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IRISH STANDARD

I.S. EN 13503-3:2000

ICS 11.040.70

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OPHTHALMIC IMPLANTS - INTRAOCULAR LENSES - PART 3: MECHANICAL PROPERTIES AND TEST METHODS (ISO 11979-3:1999, MODIFIED)

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EUROPEAN STANDARD
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English version

Ophthalmic implants - Intraocular lenses - Part 3: Mechanical properties and test methods (ISO 11979-3:1999, modified)

Implants ophtalmiques - Lentilles intraoculaires - Partie 3: Propriétés mécaniques et méthodes d'essai (ISO 11979-3:1999, modifié)

Ophthalmische Implantate - Intraokularlinsen - Teil 3: Mechanische Anforderungen und Prüfverfahren (ISO 11979-3:1999, modifiziert)

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Contents

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Foreword

This European Standard has been prepared by 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of an identical text or by endorsement, at the latest by December 2000, and conflicting national standards shall be withdrawn at the latest by December 2000.

European Standard EN 13503 was developed by CEN/TC 170, *Ophthalmic optics*, in cooperation with ISO/TC 172/SC 7, *Ophthalmic optics and instruments*, and is published in several 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

EN 13503 is the modified ISO 11979. The main difference between both series of standards is that ISO 11979 is based on the reference to ISO 14155 *Clinical investigation of medical devices* while EN 13503 is based on the reference to EN 540 *Clinical investigation of medical devices for human subjects*.

Compared with ISO 11979-3 the present European Standard EN 13503-3 does not contain the informative annex detailing mechanical data analysis (Annex I of ISO 11979-3).

Modifications of ISO 11979-3 are indicated as follows:
- text which has been deleted is striked out;
- text which has been changed or added is underlined.

Cross references to ISO 11979-3 are given where possible.

This Part 3 of EN 13503 contains seven normative annexes, A to G, and one informative annex, Annex H.

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.

Endorsement notice

The text of the draft International Standard ISO 11979-3:1999 was approved by CEN as a draft European Standard with agreed commun modifications as given in the Foreword and indicated in the text by strike-out and underlining.

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Introduction

This part of ~~ISO 11979~~ EN 13503 contains methods for which requirements are given and methods for which no requirements are formulated. The former are considered essential for the safety or performance of the intraocular lens, while the latter provide essential information to the ophthalmic surgeon or are used for other purposes.

A special purpose is the use of mechanical data to assess the need for clinical investigation of modifications of existing models as described in ~~ISO 11979-7~~ EN 13503-7 [1]. ~~Because of the complexity of this analysis detailed descriptions and examples have been given in Annex I.~~

Due to the wide variety of intraocular lens designs already on the market, it has not been possible to devise test methods that are applicable to every design under all circumstances. It can be anticipated that new materials currently under development will result in drastically new designs that will require modified or other test methods. As with all standards it is then up to the parties using the standard to modify or develop corresponding methods, and give rationale and validation for them in a spirit that is consistent with this ~~International~~ European Standard.

In the cases where different tolerances have been given depending on material or design they reflect an already existing situation with well established products.

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 European and International Standards on the clinical investigation of intraocular lenses. As a result, two different standards series have had to be prepared. It is the intention of CEN/TC 170 and ISO/TC 172/SC 7 to revise these standards with the goal to end up with identical ones as soon as identical ISO and CEN horizontal standards on clinical investigation become available.

1 Scope

This part of ~~ISO 11979~~ EN 13503 specifies requirements and test methods for certain mechanical properties of intraocular lenses (IOLs).

It is applicable to all types of IOLs intended for implantation in the anterior segment of the human eye, excluding corneal implants, provided that the test method is appropriate to the particular design.

NOTE: For certain designs and certain applications, a specific test method described in this part of ~~ISO 11979~~ EN 13503 may not be applicable. In such instances the IOL manufacturer should devise corresponding test methods and provide validation and rationale for them.

2 Normative references

This European Standard incorporates by dated or undated references, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

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

EN ISO 11979-2:1999, Ophthalmic implants - Intraocular lenses - Part 2: Optical properties and test methods.

EN ISO 11979-4:2000, Ophthalmic implants - Intraocular lenses - Part 4: Labelling and information.

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