# SLOVENSKI STANDARD
# SIST EN ISO 16671:2004

**01-februar-2004**

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**Ophthalmic implants - Irrigating solutions for ophthalmic surgery (ISO 16671:2003)**

Ophthalmic implants - Irrigating solutions for ophthalmic surgery (ISO 16671:2003)

Ophthalmische Implantate - Spüllösungen für die ophthalmische Chirurgie (ISO 16671:2003)

Implants ophtalmiques - Solutions d'irrigation pour la chirurgie ophtalmique (ISO 16671:2003)



**Ta slovenski standard je istoveten z:** **EN ISO 16671:2003**



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11.040.70 Oftalmološka oprema Ophthalmic equipment

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EUROPEAN STANDARD

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# Ophthalmic implants - Irrigating solutions for ophthalmic surgery (ISO 16671:2003)

Implants ophtalmiques - Solutions d'irrigation pour la chirurgie ophtalmique (ISO 16671:2003)

Ophthalmische Implantate - Spüllösungen für die ophthalmische Chirurgie (ISO 16671:2003)

This European Standard was approved by CEN on 3 November 2003.

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.



CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.



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

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

## Foreword

The text of ISO 16671:2003 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 16671:2003 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 May 2004, and conflicting national standards shall be withdrawn at the latest by May 2004.

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 16671:2003 has been approved by CEN as EN ISO 16671:2003 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 10993-2 | 1992 | Biological evaluation of medical devices - Part 2: Animal welfare requirements | EN ISO 10993-2 | 1998 |
| ISO 14155-1 | 2003 | Clinical investigation of medical devices for human subjects - Part 1: General requirements | EN ISO 14155-1 | 2003 |
| ISO 14155-2 | 2003 | Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plans | EN ISO 14155-2 | 2003 |
| ISO 14630 | 1997 | Non-active surgical implants - General requirements | EN ISO 14630 | 1997 |

INTERNATIONAL STANDARD

**ISO 16671**

First edition
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# Ophthalmic implants — Irrigating solutions for ophthalmic surgery

*Implants ophtalmiques — Solutions d'irrigation pour la chirurgie ophtalmique*



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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 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 16671 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

# Ophthalmic implants — Irrigating solutions for ophthalmic surgery

## 1 Scope

This International Standard defines requirements with regards to safety for the intended performance, design attributes, preclinical and clinical evaluation, sterilization, product packaging, product labelling and the information supplied by the manufacturer.

This International Standard applies to ophthalmic irrigating solutions (OISs), used during ophthalmic surgery. These solutions do not provide any primary immunological, pharmacological or metabolic function.

## 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:—[1], *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 11607:2002, *Packaging for terminally sterilized medical devices*

ISO 13408-1:1998, *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 14630:1997, *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 derivatives utilized in the manufacture of medical devices — Part 1: Analysis and management of risk*

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1) To be published. (Revision of ISO 10993-1:1997)

## 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**
**ophthalmic irrigating solution (OIS)**
aqueous solution that is physiologically compatible with the intraocular environment and functions solely by mechanical means

NOTE It does not provide any primary immunological, pharmacological or metabolic function.

## 4 Intended performance

The intended performance of the product shall be defined by the manufacturer. The intended performance shall include the general requirements for the intended performance of non-active surgical implants outlined in ISO 14630.

The extent to which the intended performance has been achieved shall be determined, taking into account published standards, published clinical and scientific literature, validated test results, preclinical evaluation and clinical trials.



## 5 Design attributes



### 5.1 General

The general requirements for non-active surgical implants outlined in ISO 14630 shall apply.

### 5.2 Concentration of the components

The concentration of each component material in the finished product shall be determined and documented, and the concentration of each component shall be expressed as weight of material per unit volume of solution. Since the testing methodology may affect the actual concentration reported, the standard physical or chemical techniques utilized shall be described and documented. Wherever possible, components shall comply with stated compendial standards.

### 5.3 Water used

The purity of the water used shall be Water for Injections (e.g. see [3]).

### 5.4 Characterization of the finished product

#### 5.4.1 General

The manufacturer shall describe and document the physical characteristics that affect the performance of the OIS efficacy in ophthalmic surgery.

NOTE These physical properties should be measured at the conditions expected and relevant at the time of use.