SLOVENSKI STANDARD
SIST EN ISO 11979-2:2000

01-julij-2000

Oļ esni vsadki (implantati) - Intraokularne leļ e - 2. del: Optiļ ne lastnosti in preskusne metode (ISO 11979-2:1999)

Ophthalmic implants - Intraocular lenses - Part 2: Optical properties and test methods (ISO 11979-2:1999)

Ophtalmische Implantate - Intraokularlinsen - Teil 2: Optische Eigenschaften und Prüfverfahren (ISO 11979-2:1999)

Implants ophtalmiques - Lentilles intraoculaires - Partie 2: Propriétés optiques et méthodes d'essai (ISO 11979-2:1999)

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EUROPEAN STANDARD

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English version

Ophthalmic implants - Intraocular lenses - Part 2: Optical properties and test methods (ISO 11979-2:1999)

Implants ophtalmiques - Lentilles intraoculaires - Partie 2: Propriétés optiques et méthodes d'essai (ISO 11979-2:1999)

Ophthalmische Implantate - Intraokularlinsen - Teil 2: Optische Eigenschaften und Prüfverfahren (ISO/FDIS 11979-2:1999)

This European Standard was approved by CEN on 15 December 1999.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of the International Standard ISO 11979-2:1999 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 June 2000, and conflicting national standards shall be withdrawn at the latest by June 2000.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

NOTE FROM CEN/CS: The foreword is susceptible to be amended on reception of the German language version. The confirmed or amended foreword, and when appropriate, the normative annex ZA for the references to international publications with their relevant European publications will be circulated with the German version.

Endorsement notice

The text of the International Standard ISO 11979-2:1999 was approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 11979-2

First edition
1999-12-15

Ophthalmic implants — Intraocular lenses —

Part 2: Optical properties and test methods

Implants ophtalmiques — Lentilles intraoculaires —
Partie 2: Propriétés optiques et méthodes d'essai

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 734 10 79
E-mail copyright@iso.ch
Web www.iso.ch

Printed 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 3.

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 part of ISO 11979 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11979-2 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, 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*

Annexes A, B and C form a normative part of this part of ISO 11979. Annexes D, E, F and G are for information only.

Introduction

This part of ISO 11979 contains several test methods for which associated requirements are given and one test method for which no requirement is formulated. The former are directly connected to the optical functions of intraocular lenses. The latter, the test for spectral transmittance, has been provided for those interested in information about UV transmission and in specific situations, e.g. when using laser light sources for medical diagnosis and treatment.

Extensive interlaboratory testing has been carried out before setting the limits specified. Some basic problems were encountered.

The accuracy in the determination of dioptric power has an error that is not negligible in relation to the half-dioptre steps in which intraocular lenses are commonly labelled. The dioptric power tolerances take this fact into account. Hence the limits set may lead to some overlap into the next labelled power, especially for high dioptre lenses. Reference [1] gives further discussion on this subject.

The majority of lenses hitherto implanted have been made from poly(methyl methacrylate) (PMMA), and were qualified using the method described in annex B. Thus the general clinical experience is associated with this level. The method in annex B is limited in its applicability, however. The limits for the more general method in annex C have been set in terms of MTF in an eye model, following two approaches. The first is by correlation to the method and limit in annex B. Further discussion can be found in reference [2]. The second is set as a percentage of what is calculated as theoretical maximum for the design, with the rationale that a minimum level of manufacturing accuracy be guaranteed. For common PMMA lenses, these two limits correspond well with each other. For lenses made of materials with lower refractive index, or with certain shape factors, or for extreme power lenses in general, the latter limit is lower than the former. However, such lenses are already in use, indicating clinical acceptance. The question arises which is the absolute lowest limit that is compatible with good vision. No definite answer can be found, but following clinical data presented to the working group, an absolute lower limit has been set for the calculation method.

