

Australian Standard™

Ophthalmic implants—Intraocular lenses

Part 8: Fundamental requirements



This Australian Standard was prepared by Committee HE-012, Surgical Implants. It was approved on behalf of the Council of Standards Australia on 16 May 2003 and published on 30 June 2003.

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Australian Chamber of Commerce and Industry
Australian College of Operating Room Nurses
Australian Dental Association
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Australian Orthopaedic Association
Australian Society for Biomaterials
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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee HE-012, Surgical Implants. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard.

This Standard is identical with and has been reproduced from ISO 11979-8:1999, *Ophthalmic implants—Intraocular lenses—Part 8: Fundamental requirements*.

The objective of this Standard is to specify fundamental requirements for all types of intraocular lenses intended for surgical implantation into the anterior segment of the human eye, excluding corneal implants and transplants.

The terms ‘normative’ and ‘informative’ are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas an informative annex is only for information and guidance.

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<i>Reference to International Standard</i>	<i>Australian Standard</i>
ISO	AS ISO
10993 Biological evaluation of medical devices	10993 Biological evaluation of medical devices
10993-7 Part 7: Ethylene oxide sterilization residuals	10993.7 Part 7: Ethylene oxide sterilization residuals
11979 Ophthalmic implants—Intraocular lenses	11979 Ophthalmic implants—Intraocular lenses
11979-1 Part 1: Vocabulary	11979.1 Part 1: Vocabulary
11979-2 Part 2: Optical properties and test methods	11979.2 Part 2: Optical properties and test methods
11979-3 Part 3: Mechanical properties and test methods	11979.3 Part 3: Mechanical properties and test methods
11979-4 Part 4: Labelling and information	11979.4 Part 4: Labelling and information
11979-5 Part 5: Biocompatibility	11979.5 Part 5: Biocompatibility
11979-6 Part 6: Shelf-life and transport stability	11979.6 Part 6: Shelf-life and transport stability
11979-7 Part 7: Clinical investigations	11979.7 Part 7: Clinical investigations