



NSAI
Standards

Irish Standard
I.S. EN ISO 11979-3:2012

Ophthalmic implants - Intraocular lenses - Part 3: Mechanical properties and test methods (ISO 11979-3:2012)

I.S. EN ISO 11979-3:2012

Incorporating amendments/corrigenda/National Annexes issued since publication:

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S.R. xxx: Standard Recommendation - recommendation based on the consensus of an expert panel and subject to public consultation.

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English Version

Ophthalmic implants - Intraocular lenses - Part 3: Mechanical properties and test methods (ISO 11979-3:2012)

Implants ophtalmiques - Lentilles intraoculaires - Partie 3:
Propriétés mécaniques et méthodes d'essai (ISO 11979-3:2012)

Ophthalmische Implantate - Intraokularlinsen - Teil 3:
Mechanische Eigenschaften und Prüfverfahren (ISO 11979-3:2012)

This European Standard was approved by CEN on 30 November 2012.

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Foreword

This document (EN ISO 11979-3:2012) 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 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of an identical text or by endorsement, at the latest by June 2013, and conflicting national standards shall be withdrawn at the latest by June 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11979-3:2006.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

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INTERNATIONAL
STANDARD

ISO
11979-3

Third edition
2012-12-01

**Ophthalmic implants — Intraocular
lenses —**
Part 3:
Mechanical properties and test methods

Implants ophtalmiques — Lentilles intraoculaires —
Partie 3: Propriétés mécaniques et méthodes d'essai



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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.

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ISO 11979-3 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 11979-3:2006), which has been technically revised in order to include relevant requirements and test methods for toric intraocular lenses and accommodating intraocular lenses.

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*

Introduction

This part of ISO 11979 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^[7]. Because of the complexity of this analysis, detailed descriptions and examples have been given in ISO/TR 22979^[8]. 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 part of ISO 11979.

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

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