National Standards Authority of Ireland

Accepted

IRISH STANDARD

I.S. EN ISO 16671:2004

ICS 11.040.70

National Standards
Authority of Ireland
Dublin 9
Ireland

Tel: (01) 807 3800
Tel: (01) 807 3838

OPHTHALMIC IMPLANTS - IRRIGATING SOLUTIONS FOR OPHTHALMIC SURGERY (ISO 16671:2003)

This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on:

January 30, 2004

Price Code J

Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 16671

November 2003

ICS 11.040.70

English version

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

Ref. No. EN ISO 16671:2003 E

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
2003-05-01

Ophthalmic implants — Irrigating solutions for ophthalmic surgery

Implants ophtalmiques — Solutions d'irrigation pour la chirurgie ophtalmique

Reference number
ISO 16671:2003(E)