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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- 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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Australian Standard®

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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.