AS ISO 14630:2015
ISO 14630:2012

AS ISO 14630:2015

Australian STANDARD

# Non-active surgical implants—General requirements



STANDARDS Australia

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The following are represented on Committee HE-012:

- Australian Dental Association
- Australian Society for Biomaterials
- Medical Technology Association of Australia
- Neurosurgical Society of Australasia
- Royal Australasian College of Surgeons
- Royal Perth Hospital
- Therapeutic Goods Administration
- University of Sydney

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Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

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Australian Standard®

# Non-active surgical implants—General requirements

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# PREFACE

This Standard was prepared by the Standards Australia Committee HE-012, Surgical Implants, to supersede AS ISO 14630—2003.

The objective of this Standard is to specify general requirements for non-active surgical implants. It also specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests to demonstrate compliance with these requirements.

This Standard is identical with, and has been reproduced from ISO 14630:2012, *Non-active surgical implants—General requirements*.

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

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

(b) 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 or Australian/New Zealand Standard* | |
|---|---|---|---|
| ISO | | AS ISO | |
| 8601 | Data elements and interchange formats—Information interchange—Representation of dates and times | 8601 | Data elements and interchange formats—Information interchange—Representation of dates and times |
| | | AS/NZS ISO | |
| 11137 | Sterilization of health care products—Radiation | 11137 | Sterilization of health care products—Radiation |
| 11137-1 | Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices | 11137.1 | Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices |

Only normative references that have been adopted as Australian or Australian/New Zealand Standard have been listed.

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# INTRODUCTION

This International Standard provides a method of addressing the fundamental principles outlined in ISO/TR 14283 as they apply to non-active surgical implants. It also provides a method for demonstrating compliance with the relevant essential requirements as outlined in the general terms in Annex 1 of the European 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 might also help manufacturers comply with the requirements of other regulatory bodies.

There are three levels of standards dealing with non-active surgical implants and related instrumentation. For the implants themselves, they are as follows, with level 1 being the highest.

— Level 1: General requirements for non-active surgical implants.

— Level 2: Particular requirements for families of non-active surgical implants.

— Level 3: Specific requirements for types of non-active surgical implants.

Level 1 standards, such as this International Standard and Reference [4], contain requirements that apply to all non-active surgical implants. They also anticipate that there are additional requirements in the level 2 and level 3 standards.

Level 2 standards (see References [5], [6], [7], [8] and [9]) apply to a more restricted set or family of non-active surgical implants, such as those designed for use in neurosurgery, cardiovascular surgery, or joint replacement.

Level 3 standards (see References [10], [11], [12] and [13]) apply to specific types of implants within a family of non-active surgical implants, such as hip joints or arterial stents.

To address all requirements for a specific implant, it is advisable that the standard of the lowest available level be consulted first.

NOTE The requirements in this International Standard correspond to international consensus. Individual or national standards or regulatory bodies can prescribe other requirements.

AUSTRALIAN STANDARD

# Non-active surgical implants—General requirements

## 1 Scope

This International Standard specifies general requirements for non-active surgical implants, hereafter referred to as implants. This International Standard is not applicable to dental implants, dental restorative material, transendodontic and transradicular implants, intra-ocular lenses and implants utilizing viable animal tissue.

With regard to safety, this International Standard specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests to demonstrate compliance with these requirements.

Additional tests are given or referred to in level 2 and level 3 standards.

NOTE This International Standard does not require that the manufacturer have a quality management system in place. However, the application of a quality management system, such as that described in ISO 13485, might be appropriate to help ensure that the implant achieves its intended performance.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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

ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 13408-1, *Aseptic processing of health care products — Part 1: General requirements*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14160, *Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*



 