NOTE It always was and still is the intention of the Technical Committees ISO/TC 172/SC 7 and CEN/TC 170 to prepare identical ISO and CEN (European Committee for Standardization) standards on intraocular lenses. However, during the preparation of part 7 of this series, problems were encountered with normative references to the existing ISO 14155 and EN 540 horizontal standards on clinical investigation of medical devices, which are similar but not identical.

ISO and CEN principles concerning normative references made it impossible to continue the preparation of identical International and European Standards on the clinical investigation of intraocular lenses. As a result, two different standards series have had to be prepared. For this part of ISO 11979, identical versions exist for ISO and CEN (ISO 11979-2 and EN ISO 11979-2). For those parts where no identical versions exist, it is the intention of ISO/TC 172/SC 7 and CEN/TC 170 to revise these standards with the goal to end up with identical ones as soon as identical ISO and CEN horizontal standards on clinical investigations become available.

Ophthalmic implants — Intraocular lenses —

Part 2:
Optical properties and test methods

1 Scope

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

It is applicable but not limited to non-toric, monofocal intraocular lenses intended for implantation into the anterior segment of the human eye, excluding corneal implants.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 11979. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11979 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 6328: —[1)], *Photography — Photographic materials — Determination of ISO resolving power.*

ISO 9334:1995, *Optics and optical instruments — Optical transfer function — Definitions and mathematical relationships.*

ISO 9335:1995, *Optics and optical instruments — Optical transfer function — Principles and procedures of measurement.*

ISO 11979-1:1999, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary.*

U.S. Mil Std 150-A-1961, *Photographic lenses.*

3 Terms and definitions

For the purposes of this part of ISO 11979, the terms and definitions given in ISO 9334 and ISO 11979-1 apply.

NOTE Some definitions from ISO 11979-1 are reproduced for information in annex G.

1) To be published. (Revision of ISO 6328:1982)

4 Requirements

4.1 General

All requirements stated below shall apply to the finished product as marketed. If applicable, the lens shall be positioned as intended for use.

NOTE 1 The methods specified below are reference methods. Alternative methods demonstrated to produce results that are equivalent to those obtained with the reference methods may also be used.

NOTE 2 Any validated procedures that ensure that IOLs are within the tolerances specified may be used in quality control.

4.2 Dioptric power

When determined by one of the methods described in annex A, the dioptric power as stated by the manufacturer (e.g. on the label of the IOL) shall, in any meridian, be within the tolerance limits specified in Table 1.

NOTE Astigmatism is implicitly limited by the requirement that dioptric power be within the tolerance limits of Table 1 in all meridians.

Table 1 — Tolerances on dioptric power

Nominal dioptric power range [a] D	Tolerance on dioptric power D
0 to ⩽ 15	± 0,3
> 15 to ⩽ 25	± 0,4
> 25 to ⩽ 30	± 0,5
> 30	± 1,0
[a] The ranges apply to positive as well as to negative dioptric powers.	

4.3 Imaging quality

Imaging quality shall be determined either according to the method described in annex B or to the method described in annex C.

NOTE The method of annex C is more general. It can be used e.g. for extreme dioptric powers and for materials which swell in aqueous humour, for which cases the method of annex B is not suitable.

a) If determined in accordance with annex B, the resolution efficiency of the IOL shall be no less than 60 % of the diffraction-limited cut-off spatial frequency. In addition, the image shall be free of aberrations other than those due to normal spherical aberration.

b) If determined in accordance with annex C, the modulation transfer function (MTF) value of the system of model eye with IOL shall, at 100 mm^{-1}, meet either of the two conditions given below:

   1) be greater or equal to 0,43;

   2) be greater or equal to 70 % of that calculated as maximum attainable for the system of model eye with the specific IOL design and power in question, but in any case greater or equal to 0,28.

NOTE 1 Spatial frequency has the dimension of reciprocal length, mm^{-1}. It is often referred to as line-pairs per mm or c/mm, where c denotes cycles.

NOTE 2 The approval levels given above correspond well with each other for PMMA lenses in the range 10 D to 30 D.

NOTE 3 Examples of calculation of maximum attainable MTF at 100 mm^{-1} are given in C.5.