SLOVENSKI STANDARD
SIST EN ISO 16672:2003

01-september-2003

Oļ esni vsadki (implantati) ï Sredstva za notranjo oļ esno tamponado (ISO 16672:2003)

Ophthalmic implants - Ocular endotamponades (ISO 16672:2003)

Ophthalmische Implantate - Okulare Endotamponaden (ISO 16672:2003)

Implants ophtalmiques - Produits de tamponnement endoculaires (ISO 16672:2003)

Ta slovenski standard je istoveten z: EN ISO 16672:2003

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

SIST EN ISO 16672:2003 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 16672

February 2003

ICS 11.040.70

English version

Ophthalmic implants - Ocular endotamponades (ISO 16672:2003)

Implants ophtalmiques - Produits de tamponnement endoculaires (ISO 16672:2003)

Ophthalmische Implantate - Okulare Endotamponaden (ISO 16672:2003)

This European Standard was approved by CEN on 2 January 2003.

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

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Foreword

This document (EN ISO 16672:2003) 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of an identical text or by endorsement, at the latest by August 2003, and conflicting national standards shall be withdrawn at the latest by August 2003.

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, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 16672:2003 has been approved by CEN as EN ISO 16672:2003 without any modifications.

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 14630	1997	Non-active surgical implants - General requirements	EN ISO 14630	1997
ISO 14971	2000	Medical devices - Application of risk management to medical devices	EN ISO 14971	2000

INTERNATIONAL STANDARD

ISO 16672

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Ophthalmic implants — Ocular endotamponades

Implants ophtalmiques — Produits de tamponnement endoculaires

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Contents

Page

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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 16672 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Ophthalmic implants — Ocular endotamponades

1 Scope

This International Standard applies to ocular endotamponades (OEs), a group of non-solid implants used in ophthalmology to flatten and position a detached retina onto the choroid, or to tamponade the retina.

With regard to the safety and efficacy of OEs, this International Standard specifies requirements for their intended performance, design attributes, pre-clinical and clinical evaluation, sterilization, product packaging, product labelling and the information supplied by the manufacturer.

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 10993-1:1997, *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 11607:1997, *Packaging for terminally sterilized medical devices*

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

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

ISO 14155-2:—[1)], *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

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

ISO 14971:2000, *Medical devices — Application of risk management to medical devices*

ISO/TR 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*

USP 24 <85> Jan/2000, *United States Pharmacopoeia* <85> *Bacterial endotoxins test*

1) To be published.