INTERNATIONAL STANDARD

ISO 11979-8

Second edition
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Ophthalmic implants — Intraocular lenses —

Part 8: Fundamental requirements

Implants ophtalmiques — Lentilles intraoculaires —
Partie 8: Exigences fondamentales

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Foreword

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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.

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

ISO 11979-8 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 11979-8:1999) which has been technically revised.

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 8: Fundamental requirements

1 Scope

This part of ISO 11979 specifies fundamental requirements for all types of intraocular lenses intended for surgical implantation into the anterior segment of the human eye, excluding corneal implants and transplants.

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 9000, *Quality management systems — Fundamentals and vocabulary*

ISO 10993-7:1995, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

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 11979-5, *Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility*

ISO 11979-6, *Ophthalmic implants — Intraocular lenses — Part 6: Shelf-life and transport stability*

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

ISO 11979-9, *Ophthalmic implants — Intraocular lenses — Part 9: Multifocal intraocular lenses*

ISO 11979-10, *Ophthalmic implants — Intraocular lenses — Part 10: Phakic intraocular lenses*

ISO 14155-1:2003, *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 14630:2005, *Non-active surgical implants — General requirements*

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 apply.

4 Safety and performance

The safety and performance of an intraocular lens shall be demonstrated by pre-clinical and clinical evaluation, including suitable risk analysis in accordance with ISO 14971.

In cases where a test method referenced in this part of ISO 11979 is not suitable for a certain design or a certain application, an alternative test method devised by the manufacturer shall be validated (see definition in ISO 9000), justified and documented.

5 Optical and mechanical properties

The manufacturer shall ensure that the intraocular lens conforms to applicable requirements in ISO 11979-2, ISO 11979-3, ISO 11979-9 and ISO 11979-10. The manufacturer shall record and justify any deviations from those standards.

6 Biocompatibility

The manufacturer shall have documented evidence that demonstrates the intraocular lens to be biocompatible by assessment in accordance with ISO 11979-5.

Manufacturers should take into consideration previous experience and data when determining the extent of further biocompatibility testing. See [1] for guidance on testing for biocompatibility.

7 Clinical evaluation

The first step in the clinical evaluation is a review of the available literature (published and unpublished) in order to determine if that information is sufficient to demonstrate the safety and performance of the intraocular lens (see Annex A of ISO 14155-1:2003). One option is to demonstrate that the new intraocular lens model is a minor modification of a model the safety and performance of which has previously been demonstrated.

NOTE Reference [2] provides a framework for assessment of whether or not a modification is minor for intraocular lenses for the correction of aphakia.

If the clinical evaluation identifies the need for a clinical investigation the requirements of ISO 14155-1 and ISO 14155-2 shall apply. In addition the following standards apply depending on the type of the intraocular lens:

a) for monofocal intraocular lenses for the correction of aphakia ISO 11979-7;

b) for multifocal intraocular lenses for the correction of aphakia ISO 11979-9;

c) for phakic monofocal intraocular lenses ISO 11979-10.

8 Manufacturing

Clause 8 of ISO 14630:2005 shall apply.

9 Sterilization

9.1 General

Clause 9 of ISO 14630:2005 shall apply with the following addition to 9.4 of that International Standard for intraocular lenses sterilized by ethylene oxide:

a) for the assay of the residue of ethylene oxide, an exhaustive solvent or head space extraction method shall be chosen;

b) the amount of residue of ethylene oxide shall conform with the requirements for intraocular lenses given in ISO 10993-7;

c) the residue of ethylene chlorohydrin shall not exceed a release of more than 2,0 µg per lens per day and not exceed 5,0 µg in total per lens.

For solvent extraction, a solvent affording exhaustive extraction should be chosen, e.g. one that adequately swells the lens material without disrupting the material itself. For headspace extraction, efficiency of extraction should be demonstrated by validation against an exhaustive solvent extraction method. In case the extraction is not exhaustive, release criteria should be lowered in proportion to the relative efficiency of the method. Supplementary guidance can be found in ISO 10993-7 and in Reference [3].

NOTE The level of ethylene glycol is correlated to the levels of ethylene oxide and ethylene chlorhydrin present. If the levels of ethylene oxide and ethylene chlorhydrin are within the limits set in b) and c), the level of ethylene glycol will be sufficiently low that there is no need to quantify it.

9.2 Bacterial endotoxins

The level of biological contamination shall be determined using a validated method for bacterial endotoxin testing in accordance with applicable pharmacopoeia [4][5][6].

The endotoxin level shall, on average, be 2,0 endotoxin units or less per lens. Lenses shall be extracted with endotoxin-free water, and test method and number of lenses per volume of water shall be chosen such that the test is sufficiently accurate to assure this level.

10 Packaging and shelf-life

The packaging shall meet the requirements of ISO 11979-6.

NOTE National and regional regulation can impose additional requirements.

11 Labelling and information

The intraocular lens as marketed shall be supplied with labelling and information in accordance with ISO 11979-4, ISO 11979-9 and ISO 11979-10 as applicable.

NOTE National and regional legislation can require additional labelling and information.

12 Documentation

All primary data, calculations, results, and reports shall be documented and kept on file by the manufacturer for as long as required by regulations.

Bibliography

[1] ISO 10993-1:2003, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

[2] ISO TR 22979, *Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications*

[3] AAMI TIR No. 19:1998, *Guidance for ANSI/AAMI/ISO 10993-7:1995, Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

[4] European Pharmacopoeia, Appendix XIV C. *Test for Bacterial Endotoxins*

[5] Japanese Pharmacopoeia, XIV 6. *Bacterial Endotoxins Test*

[6] United States Pharmacopoeia, <85> *Bacterial Endotoxins Test*