AS ISO 11979.8—2003
ISO 11979-8:1999

Australian Standard™

Ophthalmic implants—Intraocular lenses

Part 8: Fundamental requirements

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.

The following are represented on Committee HE-012:

Australian Chamber of Commerce and Industry

Australian College of Operating Room Nurses

Australian Dental Association

Australian Industry Group

Australian Orthopaedic Association

Australian Society for Biomaterials

Commonwealth Department of Health and Ageing

Department of Defence (Australia)

Medical Industry Association of Australia Inc

Neurological Society of Australasia

Royal Australasian College of Surgeons

Royal Perth Hospital

University of New South Wales

University of Sydney

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about Standards can be found by visiting the Standards Australia web site at www.standards.com.au and looking up the relevant Standard in the on-line catalogue.

Alternatively, the printed Catalogue provides information current at 1 January each year, and the monthly magazine, *The Global Standard*, has a full listing of revisions and amendments published each month.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.com.au, or write to the Chief Executive, Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001.

This Standard was issued in draft form for comment as DR 03113.

Australian Standard™

Ophthalmic implants—Intraocular lenses

Part 8: Fundamental requirements

First published as AS ISO 11979.8—2003.

COPYRIGHT

© Standards Australia International

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher.

Published by Standards Australia International Ltd
GPO Box 5420, Sydney, NSW 2001, Australia

ISBN 0 7337 5335 3

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.

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
10993-7	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

INTRODUCTION

This part of ISO 11979 provides fundamental requirements of a general nature for intraocular lenses. It refers to other standards applicable to intraocular lenses for specific methods and requirements.

It always was and still is the intention of 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 become available.

NOTES

AUSTRALIAN STANDARD

Ophthalmic implants—Intraocular lenses

Part 8: Fundamental requirements

1 Scope

This part of ISO 11979 specifies fundamental requirements for all types of intraocular lenses (IOLs) intended for surgical implantation into the anterior segment of the human eye, excluding corneal implants and transplants.

NOTE If a test method contained in an International Standard referenced by this part of ISO 11979 is not suitable for a certain design or for a certain application, the manufacturer may devise an alternative test method if validation and rationale for that method are documented.

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 10993-7:1995, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals.*

ISO 11979-1:—[1)], *Ophthalmic implants — Intraocular lenses — Part 1: Terminology.*

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

ISO 11979-3: —[1)], *Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods.*

ISO 11979-4:—[1)], *Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information.*

ISO 11979-5:—[1)], *Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility.*

ISO 11979-6:—[1)], *Ophthalmic implants — Intraocular lenses — Part 6: Shelf-life and transport stability.*

ISO 11979-7:—[1)], *Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations.*

3 Terms and definitions

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

---

1) To be published.

© Standards Australia