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STN	**Očné implantáty Vnútroočné šošovky Časť 10: Klinické overovanie vnútroočných šošoviek na korekciu ametropie afakických očí (ISO 11979-10: 2018)**	**STN EN ISO 11979-10 19 5300**

Ophthalmic implants - Intraocular lenses - Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes (ISO 11979-10:2018)

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. 10/18

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English Version

Ophthalmic implants - Intraocular lenses - Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes (ISO 11979-10:2018)

Implants ophtalmiques - Lentilles intraoculaires - Partie 10: Investigations cliniques de lentilles intraoculaires pour la correction de l'amétropie des yeux phaques (ISO 11979-10:2018)

Ophthalmische Implantate - Intraokularlinsen - Teil 10: Klinische Prüfungen von Intraokularlinsen zur Korrektion der Ametrophie in phaken Augen (ISO 11979-10:2018)

This European Standard was approved by CEN on 28 February 2018.

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European foreword

This document (EN ISO 11979-10:2018) 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of an identical text or by endorsement, at the latest by November 2018, and conflicting national standards shall be withdrawn at the latest by November 2018.

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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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 11979-10:2018 has been approved by CEN as EN ISO 11979-10:2018 without any modification.

INTERNATIONAL STANDARD

ISO 11979-10

Second edition
2018-03

Ophthalmic implants — Intraocular lenses —

Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes

Implants ophtalmiques — Lentilles intraoculaires —

Partie 10: Investigations cliniques de lentilles intraoculaires pour la correction de l'amétropie des yeux phaques

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.

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 on 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 the following URL: 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 second edition cancels and replaces the first edition (ISO 11979-10:2006) and its amendment (ISO 11979-10:2006/Amd 1:2014), which has been technically revised.

The main changes compared to the previous edition are as follows.

— modified the scope to include phakic multifocal and phakic toric intraocular lenses;

— added references to the requirements in ISO 11979-6, ISO 11979-7, and ISO 11979-8;

— modified the clinical requirements to include those for phakic multifocal and phakic toric intraocular lenses; and

— modified the informative Annex A to include elements associated with the clinical investigation of phakic multifocal and phakic toric intraocular lenses.

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

Introduction

Phakic intraocular lenses are used to correct refractive errors in patients with a non-cataractous crystalline lens. They are typically used for patients with higher amounts of myopia or hyperopia. Originally, they contained a spherical monofocal optic to correct spherical errors but later variations utilized a toric optic to also correct refractive astigmatism. Phakic intraocular lenses with a multifocal optic can be used to correct presbyopia in patients that have lost the ability to accommodate.

The requirements and recommendations in the ISO series of standards for aphakic intraocular lenses for the most part also apply to phakic intraocular lenses. Those standards should be reviewed for guidance that would also be applicable to phakic intraocular lenses (e.g. shelf-life testing, biocompatibility testing, etc.).

This document provides requirements and recommendations for phakic intraocular lens investigations of new models. Risk analysis should be used to determine the investigational design, if needed, for models that are modifications of parent phakic models. For modifications of a parent phakic model refer to ISO/TR 22979.

INTERNATIONAL STANDARD **ISO 11979-10:2018(E)**

Ophthalmic implants — Intraocular lenses —

Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes

1 Scope

This document specifies requirements for any intraocular lenses to be implanted in the anterior segment of the eye with the primary indication to modify its refractive power.

There are three main categories of phakic intraocular lenses depending on the optical design:

a) Phakic monofocal (PIOL);

b) Phakic multifocal (PMIOL); and

c) Phakic toric (PTIOL).

Each of these categories is further designated for implantation in either the anterior or posterior chamber of the anterior segment of the eye.

The basic phakic IOL requirements apply to all the types. Additional requirements apply to PMIOL and PTIOL designs.

This document addresses specific clinical requirements for phakic IOLs that are not addressed in the other parts of ISO 11979.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11979-1, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary*

ISO 11979-2, *Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods*

ISO 11979-3, *Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods*

ISO 11979-4, *Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information*

ISO 11979-5, *Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility*

ISO 11979-6, *Ophthalmic implants — Intraocular lenses — Part 6: Shelf-life and transport stability testing*

ISO 11979-7, *Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations of lenses for the correction of aphakia*

ISO 11979-8, *Ophthalmic implants — Intraocular lenses — Part 8: Fundamental requirements*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971, *Medical devices — Application of risk management to medical devices*

