SVENSK STANDARD
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Ögonimplantat – Intraokulära linser – Del 9: Multifokala intraokulära linser – Tillägg 1 (ISO 11979-9:2006/Amd 1:2014)

Ophthalmic implants – Intraocular lenses – Part 9: Multifocal intraocular lenses (ISO 11979-9:2006/Amd 1:2014)

Europastandarden EN ISO 11979-9:2006/A1:2014 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 11979-9:2006/A1:2014.

The European Standard EN ISO 11979-9:2006/A1:2014 has the status of a Swedish Standard. This document contains the official English version of EN ISO 11979-9:2006/A1:2014.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Standarden är framtagen av kommittén för Ögonoptik, SIS/TK 336.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11979-9:2006/A1

August 2014

ICS 11.040.70

English Version

Ophthalmic implants - Intraocular lenses - Part 9: Multifocal intraocular lenses (ISO 11979-9:2006/Amd 1:2014)

Implants ophtalmiques - Lentilles intraoculaires - Partie 9: Lentilles intraoculaires multifocales (ISO 11979-9:2006/Amd 1:2014)

Ophthalmische Implantate - Intraokularlinsen - Teil 9: Multifokale Intraokularlinsen (ISO 11979-9:2006/Amd 1:2014)

This amendment A1 modifies the European Standard EN ISO 11979-9:2006; it was approved by CEN on 18 July 2014.

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

This amendment 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 CEN-CENELEC 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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 11979-9:2006/A1:2014) has been prepared by Technical Committee ISO/TC 172 “Optics and photonics” in collaboration with Technical Committee CEN/TC 170 “Ophthalmic optics” the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 11979-9:2006 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2015, and conflicting national standards shall be withdrawn at the latest by February 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11979-9:2006/Amd, 1:2014 has been approved by CEN as EN ISO 11979-9:2006/A1:2014 without any modification.

Ophthalmic implants — Intraocular lenses —

Part 9:
Multifocal intraocular lenses

AMENDMENT 1

Page 1, Clause 1

In the first sentence delete “rotationally symmetric”.

Page 1, Clause 2

Delete the following references:

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*

Add the following reference:

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

Page 1, Clause 3

Replace “ISO 14155-1 and ISO 14155-2” with “ISO 14155”.

Page 2, Clause 4

Delete 4.1 and 4.2, and replace with:

“The requirements of ISO 11979-3 apply.”

Page 2, Clause 5

Delete 5.1, 5.2, 5.3 and 5.4, and replace with:

“The requirements of ISO 11979-2 apply.”

Page 3, Clause 6

In 6.1 first line, replace “ISO 14155-1” with “ISO 14155”.

In 6.1 second line, replace “ISO 14155-1, ISO 14155-2” with “ISO 14155”.

Page 4, Clause 7

Delete the entire contents of the clause and replace with:

“The requirements of ISO 11979-4 together with ISO 11979-4:2008/Amd.1:2012 apply.”

Page 6, Annex A

Delete the entire contents of this Annex and instead refer to ISO 11979-2.

Anteckningar/Notes