SLOVENSKI STANDARD
oSIST prEN ISO 11979-7:2012

01-september-2012

Očesni vsadki (implantati) - Intraokularne leče - 7. del: Klinične raziskave (ISO/DIS 11979-7:2012)

Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations (ISO/DIS 11979-7:2012)

Ophthalmische Implantate – Intraokularlinsen - Teil 7: Klinische Prüfungen (ISO/DIS 11979-7:2012)

Implants ophtalmiques - Lentilles intraoculaires - Partie 7: Investigations cliniques (ISO/DIS 11979-7:2012)

Ta slovenski standard je istoveten z: prEN ISO 11979-7

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

oSIST prEN ISO 11979-7:2012 en,fr,de

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN ISO 11979-7

June 2012

ICS 11.040.70

Will supersede EN ISO 11979-7:2006

English Version

Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations (ISO/DIS 11979-7:2012)

Implants ophtalmiques - Lentilles intraoculaires - Partie 7: Investigations cliniques (ISO/DIS 11979-7:2012)

Ophthalmische Implantate - Intraokularlinsen - Teil 7: Klinische Prüfungen (ISO/DIS 11979-7:2012)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 170.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN 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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, 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, Turkey and United Kingdom.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. prEN ISO 11979-7:2012: E

Contents

Page

Foreword

This document (prEN ISO 11979-7:2012) 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 document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 11979-7:2006.

Endorsement notice

The text of ISO/DIS 11979-7:2012 has been approved by CEN as a prEN ISO 11979-7:2012 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 11979-7

ISO/TC **172**/SC **7** Secretariat: **DIN**

Voting begins on **2012-06-21** Voting terminates on **2012-11-21**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Ophthalmic implants — Intraocular lenses —

Part 7:
Clinical investigations

Implants ophtalmiques — Lentilles intraoculaires —

Partie 7: Investigations cliniques

[Revision of second edition (ISO 11979-7:2006)]

ICS 11.040.70

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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 11979-7 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, and by Technical Committee CEN/TC 170, *Ophthalmic optics* in collaboration.

This second edition cancels and replaces the first edition (ISO 11979-7:2006, ISO 11979-7:2006/Amd1:2012), 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 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 intraocular lenses (IOLs).

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 11979-10:2006, *Ophthalmic implants — Intraocular lenses — Part 10: Phakic intraocular lenses*

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

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 and ISO 14155 shall apply.

4 Justification for a clinical investigation

A clinical evaluation in accordance with ISO 14155 shall be performed together with risk analysis, in accordance with ISO 14971.

If the need for a clinical investigation is identified, the requirements of ISO 14155 shall apply, with additional requirements given below.

If a new IOL model is a 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 [1] 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 shall apply.

6 General requirements

6.1 General

The requirements for a clinical investigation given in ISO 14155 shall apply, with additional requirements given below.

6.2 Design

6.2.1 General

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

a) As an uncontrolled investigation, in which case the results are compared to historical data on adverse events and visual acuity rates. This design is applicable only to those IOL types for which there are historical data in Annex B.

b) As a controlled investigation, with the provision that the statistical power to detect differences in the adverse event rates and visual acuity is similar to the uncontrolled investigation. The control lens shall be an IOL previously approved under national regulations.

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

6.2.2 Additional requirements for toric IOLs

For all toric IOLs, the rotational stability of a non-toric version that is mechanically and geometrically equivalent to the toric IOL shall be demonstrated.

The following performance criteria for rotational stability shall be fulfilled:

— The rotation of the meridian defined by the IOL axis indicator as measured and compared between the Day 1 (the day after surgery) post-operative examination and the 4 to 6 month examination shall be less than 10° in 90 % of the cases, and less than 20° in 99 % of the cases.

Then, if necessary due to national requirements, a clinical investigation shall be performed using the toric version of the model.

The following performance criterion for clinical investigation shall be fulfilled:

— The mean achieved reduction in cylinder shall be ≥ 68 % of the intended cylinder reduction.

In the event that a toric IOL clinical investigation is required due to national regulations, the subjects that undergo secondary surgery to correct IOL mark axis rotation shall have their clinical results prior to the secondary surgery carried forward as the final results for that subject. In the case of examinations that are scheduled to be performed later in the clinical investigation (e.g., questionnaire), the sponsor shall consider requiring each of these examinations to be performed prior to the secondary surgery, if possible.

Additional elements for toric IOLs are outlined in Annex C.

6.2.3 Additional requirements for accommodating IOLs

A clinical investigation of an accommodating IOL shall evaluate the additional safety and performance concerns outlined in Annex D, specifically including the evaluation of accommodative amplitude using at least one objective method. It shall consist of two phases, with phase two beginning only after the first phase has demonstrated that the accommodating IOL provides an average of at least 1 D of objective accommodation. The overall study shall demonstrate that the accommodating IOL provides statistically greater objective accommodative amplitude compared to the control IOL.

6.3 Variables

The following variables shall be considered. If additional claims are to be made, additional corresponding variables shall be studied.

The clinical investigational plan should provide instructions regarding recording observations. In the event of any lens displacement or dislocation from the intended position causing visual symptoms, the instructions should include obtaining a photographic image if possible (or a detailed sketch) and recording as much detailed information in the subject's chart as possible.

6.3.1 General variables

a) best spectacle corrected visual acuity (BSCVA);

b) subjective refraction;

c) intraocular pressure;

d) corneal status;

e) anterior chamber cells;

f) anterior chamber flare;

g) cystoid macular edema;

h) hypopyon;

i) endophthalmitis;

j) pupillary block;

k) retinal detachment;

l) status of anterior and posterior capsule;

m) IOL decentration [2];

n) IOL tilt [2];

o) IOL discoloration;

p) IOL opacity.

6.3.2 Toric IOL variables

a) uncorrected visual acuity;

b) keratometry;

c) IOL mark axis rotation;

d) subject questionnaire.

6.3.3 Accommodating IOL variables

a) uncorrected visual acuity at distance, intermediate and near;