ICS 11.040.70 SLOVENSKÁ TECHNICKÁ NORMA Júl 2015

STN	**Očné implantáty. Vnútroočné šošovky. Časť 8: Základné požiadavky (ISO 11979-8: 2006/Amd 1: 2011).**	**STN EN ISO 11979-8** 19 5300

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 06/15

Obsahuje: EN ISO 11979-8:2015, ISO 11979-8:2006/Amd 1:2011

Oznámením tejto normy sa ruší
STN EN ISO 11979-8 (19 5300) z augusta 2009

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11979-8

January 2015

ICS 11.040.70

Supersedes EN ISO 11979-8:2009

English Version

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

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

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

This European Standard was approved by CEN on 7 January 2015.

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 CEN-CENELEC 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 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, 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 United Kingdom.

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

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

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Foreword

The text of ISO 11979-8:2006 + Amd 1:2011 has been prepared by Technical Committee ISO/TC 172 “Optics and photonics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11979-8:2015 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 July 2015, and conflicting national standards shall be withdrawn at the latest by July 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.

This document supersedes EN ISO 11979-8:2009.

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(s).

For relationship with EU Directive(s), 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, 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.

Table – Correlations between undated normative references and dated EN and ISO standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO
ISO 9000	EN ISO 9000:2005	ISO 9000:2005
ISO 10993-7:1995	EN ISO 10993-7:1995[1)]	ISO 10993-7:1995[1)]
ISO 11979-1	EN ISO 11979-1:2012	ISO 11979-1:2012
ISO 11979-2	EN ISO 11979-2:2014	ISO 11979-2:2014
ISO 11979-3	EN ISO 11979-3:2012	ISO 11979-3:2012
ISO 11979-4	EN ISO 11979-4:2008 + A1:2012	ISO 11979-4:2008 + Amd.1:2012
ISO 11979-5	EN ISO 11979-5:2006	ISO 11979-5:2006
ISO 11979-6	EN ISO 11979-6:2014	ISO 11979-6:2014
ISO 11979-7	EN ISO 11979-7:2014	ISO 11979-7:2014
ISO 11979-9	EN ISO 11979-9:2006 + A1:2014	ISO 11979-9:2006 + Amd.1:2014
ISO 11979-10	EN ISO 11979-10:2006 + A1:2014	ISO 11979-10:2006 + Amd.1:2014
ISO 14155-1:2003	EN ISO 14155-1:2009[2)]	ISO 14155-1:2003[2)]
ISO 14155-2	EN ISO 14155-2:2009[2)]	ISO 14155-2:2003[2)]
ISO 14630	EN ISO 14630:2012	ISO 14630:2012
ISO 14971	EN ISO 14971:2007	ISO 14971:2007

Endorsement notice

The text of ISO 11979-8:2006 + Amd 1:2011 has been approved by CEN as EN ISO 11979-8:2015 without any modification.

1) Withdrawn. The version available at the time of publication of the present document is EN ISO 10993-7:2008 + AC:2009 (ISO 10993-7:2008 + Cor.1:2009).

2) Withdrawn. The version available at the time of publication of the present document is EN ISO 14155:2011 + AC:2011 (ISO 14155:2011 + Cor.1:2011).

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

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

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 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 on Medical Devices

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
9	7.2	Sterility requirement. Protection against ethylene oxide and derivatives thereof in case the device is sterilized by ethylene oxide. Protection against endotoxins.
6	7.3	For biocompatibility and interaction with YAG-laser reference to EN ISO 11979-5.
6, 9	7.5	Sterility requirement. Protection against ethylene oxide and derivatives thereof in case the device is sterilized by ethylene oxide. Protection against endotoxins. For biocompatibility and interaction with YAG-laser reference to EN ISO 11979-5.
6, 7	7.6	For biocompatibility and interaction with YAG-laser reference to EN ISO 11979-5. For clinical investigation reference to EN ISO 11979-7, 9 and -10, as applicable.

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

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
11, 12	13.2	For labelling and information reference to EN ISO 11979-4.
11, 12	13.3	For labelling and information reference to EN ISO 11979-4.
11, 12	13.5	For labelling and information reference to EN ISO 11979-4.
11, 12	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

Implants ophtalmiques — Lentilles intraoculaires —

Partie 8: Exigences fondamentales

AMENDEMENT 1

Reference number
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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, O*phthalmic optics and instruments*.