Oftalmilised implantaadid. Oftalmilised visko-kirurgilised seadmed

Opthalmioc implants - Opthalmic viscosurgical devices

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 15798:2010 sisaldab Euroopa standardi EN ISO 15798:2010 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15798:2010 consists of the English text of the European standard EN ISO 15798:2010.
Standard on kinnitatud Eesti Standardikeskuse 31.03.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	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.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.02.2010.	Date of Availability of the European standard text 01.02.2010.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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EUROPEAN STANDARD

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EN ISO 15798

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English version

Ophthalmic implants - Ophthalmic viscosurgical devices (ISO 15798:2001)

Implants ophtalmiques - Dispositifs ophtalmiques viscoélastiques (ISO 15798:2001)

Ophthalmische Implantate - Viskoelastische Substanzen (ISO 15798:2001)

This European Standard was approved by CEN on 15 June 2001.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

The text of the International Standard ISO 15798:2001 has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" 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 2001, and conflicting national standards shall be withdrawn at the latest by December 2001.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 15798:2001 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

Annex ZA (normative)
Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN	Year
ISO 10993-1	1997	Biological evaluation of medical devices - Part 1: Evaluation and testing	EN ISO 10993-1	1997
ISO 10993-2	1992	Biological evaluation of medical devices - Part 2: Animal welfare requirements	EN ISO 10993-2	1998
ISO 10993-6	1994	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	EN 30993-6	1994
ISO 10993-9	1999	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	EN ISO 10993-9	1999
ISO 10993-16	1997	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	EN ISO 10993-16	1997
ISO 14630	1997	Non-active surgical implants - General requirements	EN ISO 14630	1997

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1 Scope

This International Standard is applicable to ophthalmic viscosurgical devices (OVDs), a class of non-active surgical implants with viscous and/or viscoelastic properties, intended for use during surgery in the anterior segment of the human eye. OVDs are designed to create and maintain space, to protect intra-ocular tissues and to manipulate tissues during surgery.

This International Standard specifies requirements with regard to safety for the intended performance, design attributes, preclinical and clinical evaluation, sterilization, product packaging, product labelling and information supplied by the manufacturer of these devices.

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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-2, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*

ISO 10993-6, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

ISO 10993-9, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products*

ISO 10993-16, *Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables*

ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11137-3, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 13408-1, *Aseptic processing of health care products — Part 1: General requirements*

ISO 14155-1, *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, *Non-active surgical implants — General requirements*

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

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 2: Symbol development, selection and validation*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 22442-1, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management*

ISO 22442-2, *Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling*

ISO 22442-3, *Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents*

EN 980, *Symbols for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

3 Terms and definitions

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

3.1
absolute complex viscosity
$|\eta^*| = [(\eta')^2 + (\eta'')^2]^{0,5}$
absolute value of complex viscosity (3.2)

NOTE Absolute complex viscosity is expressed in pascal seconds (Pa·s).

3.2
complex viscosity
$\eta^* = \eta' - i \cdot \eta''$
viscosity consisting of a viscous η' and an elastic η'' component where i is an imaginary number defined by $i = (-1)^{0,5}$

3.3
delivery system
sealed container in which the product is supplied and any additional components provided to introduce the product into the eye

3.4
elasticity
tendency of a body to return to its original shape after having been deformed

NOTE Elasticity is quantitatively defined as stress (the force generated within the body) divided by strain (the change in dimensions of the body).

