SLOVENSKI STANDARD
SIST EN ISO 11979-3:2013

01-marec-2013

Nadomešča:
SIST EN ISO 11979-3:2006

Očesni vsadki (implantati) - Intraokularne leče - 3. del: Mehanske lastnosti in preskusne metode (ISO 11979-3:2012)

Ophthalmic implants - Intraocular lenses - Part 3: Mechanical properties and test methods (ISO 11979-3:2012)

Ophthalmische Implantate - Intraokularlinsen - Teil 3: Mechanische Eigenschaften und Prüfverfahren (ISO 11979-3:2012)

Implants ophtalmiques - Lentilles intraoculaires - Partie 3: Propriétés mécaniques et méthodes d'essai (ISO 11979-3:2012)

Ta slovenski standard je istoveten z: **EN ISO 11979-3:2012**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 11979-3:2013 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11979-3

December 2012

ICS 11.040.70

Supersedes EN ISO 11979-3:2006

English Version

Ophthalmic implants - Intraocular lenses - Part 3: Mechanical properties and test methods (ISO 11979-3:2012)

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Foreword

This document (EN ISO 11979-3:2012) 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of an identical text or by endorsement, at the latest by June 2013, and conflicting national standards shall be withdrawn at the latest by June 2013.

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.

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INTERNATIONAL STANDARD

ISO 11979-3

Third edition
2012-12-01

Ophthalmic implants — Intraocular lenses —

Part 3: Mechanical properties and test methods

Implants ophtalmiques — Lentilles intraoculaires —

Partie 3: Propriétés mécaniques et méthodes d'essai

Reference number
ISO 11979-3:2012(E)

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Published in Switzerland

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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.

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ISO 11979-3 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 11979-3:2006), which has been technically revised in order to include relevant requirements and test methods for toric intraocular lenses and accommodating intraocular lenses.

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*

— *Part 7: Clinical investigations*

— *Part 8: Fundamental requirements*

— *Part 9: Multifocal intraocular lenses*

— *Part 10: Phakic intraocular lenses*

Introduction

This part of ISO 11979 contains methods for which requirements are given and methods for which no requirements are formulated. The former are considered essential for the safety or performance of the intraocular lens, while the latter provide essential information to the ophthalmic surgeon or are used for other purposes.

A special purpose is the use of mechanical data to assess the need for clinical investigation of modifications of existing models as described in ISO 11979-7[7]. Because of the complexity of this analysis, detailed descriptions and examples have been given in ISO/TR 22979[8]. Due to the wide variety of intraocular lens designs already on the market, it has not been possible to devise test methods that are applicable to every design under all circumstances. It can be anticipated that new materials currently under development will result in drastically new designs that will require modified or other test methods. As with all standards, it is then up to the parties using the standard to modify or develop corresponding methods and give rationale and validation for them in a spirit that is consistent with this part of ISO 11979.

In cases where different tolerances have been given depending on material or design, they reflect an existing situation with well-established products.

Ophthalmic implants — Intraocular lenses —

Part 3: Mechanical properties and test methods

1 Scope

This part of ISO 11979 specifies requirements and test methods for certain mechanical properties of intraocular lenses (IOLs).

It is applicable to all types of IOLs intended for implantation in the anterior segment of the human eye, excluding corneal implants, provided that the test method is appropriate to the particular IOL design.

2 Normative references

The following referenced documents are indispensable for the application 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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11979-1 apply.

4 Requirements

4.1 General

For all IOLs, the mechanical properties shall be determined at *in situ* conditions. The precise composition of the solution used shall be reported in all cases. Alternative test conditions, e.g. room temperature conditions, may be used if a justification to deviate from *in situ* is given. The alternative test conditions shall be specified in the test reports.

For each of the methods described below, tests shall be performed on a minimum of three IOL lots of medium dioptric power. If dioptric power affects the property tested, the lots shall comprise one each of low, medium and high dioptric powers. For toric intraocular lenses, half of each of these three lots shall contain intraocular lenses with the highest cylindrical power, and the other half shall contain intraocular lenses with the lowest cylindrical power. The minimum sample size for each test shall be 10 IOLs per lot. The lots shall be representative of IOLs being marketed. In all cases, the sampling criteria applied shall be reported. Means and standard deviations shall be reported for the pooled samples.

If, for certain designs and certain applications, a specific test method described in this part of ISO 11979 is not applicable, the IOL manufacturer can devise a corresponding test method and provide a validation and rationale for it.

For accommodating IOLs (AIOLs) the theoretical mechanism of action to change the power of the eye shall be described e.g. the change of curvature or the movement of lens elements under compression. The general factors determining this action shall be characterized and specified. Further mechanical testing over a range that includes the maximum and minimum limits of the theoretical mechanism of

