



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



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-

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Australian Standard[®]

**Implants for surgery—Active
implantable medical devices**

**Part 1: General requirements for safety,
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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 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:

<i>Reference to International Standard</i>		<i>Australian or Australian/New Zealand Standard</i>	
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/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.

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INTRODUCTION

This part of ISO 14708 specifies general requirements for ACTIVE IMPLANTABLE MEDICAL DEVICES to provide basic assurance of safety for both patients and users.

To minimize the likelihood of a device being misused, this part of ISO 14708 also details comprehensive requirements for MARKINGS and for other information to be supplied as part of the documentation with any ACTIVE IMPLANTABLE MEDICAL DEVICE.

For particular types of ACTIVE IMPLANTABLE MEDICAL DEVICE, the general requirements can be supplemented or modified by the requirements of other parts of ISO 14708. A requirement of a particular part of ISO 14708 takes priority over the corresponding requirement of this general part of ISO 14708. Where particular parts of ISO 14708 exist, this general part of ISO 14708 is not intended to be used alone. Special care is required when applying this general part of ISO 14708 alone to ACTIVE IMPLANTABLE MEDICAL DEVICES for which no particular International Standard has yet been published.

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

1 Scope

This part of ISO 14708 specifies requirements that are generally applicable to ACTIVE IMPLANTABLE MEDICAL DEVICES.

NOTE 1 For particular types of ACTIVE IMPLANTABLE MEDICAL DEVICES, these general requirements are supplemented or modified by the requirements of particular parts of ISO 14708.

The tests that are specified in ISO 14708 are type tests and are to be carried out on samples of an ACTIVE IMPLANTABLE MEDICAL DEVICE to show compliance.

This part of ISO 14708 is applicable not only to active implantable medical devices that are electrically powered but also to those powered by other energy sources (for example by gas pressure or by springs).

This part of ISO 14708 is also applicable to some non-implantable parts and accessories of the ACTIVE IMPLANTABLE MEDICAL DEVICES.

NOTE 2 The device that is commonly referred to as an ACTIVE IMPLANTABLE MEDICAL DEVICE can be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device.

NOTE 3 In this part of ISO 14708, terms printed in small capital letters are used as defined in [Clause 3](#). Where a defined term is used as a qualifier in another term, it is not printed in small capital letters unless the concept thus qualified is also defined.

NOTE 4 The terminology used in this part of ISO 14708 is intended to be consistent with the terminology of ISO/TR 14283:2004.

2 Normative references

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

ISO 8601:2004, *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 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

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

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*