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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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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*

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## 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.