Ophthalmic implants - Intraocular lenses - Part 2: Optical properties and test methods

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 11979-2:2000 sisaldab Euroopa standardi EN ISO 11979-2:1999 + AC:2005 ingliskeelset teksti. Käesolev dokument on jõustatud 16.06.2000 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 11979-2:2000 consists of the English text of the European standard EN ISO 11979-2:1999 + AC:2005. This document is endorsed on 16.06.2000 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This part of ISO 11979 specifiies requirements and test methods for certain optical properties of intraoccular lenses (IOLs).	**Scope:** This part of ISO 11979 specifiies requirements and test methods for certain optical properties of intraoccular lenses (IOLs).

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Võtmesõnad: intraocular lenses, lenses, ophthalmic equipment, optical equipment, optical properties, optical tests, optics, specifications, tests

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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 11979-2 : 1999)

This European Standard was approved by CEN on 1999-12-15.

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.

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The European Standards exist 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.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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

Foreword

International Standard

ISO 11979-2 : 1999 Ophthalmic implants – Intraocular lenses – Part 2: Optical properties and test methods, which was prepared by ISO/TC 172 'Optics and optical instruments' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 170 'Ophthalmic optics', the Secretariat of which is held by DIN, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by June 2000 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

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

NOTE: Normative references to international publications are listed in Annex ZA (normative). A-deviations are given in Annex ZB (informative).

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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.

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.

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