



SLOVENSKI STANDARD
SIST EN ISO 11979-8:2009/A1:2011
01-julij-2011

**Očesni vsadki (implantati) - Intraokularne leče - 8. del: Temeljne zahteve -
Dopolnilo 1 (ISO 11979-8:2006/Amd 1:2011)**

Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements -
Amendment 1 (ISO 11979-8:2006/Amd 1:2011)

Ophthalmische Implantate - Intraokularlinsen - Teil 8: Grundlegende Anforderungen -
Änderung 1 (ISO 11979-8:2006/Amd 1:2011)

Implants ophtalmiques - Lentilles intraoculaires - Partie 8: Exigences fondamentales -
Amendement 1 (ISO 11979-8:2006/Amd 1:2011)

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Ta slovenski standard je istoveten z: EN ISO 11979-8:2009/A1:2011

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

SIST EN ISO 11979-8:2009/A1:2011 en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11979-8:2009/A1

May 2011

ICS 11.040.70

English Version

Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements - Amendment 1 (ISO 11979-8:2006/Amd 1:2011)

Implants ophtalmiques - Lentilles intraoculaires - Partie 8:
Exigences fondamentales - Amendement 1 (ISO 11979-
8:2006/Amd 1:2011)

Ophthalmische Implantate - Intraokularlinsen - Teil 8:
Grundlegende Anforderungen - Änderung 1 (ISO 11979-
8:2006/Amd 1:2011)

This amendment A1 modifies the European Standard EN ISO 11979-8:2009; it was approved by CEN on 14 May 2011.

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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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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 11979-8:2009/A1:2011) 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 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2011, and conflicting national standards shall be withdrawn at the latest by November 2011.

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.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive 93/42/EEC, as amended by Directive 2007/47/EC.

For relationship with EU Directive 93/42/EEC as amended by Directive 2007/47/EC, see informative Annex ZA, which is an integral part of this document.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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Endorsement notice

The text of ISO 11979-8:2006/Amd 1:2011 has been approved by CEN as a EN ISO 11979-8:2009/A1:2011 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC (Medical Device Directive)

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC (Medical Device Directive).

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 – Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4 & 5	I.1, I.3, II.9.1, II.9.2, II.12.7.1	For optical properties ref. to EN ISO 11979-2, for mechanical properties ref. to EN ISO 11979-3, for multifocal IOLs ref. to EN ISO 11979-9 and for phakic IOLs ref. to EN ISO 11979-10.
6	I.1, II.7.1, II.7.3, II.7.5, II.7.6, II.9.2	For biocompatibility and interaction with YAG-laser ref. to EN ISO 11979-5.
7	I.1, I.4, I.6, I.6a, II.7.6, II.9.2,	For clinical investigation reference to EN ISO 11979-7, -9 and -10, as applicable.
9	I.1, I.2, II.7.2, II.7.5, II.8.1, II.8.4	Sterility requirement. Protection against ethylene oxide and derivatives thereof in case the device is sterilized by ethylene oxide. Protection against endotoxins.
10	I.3, I.5, II.8.3, II.8.6, II.9.2	For shelf-life and transport reference to EN ISO 11979-6.
11 & 12	II.13.1, II.13.2, II.13.3, II.13.5, II.13.6	For labelling and information reference to EN ISO 11979-4.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO
11979-8

Second edition
2006-07-01

AMENDMENT 1
2011-05-15

Ophthalmic implants — Intraocular lenses —

Part 8: Fundamental requirements

AMENDMENT 1

iTeh STANDARD PREVIEW

(standard.iteh.ai) *Implants ophtalmiques — Lentilles intraoculaires —*

Partie 8: Exigences fondamentales

SIST EN ISO 11979-8:2009/A1:2011

AMENDEMENT 1

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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.

Amendment 1 to ISO 11979-8:2006 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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