente (ISO 10939:2007)

SIST EN ISO 10939:2007

Ta slovenski standard/je istoveten z log/stan EN ISO 10939:200794-8b2c-

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

SIST EN ISO 10939:2007 en

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EUROPEAN STANDARD NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10939

February 2007

ICS 11.040.70

Supersedes EN ISO 10939:1998

English Version

Ophthalmic instruments - Slit-lamp microscopes (ISO 10939:2007)

Instruments ophtalmiques - Microscopes avec lampe à fente (ISO 10939:2007)

Ophthalmische Instrumente - Spaltleuchten (ISO 10939:2007)

This European Standard was approved by CEN on 20 January 2007.

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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.

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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

Foreword

This document (EN ISO 10939:2007) 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of an identical text or by endorsement, at the latest by August 2007, and conflicting national standards shall be withdrawn at the latest by August 2007.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 10939:1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, 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 10939:2007 has been approved by CEN as EN ISO 10939:2007 without any modifications.

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INTERNATIONAL STANDARD

ISO 10939

Second edition 2007-02-01

Ophthalmic instruments — Slit-lamp microscopes

Instruments ophtalmiques — Microscopes avec lampe à fente

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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 10939 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 10939:1998), which has been technically revised. It also incorporates the Technical Corrigendum ISO 10939:1998/Cor.1:2000.

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Ophthalmic instruments — Slit-lamp microscopes

1 Scope

This International Standard, together with ISO 15004-1 and ISO 15004-2, specifies requirements and test methods for slit-lamp microscopes to provide slit illumination and observation under magnification of the eye and its adnexa.

This International Standard is not applicable to microscope accessories, e.g. photographic equipment and lasers.

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 results.

ISO 15004-1, Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments 0939:2007

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ISO 15004-2:2007, Ophthalmic instruments — 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

slit-lamp microscope

instrument consisting of a microscope and a swivelling illumination system providing a slit image

3.2

magnification

ratio of the viewing angle of an object, when observed through a magnifying system with the image at infinity, to that of the object, when observed by the naked eye at a reference viewing distance of 250 mm

NOTE 1 The magnification, Γ , can be calculated using the following equation:

$$\Gamma = \frac{\tan \, \sigma'}{\tan \, \sigma}$$