SLOVENSKI STANDARD
SIST EN ISO 11979-9:2006

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Oļ esni vsadki (implantati) - Intraokularne leļ e - 9. del: Veļ goriġļ na intraokularna stekla (ISO 11979-9:2006)

Ophthalmic implants - Intraocular lenses - Part 9: Multifocal intraocular lenses (ISO 11979-9:2006)

Ophthalmische Implantate - Intraokularlinsen - Teil 9: Multifokale Intraokularlinsen (ISO 11979-9:2006)

Implants ophtalmiques - Lentilles intraoculaires - Partie 9: Lentilles intraoculaires multifocales (ISO 11979-9:2006)

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This European Standard was approved by CEN on 19 August 2006.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This document (EN ISO 11979-9:2006) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" 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of an identical text or by endorsement, at the latest by March 2007, and conflicting national standards shall be withdrawn at the latest by March 2007.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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 11979-9:2006 has been approved by CEN as EN ISO 11979-9:2006 without any modifications.

INTERNATIONAL STANDARD

ISO 11979-9

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Ophthalmic implants — Intraocular lenses —

Part 9: Multifocal intraocular lenses

Implants ophtalmiques — Lentilles intraoculaires —
Partie 9: Lentilles intraoculaires multifocales

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Contents

Page

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 11979-9 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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*

Ophthalmic implants — Intraocular lenses —

Part 9:
Multifocal intraocular lenses

1 Scope

This part of ISO 11979 is applicable to any intraocular lens whose optic provides two or more rotationally symmetric powers and whose primary indication is the correction of aphakia with the added benefit of useful vision at more than one distance (e.g. far and near).

NOTE The term “near vision” as used in this part of ISO 11979 includes useful vision at a distance of claimed benefit; e.g. near and/or intermediate distances.

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*

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 11979-7, *Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations*

ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11979-1, ISO 14155-1 and ISO 14155-2 apply.

4 Physical requirements

4.1 General

This clause is applicable to the physical properties of multifocal intraocular lenses (MIOLs) in the assembled or final form, as intended for implantation in the human eye.

4.2 Tolerances and dimensions

For tolerances and dimensions, the requirements of ISO 11979-3 apply, together with the following additional requirement that the manufacturer shall establish tolerances with respect to the optical design.

5 Optical requirements

5.1 General

This clause is applicable to the optical properties and performance requirements of MIOLs in their final form, as intended for implantation in the human eye.

5.2 Dioptric power

For dioptric power, ISO 11979-2 applies to the far power of an MIOL and to any distinct near power(s).

Two alternative methods for the determination of dioptric power, given in ISO 11979-2, can be applied to MIOLs. For each near image plane, these methods are modified as follows:

a) for the determination of dioptric power from measured back focal length, once the microscope is focused on the far image plane and the distance from the back vertex of the MIOL to the distant focal point is determined, focus the microscope on the near image plane and determine the distance from the back vertex of the MIOL to the near focal point;

b) for the determination of dioptric power from measured magnification, once the microscope is focused on the far image plane and the linear dimension, h_{image}, in the image is determined, focus the microscope on the near image plane and determine the linear dimension, h_{image}, in the image.

Depending on the MIOL optic design the correction formulas given in ISO 11979-2 could be invalid. In such cases, the manufacturer shall derive and justify corrections that result in dioptric powers that are consistent with power labelling of monofocal IOLs.

If the focusing conditions of ISO 11979-2 are not appropriate for the particular design, another focusing condition shall be developed with justification.

5.3 Imaging quality

The imaging quality shall be evaluated for the far power and any claimed near power(s) or power range. The imaging quality specifications apply in all meridians.

For designs that have no distinct near power, a specification describing the through-focus response performance shall be developed.

The manufacturer shall demonstrate that all available powers meet the imaging quality specifications.

The imaging quality of a MIOL shall be evaluated by modulation transfer function (MTF) testing in the eye model described in ISO 11979-2 with the following additions:

ISO 11979-2 is modified such that best focus for the power under evaluation is obtained by maximizing the MTF at 50 cycles/mm with a (3 ± 0,25) mm aperture. Using that focus, record the MTF values at the following conditions:

a) small aperture (2 mm to 3 mm), 25 cycles/mm and 100 cycles/mm, for the far power;

b) small aperture (2 mm to 3 mm), 25 cycles/mm and 100 cycles/mm, for the near power(s) or power range;

c) large aperture (4 mm to 5 mm), 25 cycles/mm and 50 cycles/mm, for the far power.

The converging beam from the model cornea described in ISO 11979-2 exposes a central diameter of the MIOL (± 0,1 mm) to, interchangeably, either the small or the large aperture that is chosen to best control the MTF performance.

In order to best control the MTF performance of the MIOL, the small and large apertures used for testing shall be chosen and defined for the lens model over the range of apertures provided above with a tolerance of ± 0,25 mm. The manufacturer shall have the option of setting the minimum MTF specification based on the area under the curve between the two spatial frequencies or on the MTF value for each individual spatial frequency.

The minimum MTF specification shall be set such that it results in acceptable visual outcome, verifiable, or to be verified, by clinical data.

NOTE 1 The minimum MTF specification is typically set as the mean value minus an acceptable level of deviation, e.g. mean value minus two standard deviations.

NOTE 2 The apertures above represent the exposed diameter of the test MIOL and can differ from the aperture stop of the optical bench.

NOTE 3 It can be necessary to have a different imaging quality specification for each combination of test aperture and focus.

5.4 Additional optical characterization

5.4.1 Optical design

Tests that shall be performed to characterize the MIOL optical design are described in Annex A.

5.4.2 Spectral transmittance

For spectral transmittance, ISO 11979-2 applies.

6 Clinical investigation

6.1 General

If clinical evaluation, in accordance with ISO 14155-1, together with risk assessment, in accordance with ISO 14971, identifies the need for a clinical investigation, the requirements of ISO 14155-1, ISO 14155-2 and ISO 11979-7 apply, with additional requirements given in 6.2.

NOTE Considerations for the risk analysis regarding modifications to one or more existing designs are found in ISO/TR 22979 [1].