

Ophthalmic implants — Intraocular lenses —

Part 10: Phakic intraocular lenses

ICS 11.040.70

National foreword

This British Standard is the UK implementation of EN ISO 11979-10:2006+A1:2014. It is identical to ISO 11979-10:2006, incorporating amendment 1:2014. It supersedes BS EN ISO 11979-10:2006, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted by Technical Committee CH/172, Ophthalmic optics, to Subcommittee CH/172/7, Eye implants.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

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intraocular lenses (ISO 11979-10:2006)

Implants ophtalmiques - Lentilles intraoculaires - Partie 10:
Lentilles intraoculaires phaques (ISO 11979-10:2006)

Ophthalmische Implantate - Intraokularlinsen - Teil 10:
Phake Intraokularlinsen (ISO 11979-10:2006)

This European Standard was approved by CEN on 7 August 2006.

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Foreword

This document (EN ISO 11979-10:2006) 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.

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of an identical text or by endorsement, at the latest by February 2007, and conflicting national standards shall be withdrawn at the latest by February 2007.

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Endorsement notice

The text of ISO 11979-10:2006 has been approved by CEN as EN ISO 11979-10:2006 without any modifications.

Foreword to amendment A1

This document (EN ISO 11979-10:2006/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 11979-10:2006 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.

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.

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Endorsement notice

The text of ISO 11979-10:2006/A1:2014 has been approved by CEN as EN ISO 11979-10:2006/A1:2014 without any modification.

INTERNATIONAL STANDARD

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Ophthalmic implants — Intraocular lenses —

Part 10: Phakic intraocular lenses

*Implants ophtalmiques — Lentilles intraoculaires —
Partie 10: Lentilles intraoculaires phaques*



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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 11979-10 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 10: Phakic intraocular lenses

1 Scope

This part of ISO 11979 is applicable to any intraocular lens (IOL) whose primary indication is the modification of the refractive power of a phakic eye ^{A1}. ^{A1}

This part of ISO 11979 addresses specific requirements for PIOLs not addressed in the other parts of ISO 11979.

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*

^{A1} Text deleted ^{A1}

^{A1} ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice* ^{A1}

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11979-1 ^{A1} ISO 14155 applies. ^{A1}

4 Optical requirements

^{A1} The requirements of ISO 11979-2 apply. ^{A1}