AS ISO 11979.5—2003
ISO 11979-5:1999

Australian Standard™

Ophthalmic implants—Intraocular lenses

Part 5: Biocompatibility

Standards Australia

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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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 11979-5:1999, *Ophthalmic implants—Intraocular lenses—Part 5: Biocompatibility.*

The objective of this Standard is to specify particular requirements for the biological evaluation of intraocular lenses which are in addition to the requirements outlined in the relevant parts of ISO 10993. It also gives guidance on conducting an ocular implantation test.

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.

As this Standard is reproduced from an international Standard, the following applies:

(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text 'this International Standard' should read 'this Australian Standard'.

(c) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards as follows:

Reference to International Standard		*Australian Standard*	
ISO		AS ISO	
10993	Biological evaluation of medical devices	10993	Biological evaluation of medical devices
10993-1	Part 1: Evaluation and testing	10993.1	Part 1: Evaluation and testing
10993-6	Part 6: Tests for local effects after implantation	10993.6	Part 6: Tests for local effects after implantation
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

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INTRODUCTION

ISO 10993-1 indicates the fundamental principles governing the biological evaluation of medical devices, the definition 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.

NOTE It always was and still is the intention of the Technical Committees ISO/TC 172/SC 7 and CEN/TC 170 to prepare identical ISO and CEN (European Committee for Standardization) standards on intraocular lenses. However, during the preparation of part 7 of this series, problems were encountered with normative references to the existing ISO 14155 and EN 540 horizontal standards on clinical investigation of medical devices, which are similar but not identical.

ISO and CEN principles concerning normative references made it impossible to continue the preparation of identical International and European Standards on the clinical investigation of intraocular lenses. As a result, two different standards series have had to be prepared. It is the intention of ISO/TC 172/SC 7 and CEN/TC 170 to revise these standards with the goal to end up with identical ones as soon as identical ISO and CEN horizontal standards on clinical investigations become available.

AUSTRALIAN STANDARD

Ophthalmic implants—Intraocular lenses

Part 5: Biocompatibility

1 Scope

This part of ISO 11979 specifies particular requirements for the the biological evaluation of intraocular lenses (IOLs) which are in addition to the requirements outlined in the relevant parts of ISO 10993. It also gives guidance on conducting an ocular implantation test.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 11979. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11979 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 10993-1:1997, *Biological evaluation of medical devices — Part 1: Evaluation and testing*.

ISO 10993-6:1994, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*.

ISO 11979-1:1999 , *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary*.

ISO 11979-2:—[1)], *Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods*.

ISO 11979-3:1999, *Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods*.

ISO 14971-1:1998, *Medical devices — Risk management — Part 1: Application of risk analysis*.

3 Terms and definitions

For the purposes of this part of ISO 11979, the terms and definitions given in ISO 11979-1 apply.

NOTE Some definitions from ISO 11979-1 are reproduced for information in annex E.

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