

Australian Standard™

**Ophthalmic optics—Contact lenses and
contact lens care products—
Fundamental requirements**

This Australian Standard was prepared by Committee MS-063, Contact lenses. It was approved on behalf of the Council of Standards Australia on 21 May 2003 and published on 30 June 2003.

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Board of Optometrical Registration (NSW)
Commonwealth Department of Health and Ageing
Consumers' Federation of Australia
Contact Lens Society of Australia
Medical Industry Association of Australia Inc
Optical Dispensers Licensing Board of NSW
Optical Distributors and Manufacturers Association of Australia
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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/ Standards New Zealand Committee MS-063, Contact Lenses. 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 14534:2002, *Ophthalmic optics—Contact lenses and contact lens care products—Fundamental requirements*.

The objective of this Standard is to specify safety and performance requirements for contact lenses, contact lens care products and other accessories for contact lenses.

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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- (a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.
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References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards as follows:

<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
10993-1	Part 1: Evaluation and testing	10993.1	Part 1: Evaluation and testing

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INTRODUCTION

Currently, contact lenses and contact lens care products are regulated in different ways in different countries. This International Standard was mandated by the Commission of the European Communities to CEN and was originally developed by a joint ISO/CEN working group to ensure a global input; its first edition was published in 1997. Other requirements may now be needed in certain countries outside the European Union. It is hoped that the adoption of the current revision of this International Standard will be yet another step towards the harmonization of standards and mutual recognition.

AUSTRALIAN STANDARD

**Ophthalmic optics—Contact lenses and contact lens care products—
Fundamental requirements****1 Scope**

This International Standard specifies safety and performance requirements for contact lenses, contact lens care products and other accessories for contact lenses.

This International Standard does not specify electrical safety and electromagnetic compatibility considerations that might arise from the use of electrical equipment in conjunction with contact lenses and/or contact lens care products.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard 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 8320-1:—¹⁾, *Contact lenses and contact lens care products — Vocabulary — Part 1: Contact lenses*

ISO 8320-2, *Contact lenses and contact lens care products — Vocabulary — Part 2: Contact lens care products*

ISO 8321-1:—²⁾, *Ophthalmic optics — Specifications for material, optical and dimensional properties of contact lenses — Part 1: Rigid corneal and scleral contact lenses*

ISO 8321-2, *Ophthalmic optics — Specifications for material, optical and dimensional properties of contact lenses — Part 2: Single-vision hydrogel contact lenses*

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

ISO 11978, *Ophthalmic optics — Contact lenses and contact lens care products — Information supplied by the manufacturer*

ISO 11987, *Ophthalmic optics — Contact lenses — Determination of shelf-life*

ISO 13212, *Ophthalmic optics — Contact lens care products — Guidelines for determination of shelf-life*

ISO 14729:2001, *Ophthalmic optics — Contact lens care products — Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses*

1) To be published. (Revision in parts of ISO 8320:1986)

2) To be published. (Revision of ISO 8321-1:1991)