

IRISH STANDARD

I.S. EN ISO 16672:2003

ICS 11.040.70

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OPHTHALMIC IMPLANTS — OCULAR ENDOTAMPONADES (ISO 16672:2003)

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### 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

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

#### EN ISO 16672:2003 (E)

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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of an identical text or by endorsement, at the latest by August 2003, and conflicting national standards shall be withdrawn at the latest by August 2003.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).

EN ISO 16672:2003 (E)

## 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.

| <u>Publication</u> | <u>Year</u> | <u>Title</u>  | <u>EN</u>      | <u>Year</u> |
|--------------------|-------------|---|----------------|-------------|
| 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 -<br>Part 2: Animal welfare requirements                   | EN ISO 10993-2 | 1998        |
| ISO 10993-6        | 1994        | Biological evaluation of medical devices -<br>Part 6: Tests for local effects after<br>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        |

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# INTERNATIONAL STANDARD

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## Ophthalmic implants — Ocular endotamponades

Implants ophtalmiques — Produits de tamponnement endoculaires





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