Optické prístroje Mikroskopy so štrbinovou lampou (ISO 10939: 2017) STN EN ISO 10939 19 5007

Ophthalmic instruments - Slit-lamp microscopes (ISO 10939:2017)

Táto norma obsahuje anglickú verziu európskej normy. This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 11/17

Obsahuje: EN ISO 10939:2017, ISO 10939:2017

Oznámením tejto normy sa ruší STN EN ISO 10939 (19 5007) z júla 2007

EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN ISO 10939

June 2017

ICS 11.040.70

Supersedes EN ISO 10939:2007

English Version

Ophthalmic instruments - Slit-lamp microscopes (ISO 10939:2017)

Instruments ophtalmiques - Microscopes avec lampe à fente (ISO 10939:2017)

Ophthalmische Instrumente - Spaltleuchten (ISO 10939:2017)

This European Standard was approved by CEN on 5 March 2017.

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EN ISO 10939:2017 (E)

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European foreword

This document (EN ISO 10939:2017) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" 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of an identical text or by endorsement, at the latest by December 2017, and conflicting national standards shall be withdrawn at the latest by December 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 10939:2017 has been approved by CEN as EN ISO 10939:2017 without any modification.

INTERNATIONAL STANDARD

ISO 10939

Third edition 2017-05

Ophthalmic instruments — Slit-lamp microscopes

Instruments ophtalmiques — Microscopes avec lampe à fente



ISO 10939:2017(E)



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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

This third edition cancels and replaces the second edition (ISO 10939:2007), of which it constitutes a minor revision with the following changes:

- technical correction of inconsistency in <u>Table 1</u>, Item No. 9 "Slit image": "Parallelism of the sides (for a slit image of 0,2 mm × 8,0 mm)";
- update of the dated normative reference to IEC 60601-1:2005 to include the Amendment AMD1: 2012, where appropriate.

Ophthalmic instruments — Slit-lamp microscopes

1 Scope

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

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 15004-2:2007, Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection

IEC 60601-1:2005+AMD1:2012, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

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