AS ISO 11979.4—2003
ISO 11979-4:2000

Australian Standard™

Ophthalmic implants—Intraocular lenses

Part 4: Labelling and information

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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Australian Dental Association

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Part 4: Labelling and information

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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 11979-4:2000, *Ophthalmic implants—Intraocular lenses—Part 4: Labelling and information.*

The objective of this Standard is to specify the labelling requirements for intraocular lenses and the information to be provided within or on the packaging.

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	
11979	Ophthalmic implants—Intraocular lenses	11979	Ophthalmic implants—Intraocular lenses
11979-1	Part 1: Vocabulary	11979.1	Part 1: Vocabulary

CONTENTS

INTRODUCTION

This part of ISO 11979 contains requirements and guidance for the labelling of intraocular lenses and the information supplied with them.

Labelling requirements for medical devices in general are given in EN 1041. However, in order to provide correct and necessary information to the ophthalmic surgeon, some additional information is required for intraocular lenses. This information concerns technical and optical data as well as information about the materials used.

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. For this part of ISO 11979, identical versions exist for ISO and CEN (ISO 11979-4 and EN ISO 11979-4). For those parts where no identical versions exist, 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 4: Labelling and information

1 Scope

This part of ISO 11979 specifies the labelling requirements for intraocular lenses (IOLs) and the information to be provided within or on the packaging.

NOTE This part of ISO 11979 attempts to harmonize the recognized labelling requirements for IOLs throughout the world. However, there may be additional national requirements.

2 Normative reference

The following normative document contains 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 edition of the normative document 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 11979-1:1999, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary*.

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 terms and definitions of ISO 11979-1 relevant to this part of ISO 11979 are reproduced for information in annex A.

4 Labelling

Table 1 lists minimal information that shall be included in the labelling of intraocular lenses and indicates where on the packaging it shall be given. Table 2 lists additional information that shall be given if applicable.