Irish Standard
I.S. EN ISO 11979-4:2008

Ophthalmic implants - Intraocular lenses - Part 4: Labelling and information (ISO 11979-4:2008)

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English Version

Ophthalmic implants - Intraocular lenses - Part 4: Labelling and information (ISO 11979-4:2008)

Implants ophtalmiques - Lentilles intraoculaires - Partie 4: Étiquetage et informations (ISO 11979-4:2008)

Ophthalmische Implantate - Intraokularlinsen - Teil 4: Etikettierung und Information (ISO 11979-4:2008)

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Foreword

This document (EN ISO 11979-4:2008) 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of an identical text or by endorsement, at the latest by June 2009, and conflicting national standards shall be withdrawn at the latest by June 2009.

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.

This document supersedes EN ISO 11979-4:2000.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 11979-4:2008 has been approved by CEN as a EN ISO 11979-4:2008 without any modification.

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I.S. EN ISO 11979-4:2008

INTERNATIONAL STANDARD

ISO 11979-4

First 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

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.

Attention is drawn to the possibility that some of the elements of this part of ISO 11979 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11979-4 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: 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*

Annex A of this part of ISO 11979 is for information only.

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 provide 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 the materials used.

NOTE It always was and still is the intention of the 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. For this part of ISO 11979, identical versions exist for ISO and CEN (ISO 11979-4 and EN ISO 11979-4). For those parts where no identical versions exist, 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 on clinical investigations become available.

INTERNATIONAL STANDARD **ISO 11979-4:2000(E)**

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 may be additional national requirements.

2 Normative reference

The following normative document contains 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 edition of the normative document 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 11979-1:1999, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary*.

3 Terms and definitions

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

NOTE Some terms and definitions of ISO 11979-1 relevant to this part of ISO 11979 are reproduced for information in annex A.

4 Labelling

Table 1 lists minimal information that shall be included in the labelling of intraocular lenses and indicates where on the packaging it shall be given. Table 2 lists additional information that shall be given if applicable.