AS ISO 14630—2003
ISO 14630:1997

Australian Standard™

Non-active surgical implants—General 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 21 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
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Australian Standard™

Non-active surgical implants—General requirements

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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 14630:1997, *Non-active surgical implants—General requirements*, which was prepared by the European Committee for Standardization (CEN) Technical Committee TC 285, Non-active surgical implants, in collaboration with ISO Technical Committee TC 150, Implants for surgery, in accordance with the Vienna Agreement on technical cooperation between ISO and CEN.

The objective of this Standard is to specify general requirements for non-active surgical implants. It is not applicable to dental implants, dental restorative materials, transendodontic and transradicular implants and intra-ocular lenses. With regard to safety, this Standard gives requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests.

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.

Whilst Annex A is informative, Clause A.3 includes a list of normative referenced European Standards and their identical and technically related ISO Standards.

As this Standard is reproduced from a European 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 European Standard' should read 'this Australian Standard'.

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

References to International Standards and European 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
10993-7	Part 7: Ethylene oxide sterilization residuals	10993.7	Part 7: Ethylene oxide sterilization residuals
11134	Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization	11134	Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization
11135	Medical devices—Validation and routine control of ethylene oxide sterilization	11135	Medical devices—Validation and routine control of ethylene oxide sterilization

Reference to International Standard		*Australian Standard*	
ISO		AS ISO	
11137	Sterilization of health care products—Requirements for validation and routine control—Radiation sterilization	11137	Sterilization of health care products—Requirements for validation and routine control—Radiation sterilization
IEC		AS	
60068	Environmental testing	60068	Environmental testing
60068-2-27	Part 2: Tests—Test Ea and guidance: Shock	60068.2.27	Part 2.27: Tests—Test Ea and guidance: Shock
60068-2-32	Part 2: Tests—Test Ed: Free fall	60068.2.32	Part 2.32: Tests—Test Ed: Free fall

Reference to European Standard		*Australian Standard*	
EN		AS EN	
540	Clinical investigation of medical devices for human subjects	540	Clinical investigation of medical devices for human subjects
556	Sterilization of medical devices—Requirements for terminally sterilized medical devices to be labelled 'STERILE'	556	Sterilization of medical devices—Requirements for medical devices to be designated [STERILE]
		556.1	Part 1: Requirements for terminally sterilized medical devices

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INTRODUCTION

This European Standard provides a method to demonstrate compliance with the relevant essential requirements as outlined in general terms in Annex 1 of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as they apply to non-active surgical implants, hereafter referred to as implants. It also provides a method of addressing the fundamental principles outlined in ISO/TR 14283, as they apply to non active surgical implants.
For such products, particular and specific requirements may apply. These additional requirements are specified in the level 2 and 3 standards or their parts.

NOTE: The structure of this standard and the normative references of this standard are based on the use of the standard in supporting Council Directive 93/42/EEC.
For the European Standards listed in the normative references (see clause 2), in some cases International Standards are available (see also clause 2, NOTE 1). Users of International Standards should be aware that they may not necessarily meet the essential requirements of the Council Directive 93/42/EEC or other regulatory requirements for other countries or regions.

NOTES

AUSTRALIAN STANDARD

Non–active surgical implants—General requirements

1 Scope

This European Standard specifies general requirements for non-active surgical implants. This standard is not applicable to dental implants, dental restorative materials, transendodontic and transradicular implants and intra-ocular lenses.

With regard to safety, this standard gives requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests.
Tests required to be used to demonstrate compliance with this standard are contained in other levels.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 540	Clinical investigations of medical devices for human subjects.
EN 550	Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization.
EN 552	Sterilization of medical devices - Validation and routine control of sterilization by irradiation.
EN 554	Sterilization of medical devices - Validation and routine control of steam sterilization by moist heat.
EN 556	Sterilization of medical devices - Requirements for medical devices labelled "Sterile".
EN 868-1	Packaging materials for sterilization of wrapped goods - Part 1: General requirements and requirements for the validation of packaging for terminally sterilized devices.
EN 980	Terminology, symbols and information provided with medical devices - Graphical symbols for use in the labelling of medical devices.
prEN 1041	Terminology, symbols and information provided with medical devices - Information supplied by the manufacturer with medical devices.
prEN 1441	Medical devices - Risk analysis.
prEN ISO 10993-1	Biological evaluation of medical and dental materials and devices - Part 1: Guidance on selection of tests.

NOTE 1: For some of the European Standards listed in this clause, an identical or technically related International Standards is available. These International Standards are listed in A.3.