International Standard

ISO 11979-4

# Ophthalmic implants — Intraocular lenses —

## Part 4: Labelling and information

*Implants ophtalmiques — Lentilles intraoculaires —*

*Partie 4: Étiquetage et informations*

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# Contents

Page

# Foreword

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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.

# 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.