AS ISO 14708.1:2015
ISO 14708-1:2014

AS ISO 14708.1:2015

Australian STANDARD

Implants for surgery—Active implantable medical devices

Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

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 2 July 2015.
This Standard was published on 17 July 2015.

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

This Standard was issued in draft form for comment as DR AS ISO 14708.1:2015.

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.

Keeping Standards up-to-date

Australian Standards® are living documents that reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued.

Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments that may have been published since the Standard was published.

Detailed information about Australian Standards, drafts, amendments and new projects can be found by visiting www.standards.org.au

Standards Australia welcomes suggestions for improvements, and encourages readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.org.au, or write to Standards Australia, GPO Box 476, Sydney, NSW 2001.

Australian Standard®

Implants for surgery—Active implantable medical devices

Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Originated as AS ISO 14708.1—2003.
Second edition AS ISO 14708.1:2015.

Published by SAI Global Limited under licence from Standards Australia Limited, GPO Box 476, Sydney, NSW 2001, Australia

ISBN 978 1 76035 162 5

PREFACE

This Standard was prepared by the Standards Australia Committee HE-012, Surgical Implants, to supersede AS ISO 14708.1—2003.

The objective of this Standard is to provide general requirements on safety, marking and information to be provided by manufacturers of active implantable medical devices.

This Standard is identical with, and has been reproduced from ISO 14708-1:2014, *Implants for surgery—Active implantable medical devices,* Part 1*: General requirements for safety, marking and for information to be provided by the manufacturer*.

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

(a) In the source text 'this part of ISO 14708' 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.

The term 'informative' has been used in this Standard to define the application of the annex to which it applies. An 'informative' annex is only for information and guidance.

CONTENTS