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Ophthalmic implants — Intraocular lenses —

Part 5: Biocompatibility

*Implants ophtalmiques — Lentilles intraoculaires —
Partie 5: Biocompatibilité*



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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.

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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 11979-5 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 11979-5:1999), 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*

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Introduction

This part of ISO 11979 follows the general principles given in ISO 10993-1. ISO 10993-1 describes the principles governing the biological evaluation of medical devices, the definitions of categories based on the nature and duration of contact with the body, and selection of appropriate tests. Other parts of ISO 10993 present biological test methods, tests for ethylene oxide residues, tests for degradation and principles for sample preparation.