

SLOVENSKI STANDARD

SIST EN ISO 11979-8:2017

01-september-2017

Nadomešča:

SIST EN ISO 11979-8:2015

Očesni vsadki (implantati) - Intraokularne leče - 8. del: Temeljne zahteve (ISO 11979-8:2017)

Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements (ISO 11979-8:2017)

Ophthalmische Implantate - Intraokularlinsen - Teil 8: Grundlegende Anforderungen (ISO 11979-8:2017)

Implants ophtalmiques - Lentilles intraoculaires - Partie 8: Exigences fondamentales (ISO 11979-8:2017) <https://standards.iteh.ai/catalog/standards/sist/ae5c0854-a40d-4cff-be0a-07ae06e2624a/sist-en-iso-11979-8-2017>

Ta slovenski standard je istoveten z: EN ISO 11979-8:2017

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment
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en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11979-8

May 2017

ICS 11.040.70

Supersedes EN ISO 11979-8:2015

English Version

**Ophthalmic implants - Intraocular lenses - Part 8:
Fundamental requirements (ISO 11979-8:2017)**

Implants ophtalmiques - Lentilles intraoculaires -
Partie 8: Exigences fondamentales (ISO 11979-8:2017)

Ophthalmische Implantate - Intraokularlinsen - Teil 8:
Grundlegende Anforderungen (ISO 11979-8:2017)

This European Standard was approved by CEN on 8 March 2017.

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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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

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European foreword

This document (EN ISO 11979-8:2017) 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 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 2017, and conflicting national standards shall be withdrawn at the latest by November 2017.

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 11979-8:2015.

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.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table 1 — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
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

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Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 11979-10	EN ISO 11979-10:2006 + A1:2014	ISO 11979-10:2006 + Amd.1:2014
ISO 14155	EN ISO 14155:2011 + AC:2011	ISO 14155:2011 + Cor.1:2011
ISO 14630	EN ISO 14630:2012	ISO 14630:2012
ISO 14971	EN ISO 14971:2012	ISO 14971:2007

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11979-8:2017 has been approved by CEN as EN ISO 11979-8:2017 without any modification.

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Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request [M/023 concerning the development of European Standards related to medical devices] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

**Table ZA.1 — Correspondence between this European Standard and
Annex I of Directive 93/42/EEC [OJ L 169]**

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
7.2	9.1, 9.2	ER 7.2 is only met in respect of ethylene oxide and bacterial endotoxins and only in respect of manufacturing.
7.5	9.1, 9.2	ER 7.5 is only met in respect of ethylene oxide and bacterial endotoxins and only in respect of manufacturing.
8.1	9.1, 9.2	ER 8.1 is met in respect of ethylene oxide and bacterial endotoxins only.
8.4	9.1	ER 8.4 is met in respect of ethylene oxide sterilization only. Manufacturing is not covered.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

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INTERNATIONAL STANDARD

ISO
11979-8

Third edition
2017-04

Ophthalmic implants — Intraocular lenses —

Part 8: Fundamental requirements

Implants ophtalmiques — Lentilles intraoculaires —

Partie 8: Exigences fondamentales

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Reference number
ISO 11979-8:2017(E)

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