Oftalmilised implantaadid. Intraokulaarsed läätsed. Osa 8: Põhinõuded

Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 11979-8:2009 sisaldab Euroopa standardi EN ISO 11979-8:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11979-8:2009 consists of the English text of the European standard EN ISO 11979-8:2009.
Standard on kinnitatud Eesti Standardikeskuse 29.05.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 29.05.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 08.04.2009.	Date of Availability of the European standard text 08.04.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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Võtmesõnad: intraocular lenses, labelling, lenses, optical equipment, optics, packaging, performance, safety, shelf-life, specifications, sterile equipment, surgical implants

EUROPEAN STANDARD

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English Version

Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements (ISO 11979-8:2006)

Implants ophtalmiques - Lentilles intraoculaires - Partie 8: Exigences fondamentales (ISO 11979-8:2006)

Ophthalmische Implantate - Intraokularlinsen - Teil 8: Grundlegende Anforderungen (ISO 11979-8:2006)

This European Standard was approved by CEN on 7 March 2009.

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Ref. No. EN ISO 11979-8:2009: E

Foreword

The text of ISO 11979-8:2006 has been prepared by Technical Committee ISO/TC 172 “Optics and optical instruments” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11979-8:2009 by 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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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For relationship with EU Directive 93/42/EEC as amended by Directive 2007/47/EC, see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 11979-8:2006 has been approved by CEN as a EN ISO 11979-8:2009 without any modification.

Ophthalmic implants — Intraocular lenses —

Part 8:
Fundamental requirements

1 Scope

This part of ISO 11979 specifies fundamental requirements for all types of intraocular lenses intended for surgical implantation into the anterior segment of the human eye, excluding corneal implants and transplants.

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 9000, *Quality management systems — Fundamentals and vocabulary*

ISO 10993-7:1995, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 11979-1, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary*

ISO 11979-2, *Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods*

ISO 11979-3, *Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods*

ISO 11979-4, *Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information*

ISO 11979-5, *Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility*

ISO 11979-6, *Ophthalmic implants — Intraocular lenses — Part 6: Shelf-life and transport stability*

ISO 11979-7, *Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations*

ISO 11979-9, *Ophthalmic implants — Intraocular lenses — Part 9: Multifocal intraocular lenses*

ISO 11979-10, *Ophthalmic implants — Intraocular lenses — Part 10: Phakic intraocular lenses*

ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 14630:2005, *Non-active surgical implants — General requirements*

ISO 14971, *Medical devices — Application of risk management to medical devices*