

**SLOVENSKI STANDARD**  
**SIST EN ISO 11979-2:2014****01-november-2014****Nadomešča:****SIST EN ISO 11979-2:2000****SIST EN ISO 11979-2:2000/AC:2005**

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**Očesni vsadki (implantati) - Intraokularne leče - 2. del: Optične lastnosti in preskusne metode (ISO 11979-2:2014)**

Ophthalmic implants - Intraocular lenses - Part 2: Optical properties and test methods (ISO 11979-2:2014)

**iTeh STANDARD PREVIEW**

Ophthalmische Implantate - Intraokularlinsen - Teil 2: Optische Eigenschaften und Prüfverfahren (ISO 11979-2:2014)

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Implants ophtalmiques - Lentilles intraoculaires - Partie 2: Propriétés optiques et méthodes d'essai (ISO 11979-2:2014)

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11.040.70      Oftalmološka oprema      Ophthalmic equipment

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 11979-2**

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English Version

## Ophthalmic implants - Intraocular lenses - Part 2: Optical properties and test methods (ISO 11979-2:2014)

Implants ophtalmiques - Lentilles intraoculaires - Partie 2:  
Propriétés optiques et méthodes d'essai (ISO 11979-  
2:2014)

Ophthalmische Implantate - Intraokularlinsen - Teil 2:  
Optische Eigenschaften und Prüfverfahren (ISO 11979-  
2:2014)

This European Standard was approved by CEN on 25 July 2014.

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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.

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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

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## Foreword

This document (EN ISO 11979-2:2014) 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 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 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.

This document supersedes EN ISO 11979-2:1999.

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 11979-2:2014 has been approved by CEN as EN ISO 11979-2:2014 without any modification.

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INTERNATIONAL  
STANDARD

ISO  
11979-2

Second edition  
2014-08-15

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**Ophthalmic implants — Intraocular  
lenses —**

**Part 2:  
Optical properties and test methods**

*Implants ophtalmiques — Lentilles intraoculaires —*

*Partie 2: Propriétés optiques et méthodes d'essai*

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## ISO 11979-2:2014(E)

### 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.

ISO 11979-2 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 11979-2:1999), which has been technically revised. It also incorporates the Technical Corrigendum ISO 11979-2:1999/Cor.1:2003.

ISO 11979 consists of the following parts, under the general title *Ophthalmic implants — Intraocular lenses*:

- Part 1: Vocabulary
- Part 2: Optical properties and test methods
- Part 3: Mechanical properties and test methods
- Part 4: Labelling and information
- Part 5: Biocompatibility
- Part 6: Shelf-life and transport stability testing
- Part 7: Clinical investigations
- Part 8: Fundamental requirements
- Part 9: Multifocal intraocular lenses
- Part 10: Phakic intraocular lenses

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## Introduction

This part of ISO 11979 initially addressed monofocal IOLs and now has been revised to include the requirements and test methods for spherical monofocal, aspheric monofocal, toric, multifocal, and accommodative IOLs. This part of ISO 11979 contains several test methods for which associated requirements are given and one test method for which no requirement is formulated. The former are directly connected to the optical functions of intraocular lenses. The latter, the test for spectral transmittance, has been provided for information about UV transmission and in specific situations, e.g. when using laser light sources for diagnosis and treatment.

For the original spherical monofocal IOLs, extensive interlaboratory testing was carried out before setting the limits specified. During this testing some basic problems were encountered as described in Reference [1]. The accuracy in the determination of dioptric power has an error that is not negligible in relation to the half dioptre steps in which intraocular lenses are commonly labelled. The dioptric power tolerances take this fact into account. Hence the limits set may lead to some overlap into the next labelled power, especially for high dioptre lenses. Reference [1] gives further discussion on this subject.

The majority of lenses hitherto implanted were qualified using the method described in [Annex B](#) or [Annex C](#) (model eye 1). The method in [Annex B](#) is limited in its applicability, however. The limits for the more general method in [Annex C](#) have been set in terms of MTF in a model eye, following two approaches. The first is by correlation to the method and limit in [Annex B](#). Further discussion can be found in Reference [2]. The second is set as a percentage of what is calculated as theoretical maximum for the design, with the rationale that a minimum level of manufacturing accuracy be guaranteed. For common PMMA lenses, these two limits correspond well with each other. For lenses made of materials with lower refractive index, or with certain shape factors, or for extreme power lenses in general, the latter limit is lower than the former. However, such lenses are already in use, indicating clinical acceptance. The question of which is the absolute lowest limit that is compatible with good vision arises. No definite answer can be found, but following clinical data presented to the working group, an absolute lower limit has been set for the calculation method.

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