



**International  
Standard**

**ISO 11979-4**

**Ophthalmic implants — Intraocular  
lenses —**

**Part 4:  
Labelling and information**

*Implants ophtalmiques — Lentilles intraoculaires —  
Partie 4: Étiquetage et informations*

**Third edition  
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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](http://www.iso.org/directives)).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at [www.iso.org/patents](http://www.iso.org/patents). ISO shall not be held responsible for identifying any or all such patent rights.

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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](http://www.iso.org/members.html).

## Introduction

Labelling requirements for medical devices in general are given in ISO 20417<sup>[5]</sup>. 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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