SLOVENSKI STANDARD
SIST EN ISO 11979-1:2019

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Nadomešča:
SIST EN ISO 11979-1:2012

Očesni vsadki (implantati) - Intraokularne leče - 1. del: Slovar (ISO 11979-1:2018)

Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary (ISO 11979-1:2018)

Ophthalmische Implantate - Intraokularlinsen - Teil 1: Vokabular (ISO 11979-1:2018)

Implants ophtalmiques - Lentilles intraoculaires - Partie 1: Vocabulaire (ISO 11979-1:2018)

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ICS:

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11.040.70	Oftalmološka oprema	Ophthalmic equipment

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Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary (ISO 11979-1:2018)

Implants ophtalmiques - Lentilles intraoculaires - Partie 1: Vocabulaire (ISO 11979-1:2018)

Ophthalmische Implantate - Intraokularlinsen - Teil 1: Vokabular (ISO 11979-1:2018)

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 11979-1:2018) 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of an identical text or by endorsement, at the latest by June 2019, and conflicting national standards shall be withdrawn at the latest by June 2019.

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

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Endorsement notice

The text of ISO 11979-1-2018 has been approved by CEN as EN ISO 11979-1:2018 without any modification.

INTERNATIONAL STANDARD

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Ophthalmic implants — Intraocular lenses —

Part 1: Vocabulary

Implants ophtalmiques — Lentilles intraoculaires —

Partie 1: Vocabulaire

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This fourth edition cancels and replaces the third edition (ISO 11979-1:2012), which has been technically revised.

A list of all parts in the ISO 11979 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Ophthalmic implants — Intraocular lenses —

Part 1:
Vocabulary

1 Scope

This document defines terms applicable to intraocular lenses, and to the methods used to evaluate them.

NOTE Terms are listed in the alphabetical order of the English terms in the English version of this document.

2 Normative references

No normative references are given in this document.

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1.1
accelerated shelf-life study
stability study designed to increase the rate of chemical or physical degradation of a product by using exaggerated storage conditions (e.g. temperature, humidity) to determine kinetic degradation parameters to predict the tentative expiration dating period

3.1.2
accommodating intraocular lens
AIOL
intraocular lens which provides continuous focusing from far point to near point by changing the dioptric power of the eye

3.1.3
accommodative amplitude
difference in refractive power between the near point and the far point of the eye

3.1.4
additional wrapping
container used in addition to the primary packaging and which could be used to maintain sterility of the intraocular lens

3.1.5
addition power
difference between the distance power and the near power of the lens portion, measured under specified conditions