

**Oftalmilised instrumendid. Endoilluminaatorid.
Põhinõuded ja katsemeetodid optilise kiirguse kaitse
tagamiseks**

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 15752:2010 sisaldab Euroopa standardi EN ISO 15752:2010 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 31.03.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.01.2010.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 15752:2010 consists of the English text of the European standard EN ISO 15752:2010.

This standard is ratified with the order of Estonian Centre for Standardisation dated 31.03.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

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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)

This European Standard was approved by CEN on 9 January 2010.

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

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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of an identical text or by endorsement, at the latest by July 2010, and conflicting national standards shall be withdrawn at the latest by July 2010.

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Endorsement notice

The text of ISO 15752:2010 has been approved by CEN as a EN ISO 15752:2010 without any modification.

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