SLOVENSKI STANDARD
SIST EN ISO 15798:2002

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

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

Ophthalmische Implantate - Viskoelastische Substanzen (ISO 15798:2001)

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

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11.040.70 Oftalmološka oprema Ophthalmic equipment

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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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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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of an identical text or by endorsement, at the latest by December 2001, and conflicting national standards shall be withdrawn at the latest by December 2001.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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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 15798 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Annexes A and B form an integral part of this International Standard. Annexes C and D are for information only.

Ophthalmic implants — Ophthalmic viscosurgical devices

1 Scope

This International Standard applies 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. OVDs are not designed to have any pharmacological effect.

This International Standard defines 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 normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 10993-1:1997, *Biological evaluation of medical devices — Part 1: Evaluation and testing.*

ISO 10993-2:1992, *Biological evaluation of medical devices — Part 2: Animal welfare requirements.*

ISO 10993-6:1994, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation.*

ISO 10993-9:1999, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products.*

ISO 10993-16:1997, *Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables.*

ISO 11134:1994, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization*.

ISO 11135:1994, *Medical devices — Validation and routine control of ethylene oxide sterilization*.

ISO 11137:1995, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*.

ISO 11607:—[1)], *Packaging for terminally sterilized medical devices*.

ISO 13408-1:1998, *Aseptic processing of health care products — Part 1: General requirements*.

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1) To be published. (Revision of ISO 11607:1997)

ISO 14155:1996, *Clinical investigation of medical devices*.

ISO 14630:1997, *Non-active surgical implants — General requirements*.

ISO 14971-1:1998, *Medical devices — Risk management — Part 1: Application of risk analysis*.

ISO 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*.

EN 868-1:1997, *Packaging materials and systems for medical devices which are to be sterilized — Part 1: General requirements and test methods*.

EN 1041:1998, *Information supplied by the manufacturer with medical devices*.

EN 12442-1:2000, *Animal tissues and their derivates utilized in the manufacture of medical devices — Part 1: Analysis and management of risk*.

EN 12442-2:2000, *Animal tissues and their derivates utilized in the manufacture of medical devices — Part 2: Controls on sourcing, collection and handling*.

EN 12442-3:2000, *Animal tissues and their derivates utilized in the manufacture of medical devices — Part 3: Validation of elimination and/or inactivation of viruses and other transmissible agents*.

USP 24 <85>, United States Pharmacopoeia, 24th revision, <85> *Bacterial endotoxins test*.

3 Terms and definitions

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

3.1
delivery system
sealed container in which the product is supplied and any additional components provided to introduce the product into the eye

3.2
elasticity
tendency of a body to return to its original shape after being deformed in some way

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

3.3
lost to follow-up patient
subject in the clinical trial for whom the final post-operative case report is overdue and who cannot be contacted despite extensive written and telephone follow-ups to determine their final clinical outcome

3.4
ophthalmic viscosurgical device
OVD
generic term that includes a variety of materials with viscous and/or viscoelastic properties, that are designed to create and maintain space, to protect intra-ocular tissues and to manipulate tissues during surgery in the anterior segment of the human eye