SLOVENSKI STANDARD
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Oļ esni vsadki (implantati) - Intraokularne leļ e - 7. del: Kliniļ ne raziskave (ISO 11979-7:2006)

Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations (ISO 11979-7:2006)

Ophthalmische Implantate - Intraokularlinsen - Teil 7: Klinische Prüfungen (ISO 11979-7:2006)

Implants ophtalmiques - Lentilles intraoculaires - Partie 7: Investigations cliniques (ISO 11979-7:2006)

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11.040.70	Oftalmološka oprema	Ophthalmic equipment

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Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations (ISO 11979-7:2006)

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Foreword

This document (EN ISO 11979-7:2006) 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of an identical text or by endorsement, at the latest by November 2006, and conflicting national standards shall be withdrawn at the latest by November 2006.

This document supersedes EN 13503-7:2001.

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 11979-7:2006 has been approved by CEN as EN ISO 11979-7:2006 without any modifications.

INTERNATIONAL STANDARD

ISO 11979-7

Second edition
2006-05-01

Ophthalmic implants — Intraocular lenses —

Part 7: Clinical investigations

Implants ophtalmiques — Lentilles intraoculaires — Partie 7: Investigations cliniques

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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.

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 11979-7 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 11979-7:2001), which has been technically revised.

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 7:
Clinical investigations

1 Scope

This part of ISO 11979 specifies particular requirements for clinical investigations for posterior and anterior chamber monofocal intraocular lenses (IOLs) for the correction of aphakia.

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 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*

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 Justification for a clinical investigation

The requirements given in ISO 14155-1 shall apply.

If a new model is a minor modification of a model for which the safety and performance have been established through clinical investigation in accordance with this part of ISO 11979, no or limited clinical investigation is needed. ISO/TR 22979 provides guidance in determining if a modification is minor.

5 Ethical considerations

For clinical investigations of medical devices for human subjects, the requirements in ISO 14155-1 shall apply.

6 General requirements

6.1 General

The general requirements for a clinical investigation given in ISO 14155-1 and the clinical investigation plan requirements in ISO 14155-2 shall apply, with additional requirements given below.

6.2 Additional requirements

6.2.1 Design

A clinical investigation of an IOL model shall be designed in one of two ways:

a) as an uncontrolled study, in which case the results are compared to the adverse events and visual acuity rates given in Annex B.

b) as a controlled study, with the provision that the statistical power to detect differences in the adverse event rates and visual acuity is similar to the uncontrolled study. The control lens shall conform with applicable parts of ISO 11979.

NOTE Annex A provides guidance for the design of a clinical investigation.

6.2.2 Variables

The following variables shall be considered:

— best spectacle corrected visual acuity (BSCVA);

— refraction;

— intraocular pressure;

— corneal status;

— iritis;

— IOL decentration;

— IOL tilt;

— IOL discoloration;

— IOL opacity;

— cystoid macular oedema;

— hypopyon;

— endophthalmitis;

— pupillary block;

— retinal detachment;

— status of anterior and posterior capsule.

Additional variables can be studied in the clinical investigation to support specific claims.

6.2.3 Other considerations

To minimize the risks associated with the clinical investigation of a new IOL, subject enrolment shall occur in stages. The subject data from each stage shall be evaluated and found acceptable by the sponsor and the coordinating investigator prior to the continuation of the clinical investigation. Guidance on phased enrolment is included in Annex A.

Only the first eye of each subject shall be included in the primary statistical analysis.

Any plans for fellow eye implantation shall be described in the clinical investigation plan. Bilateral implantation shall not be implemented until initial safety and effectiveness data have been collected, evaluated and confirmed by the sponsor and principal investigators.

The review of data from at least 50 eyes with six months of follow-up is recommended. Previous clinical experience, i.e. results from well-documented clinical investigations, may be adequate justification to begin bilateral implantation earlier in the study.

The duration of the clinical investigation shall be one year for all posterior chamber IOLs, and 3 years for all anterior chamber IOLs.

The clinical investigation plan shall contain descriptions of the surgical technique, the intraoperative use of ophthalmic viscosurgical devices, and the use of preoperative, intra-operative and post-operative medications. Any deviation shall be recorded on the case report forms.

The clinical investigation plan shall describe how subject visits and ophthalmic adverse events in between reporting periods will be handled in the data analyses.

All subjects in a clinical investigation shall be monitored for the duration of the investigation. The clinical investigation shall be considered completed when all subjects that have been enrolled in the investigation, including subjects whose IOL was removed or replaced, have reached the final reporting period.

Serious ophthalmic adverse events and all adverse device effects shall be reported using a special case report form and forwarded to the sponsor as required. All other ophthalmic adverse events shall be reported using the standard visit case report forms and are collected during monitoring.