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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 170, *Ophthalmic optics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 11979-4:2008), which has been technically revised. It also incorporates the Amendment ISO 11979-4:2008/Amd.1:2012.

The main changes are as follows:

— normative references have been updated and retired standards have been removed or replaced;

— Table 1 has been updated with additional information to be included in the packaging; e.g. expiration date on primary package;

— new categories and clinical requirements for SVIOLs were published in ISO 11979-7. ISO 11979-4 is updated to reflect these changes also in labelling;

— information can be provided electronically if national regulations allow.

A list of all parts in the ISO 11979 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Labelling requirements for medical devices in general are given in ISO 20417[5]. However, in order to ensure correct and necessary information to the ophthalmic surgeon, additional specific information is required for intraocular lenses. Such information concerns technical and optical data as well as information about the materials used.

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Ophthalmic implants — Intraocular lenses —

Part 4: Labelling and information

1 Scope

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

NOTE This document attempts to harmonize the recognized labelling requirements for IOLs throughout the world. However, there can be additional national requirements.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 11979-7, *Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations of intraocular lenses for the correction of aphakia*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

4 Labelling, instruction for use and labels

4.1 Labelling

Table 1 lists the minimal information that shall be included with the labelling of IOLs and the location on the packaging where labelling shall be presented. It further lists information that shall be given in applicable cases.

The information may be supplied electronically where regulations allow.

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