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Ophthalmic instruments - Endoilluminators - Fundamental requirements and test methods for optical radiation safety (ISO 15752:2010)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15752

January 2010

ICS 11.040.70

English Version

Ophthalmic instruments - Endoilluminators - Fundamental requirements and test methods for optical radiation safety (ISO 15752:2010)

Instruments ophtalmiques - Sondes endolumineuses - Exigences fondamentales et méthodes d'essai relatives à la sécurité vis-à-vis des rayonnements optiques (ISO 15752:2010)

Ophthalmische Instrumente - Endoilluminatoren - Grundlegende Anforderungen und Prüfverfahren in Bezug auf die optische Strahlungssicherheit (ISO 15752:2010)

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Foreword

This document (EN ISO 15752:2010) 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of an identical text or by endorsement, at the latest by July 2010, and conflicting national standards shall be withdrawn at the latest by July 2010.

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INTERNATIONAL STANDARD

ISO 15752

Second edition
2010-01-15

Ophthalmic instruments — Endoilluminators — Fundamental requirements and test methods for optical radiation safety

Instruments ophtalmiques — Sondes endolumineuses — Exigences fondamentales et méthodes d'essai relatives à la sécurité vis-à-vis des rayonnements optiques

Reference number
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Foreword

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ISO 15752 was prepared by Technical Committee ISO/TC 172, *Optics and photonic*s, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 15752:2000), which has been technically revised.

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Ophthalmic instruments — Endoilluminators — Fundamental requirements and test methods for optical radiation safety

1 Scope

This International Standard specifies optical radiation safety aspects of endoilluminator light sources and endoilluminator light guides which are used to illuminate the interior of the eye during ocular surgery.

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 15004-2:2007, *Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15004-2 and the following apply.

3.1
exit aperture
portion of the endoilluminator light guide from which light from the endoilluminator light source emerges

3.2
endoilluminator
device consisting of an endoilluminator light source and an associated fibre-optic endoilluminator light guide that is intended for insertion into the eye to illuminate any portion of the interior of the eye

NOTE Adapted from ISO 15004-2:2007.

3.3
endoilluminator light guide
device that transmits light from the endoilluminator light source into the eye

3.4
chandelier
endoilluminator light guide intended to be positioned adjacent to the sclera with an output divergence half-angle equal to or greater than 90°

3.5
pic
forceps
device incorporated into the tip of an endoilluminator light guide for tissue manipulation

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