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NSAI Standards

Irish Standard
I.S. EN ISO 10939:2017

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

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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)

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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of an identical text or by endorsement, at the latest by December 2017, and conflicting national standards shall be withdrawn at the latest by December 2017.

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INTERNATIONAL STANDARD

ISO 10939

Third edition
2017-05

Ophthalmic instruments — Slit-lamp microscopes

Instruments ophtalmiques — Microscopes avec lampe à fente

Reference number
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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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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 Table 1, 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.

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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*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

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 to entry: The magnification, Γ, can be calculated using the following formula:

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

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