INTERNATIONAL STANDARD

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Second edition
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Ophthalmic implants — Intraocular lenses —

Part 4: Labelling and information

Implants ophtalmiques — Lentilles intraoculaires —

Partie 4: Étiquetage et informations

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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 11979-4 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 11979-4:2000), 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*

Introduction

This part of ISO 11979 contains requirements and guidance for the labelling of intraocular lenses and the information supplied with them.

Labelling requirements for medical devices in general are given in EN 1041. However, in order to ensure correct and necessary information to the ophthalmic surgeon, some additional information is required for intraocular lenses. This information concerns technical and optical data as well as information about materials used.

Ophthalmic implants — Intraocular lenses —

Part 4:
Labelling and information

1 Scope

This part of ISO 11979 specifies the labelling requirements for intraocular lenses (IOLs) and the information to be provided within or on the packaging.

NOTE This part of ISO 11979 attempts to harmonize the recognized labelling requirements for IOLs throughout the world. However, there might be additional national requirements.

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 11979-9:2006, *Ophthalmic implants — Intraocular lenses — Part 9: Multifocal intraocular lenses*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

EN 980, *Symbols for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer with medical devices*

3 Terms and definitions

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

4 Information provision

The general requirements for information provision provided with medical devices by manufacturers included in EN 1041 shall be taken into account.

5 Labelling

Table 1 lists minimal information that shall be included with the labelling of IOLs and whereabouts on the packaging it shall be given. Table 2 lists information that shall be given in applicable cases.

Table 1 — Information that shall be included with the packaging of IOLs

Item	Information	Primary package [a, b] and/or additional wrapping(s)	Storage container [b]	Comments
1	Name or trade name of the manufacturer [c]	X	X	The manufacturer's logotype may be added.
2	Address of the manufacturer and country of manufacture		X	
3	Trade name and/or model designation of the product	X	X	
4	Batch code or serial number	X	X	Symbols may be used.
5	The word “STERILE”	X	X [d]	Symbols may be used.
6	Method of sterilization		X	Symbols may be used.
7	The statement “Do not resterilize”		X	
8	The statement “For single use”		X	Symbols may be used.
9	Expiration date (year and month; format: YYYY MM)		X	Symbols may be used.
10	Dioptric power	X	X	The unit is m^{-1}; in ocular optics often denoted by the special symbol D.
11	Overall diameter, in millimetres	X	X	May be indicated by the symbol ∅ or in a drawing.
12	Diameter (minimum and maximum dimensions, if non-circular) of the body, in millimetres	X	X	May be indicated in a drawing.
13	Drawing depicting the configuration of the lens		X	
14	Statement about intended placement		X	For instance: anterior chamber; posterior chamber; in the bag; etc.
15	Information aiding the surgeon to calculate the dioptric power to implant		X	Currently, there is no standardized methodology available.
16	Information on the recommended storage conditions for the lens		X	To be included where specific storage conditions are required.

[a] There are different systems in use with regard to primary container and additional wrapping(s). The information listed in the column is to be given on the appropriate component as to guarantee safe use and proper handling of the device.

[b] In ISO 11607-1 and ISO 11607-2 “primary package” is now “sterile barrier system”; “storage container” is now “protective packaging”.

[c] See definition of “manufacturer” in ISO 11979-1.

[d] If a statement about sterility is made on the storage container, it is to read “contains (number) sterile IOL(s)”, if the storage container contains more than one IOL.

Table 2 — Information that shall be included with the packaging of IOLs in applicable cases

Item	Information	Primary package and/or additional wrapping(s)	Storage container	Comments
17	Additional descriptions the manufacturer wishes to provide		X	For instance: about optic shape, type and material; haptic type and material; UV-absorber; foldable; etc.
18	Statement “Custom made device”		X	
19	Statement “Exclusively for clinical investigation”		X	
20	For multifocal intraocular lenses: base power and add power(s)		X	

6 Package insert

The package insert, in the form of a leaflet or similar, shall be included in the storage container in such a way that it can be consulted without damage to the sterile packaging. It shall contain at least the following information.

a) name or trade name and address of the manufacturer;

b) detailed description of the lens including material(s) used;

c) method of sterilization;

d) conditions of storage and transport (if appropriate);

e) instructions for the removal of the IOL from the primary container;

f) instructions for use;

NOTE European Directive 93/42/EEC as amended by Directive 2007/47/EC requires date of issue or the latest revision of the instructions for use for medical devices sold in Europe.

g) indication(s) of the circumstances under which the IOL can be used;

h) contra-indication(s) of the circumstances under which the IOL should not be used;

i) complication(s) that may occur;

j) warning not to implant the IOL if the container which maintains sterility has been opened or damaged;

k) warning not to re-use the IOL;

l) warning not to re-sterilize the IOL;

m) for multifocal and phakic intraocular lenses, a summary of the results of the clinical investigation, if any;

n) for multifocal intraocular lenses, a graph of the MTF (modulation transfer function) through focus response performance of the intraocular lens in the model eye, using the conditions described in Annex A of ISO 11979-9:2006; informative text shall accompany the figure explaining that the MTF values in the graph describe the lens' optical performance in a standardized eye model at 50 c/mm as the focus is gradually shifted from that of a far object to increasingly near objects and that higher numbers indicate

better performance, and a graph of spectral transmittance through the lens in the range of 300 nm to 1 100 nm (see also ISO 11979-2);

o) for phakic intraocular lenses, recommendations for periodic evaluations after implantation, based on risk analysis and/or any clinical investigation performed, and a restriction in the indications for use if necessitated by the anatomical clearance analysis and clinical evaluation;

p) other appropriate warning(s).

7 Self-adhesive label

If supplied, a self-adhesive label shall contain at least the following information.

a) name or trade name of the manufacturer;

b) trade name and/or model designation of the product;

c) batch code or serial number (symbols may be used);

d) dioptric power;

e) add power (for multifocal IOLs);

f) overall diameter (may be indicated by the symbol ∅ or in a drawing);

g) diameter of the body (minimum and maximum dimensions, if non-circular); this can be indicated in a drawing.

8 Use of symbols

Symbols can be used instead of text where appropriate. When symbols are used, ISO 15223-1 or EN 980, depending on region, apply.

Bibliography

[1] ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

[2] ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

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