INTERNATIONAL STANDARD

ISO 11979-8

First edition
1999-08-01

Ophthalmic implants — Intraocular lenses —

Part 8:
Fundamental requirements

Implants ophtalmiques — Lentilles intraoculaires —
Partie 8: Exigences fondamentales

Reference number
ISO 11979-8:1999(E)

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 3.

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.

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

ISO 11979 consists of the following parts, under the general title *Ophthalmic implants — Intraocular lenses*:

— *Part 1: Terminology*

— *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*

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet iso@iso.ch

Printed in Switzerland

Introduction

This part of ISO 11979 provides fundamental requirements of a general nature for intraocular lenses. It refers to other standards applicable to intraocular lenses for specific methods and requirements.

It always was and still is the intention of Technical Committees ISO/TC 172/SC 7 and CEN/TC 170 to prepare identical ISO and CEN (European Committee for Standardization) standards on intraocular lenses. However, during the preparation of Part 7 of this series, problems were encountered with normative references to the existing ISO 14155 and EN 540 horizontal standards on clinical investigation of medical devices, which are similar but not identical.

ISO and CEN principles concerning normative references made it impossible to continue the preparation of identical International and European Standards on the clinical investigation of intraocular lenses. As a result, two different standards series have had to be prepared. It is the intention of ISO/TC 172/SC 7 and CEN/TC 170 to revise these standards with the goal to end up with identical ones as soon as identical ISO and CEN horizontal standards become available.

Ophthalmic implants — Intraocular lenses —

Part 8:
Fundamental requirements

1 Scope

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

NOTE If a test method contained in an International Standard referenced by this part of ISO 11979 is not suitable for a certain design or for a certain application, the manufacturer may devise an alternative test method if validation and rationale for that method are documented.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 11979. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11979 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

ISO 11979-1:—[1)], *Ophthalmic implants — Intraocular lenses — Part 1: Terminology.*

ISO 11979-2:—[1)], *Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods.*

ISO 11979-3: —[1)], *Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods.*

ISO 11979-4:—[1)], *Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information.*

ISO 11979-5:—[1)], *Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility.*

ISO 11979-6:—[1)], *Ophthalmic implants — Intraocular lenses — Part 6: Shelf-life and transport stability.*

ISO 11979-7:—[1)], *Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations.*

3 Terms and definitions

For the purposes of this part of ISO 11979, the terms and definitions given in ISO 11979-1 apply.

---

1) To be published.

4 Safety and performance

The safety of the IOL shall be demonstrated by pre-clinical and clinical evaluation, including suitable risk analysis.

The manufacturer shall ensure that the IOL conforms to applicable requirements in ISO 11979-2 and ISO 11979-3. The manufacturer shall record and justify any deviations from ISO 11979-2 and ISO 11979-3.

In addition, all information shall be retained by the manufacturer in compliance with applicable regulatory requirements.

5 Materials

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

NOTE Manufacturers should take into consideration previous clinical experience and data when determining the extent of further pre-clinical testing (see also clause 6). See ISO 10993-1 for guidance on testing for biocompatibility.

6 Clinical evaluation

The IOL shall be demonstrated to be clinically safe and effective by one of the following:

a) having undergone clinical evaluation in accordance with ISO 11979-7;

b) being supported by retrospective data which provide a level of assurance of safety and effectiveness which is equivalent to a clinical assessment in accordance with ISO 11979-7;

c) being a minor modification of a parent model for which safety and effectiveness has been established in accordance with ISO 11979-7.

NOTE Examples of modifications that may be considered minor are given in ISO 11979-7.

7 Manufacturing

Intraocular lenses shall be manufactured in accordance with documented specified design attributes.

8 Sterilization

The manufacturer shall ensure that the IOL in its packaging (see clause 9) will maintain its sterility up to the expiration date stated.

NOTE EN 556 gives requirements for terminally sterilized medical devices to be labelled "Sterile". The current International Standards describing procedures for validating methods of sterilization are:

a) steam sterilization (ISO 11134 and EN 554);

b) ethylene oxide sterilization (ISO 11135 and EN 550); and

c) radiation sterilization (ISO 11137 and EN 552).

Whichever method of sterilization is used, the manufacturer shall have documented evidence to demonstrate both the effectiveness of the method and its validation.

9 Packaging and shelf-life

The packaging shall be so designed that, under conditions specified by the manufacturer for storage, transport and handling, the IOL will be protected against damage and deterioration which would impair its safety in use (see requirements in ISO 11979-6). In addition, the packaging shall be so designed that, at the expiration date, the IOL will still conform to clauses 4 and 8 of this part of ISO 11979.

10 Labelling and information

The IOL as marketed shall be supplied with labelling and information in accordance with ISO 11979-4.

Bibliography

[1] ISO 10993-1:1997, *Biological evaluation of medical devices — Part 1: Evaluation and testing.*

[2] ISO 11134:1994, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization.*

[3] ISO 11135:1994, *Medical devices — Validation and routine control of ethylene oxide sterilization.*

[4] ISO 11137:1995, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization.*

[5] EN 550:1994, *Sterilization of medical devices — Validation and routine control of ethylene oxide sterilization.*

[6] EN 552:1994, *Sterilization of medical devices — Validation and routine control of sterilization by irradiation.*

[7] EN 554:1994, *Sterilization of medical devices — Validation and routine control of sterilization by moist heat.*

[8] EN 556:1994, *Sterilization of medical devices — Requirements for medical devices to be labelled "Sterile".*