Irish Standard
I.S. EN ISO 11979-9:2006&A1:2014

Ophthalmic implants - Intraocular lenses - Part 9: Multifocal intraocular lenses (ISO 11979-9:2006)

I.S. EN ISO 11979-9:2006&A1:2014

Incorporating amendments/corrigenda/National Annexes issued since publication:

EN ISO 11979-9:2006/A1:2014

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Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11979-9:2006/A1

August 2014

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English Version

Ophthalmic implants - Intraocular lenses - Part 9: Multifocal intraocular lenses (ISO 11979-9:2006/Amd 1:2014)

Implants ophtalmiques - Lentilles intraoculaires - Partie 9: Lentilles intraoculaires multifocales (ISO 11979-9:2006/Amd 1:2014)

Ophthalmische Implantate - Intraokularlinsen - Teil 9: Multifokale Intraokularlinsen (ISO 11979-9:2006/Amd 1:2014)

This amendment A1 modifies the European Standard EN ISO 11979-9:2006; it was approved by CEN on 18 July 2014.

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Foreword

This document (EN ISO 11979-9:2006/A1:2014) 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 Amendment to the European Standard EN ISO 11979-9:2006 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2015, and conflicting national standards shall be withdrawn at the latest by February 2015.

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Endorsement notice

The text of ISO 11979-9:2006/Amd, 1:2014 has been approved by CEN as EN ISO 11979-9:2006/A1:2014 without any modification.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

Ophthalmic implants - Intraocular lenses - Part 9: Multifocal intraocular lenses (ISO 11979-9:2006)

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Foreword

This document (EN ISO 11979-9:2006) 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.

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Endorsement notice

The text of ISO 11979-9:2006 has been approved by CEN as EN ISO 11979-9:2006 without any modifications.

INTERNATIONAL STANDARD

ISO 11979-9

First edition
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Ophthalmic implants — Intraocular lenses —

Part 9: Multifocal intraocular lenses

Implants ophtalmiques — Lentilles intraoculaires —

Partie 9: Lentilles intraoculaires multifocales

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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 11979-9 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, 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*

— *Part 9: Multifocal intraocular lenses*

— *Part 10: Phakic intraocular lenses*

Ophthalmic implants — Intraocular lenses —

Part 9:
Multifocal intraocular lenses

1 Scope

This part of ISO 11979 is applicable to any intraocular lens whose optic provides two or more rotationally symmetric powers and whose primary indication is the correction of aphakia with the added benefit of useful vision at more than one distance (e.g. far and near).

NOTE The term “near vision” as used in this part of ISO 11979 includes useful vision at a distance of claimed benefit; e.g. near and/or intermediate distances.

2 Normative references

The following referenced documents are indispensable for the application of this document. 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 11979-2, *Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods*

ISO 11979-3, *Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods*

ISO 11979-4, *Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information*

ISO 11979-7, *Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations*

ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

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, ISO 14155-1 and ISO 14155-2 apply.