Irish Standard
I.S. EN ISO 11979-7:2014

Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations (ISO 11979-7:2014)

I.S. EN ISO 11979-7:2014

Incorporating amendments/corrigenda/National Annexes issued since publication:

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EUROPEAN STANDARD

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English Version

Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations (ISO 11979-7:2014)

Implants ophtalmiques - Lentilles intraoculaires - Partie 7: Investigations cliniques (ISO 11979-7:2014)

Ophthalmische Implantate - Intraokularlinsen - Teil 7: Klinische Prüfungen (ISO 11979-7:2014)

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Foreword

This document (EN ISO 11979-7:2014) 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of an identical text or by endorsement, at the latest by March 2015, and conflicting national standards shall be withdrawn at the latest by March 2015.

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 11979-7:2006.

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Endorsement notice

The text of ISO 11979-7:2014 has been approved by CEN as EN ISO 11979-7:2014 without any modification.

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INTERNATIONAL STANDARD

ISO 11979-7

Third edition
2014-09-01

Ophthalmic implants — Intraocular lenses —

Part 7: Clinical investigations

Implants ophtalmiques — Lentilles intraoculaires —

Partie 7: Investigations cliniques

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the third edition (ISO 11979-7:2006), which has been technically revised. It also incorporates the Amendment ISO 11979-7:2006/Amd1:2012 .

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 testing*

— *Part 7: Clinical investigations*

— *Part 8: Fundamental requirements*

— *Part 9: Multifocal intraocular 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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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, *Ophthalmic implants — Intraocular lenses — Part 10: Phakic intraocular lenses*

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

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 apply.

4 Justification for a clinical investigation

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 whether or not 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.