AS ISO 14708.1—2003
ISO 14708-1:2000

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 21 May 2003 and published on 30 June 2003.

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Australian Dental Association

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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 14708-1:2000, *Implants for surgery—Active implantable medical devices—Part 1: General requirements for safety, marking and for information to be provided by the manufacturer.*

The objective of this Standard is to specify requirements that are generally applicable to active implantable medical devices. For particular types of active implantable medical devices, these general requirements are supplemented or modified by the requirements of particular standards which form additional parts of ISO 14708. Special care is required in applying this Standard to active implantable medical devices where no particular standard exists. The tests that are specified in this Standard are type tests intended to be carried out on samples of a device to show compliance, and are not intended to be used for the routine testing of manufactured products. This Standard is applicable not only to active implantable medical devices that are electrically powered, but also to those powered by other energy sources (for example gas pressure or springs). It is also applicable to some non-implantable parts and accessories of the devices.

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.

As this Standard is reproduced from an international 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 International Standard’ should read ‘this Australian Standard’.

(c) 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 Standard*	
ISO		AS/NZS	
8601	Data elements and interchange formats—Information interchange—Representation of dates and times	3802	Data elements and interchange formats—Information interchange—Representation of dates and times
ISO		AS ISO	
14155	Clinical investigation of medical devices	14155	Clinical investigation of medical devices

Reference to International Standard		*Australian Standard*	
IEC		AS	
60068	Environmental testing	60068	Environmental testing
60068-2-14	Part 2: Tests—Test N: Change of temperature	60068.2.14	Part 2.14: Tests—Test N: Change of temperature
60068-2-32	Part 2: Tests—Test Ed: Free fall	60068.2.32	Part 2.32: Tests—Test Ed: Free fall
IEC		AS/NZS	
60601	Medical electrical equipment	3200	Approval and test specification —Medical electrical equipment
60601-1	Part 1: General requirements for safety	3200.1.0	Part 1.0: General requirements for safety—Parent Standard
60601-1-1	Part 1-1: General requirements for safety—Collateral standard: Safety requirements for medical electrical systems	3200.1.1	Part 1.1: General requirements for safety—Collateral Standard: Safety requirements for medical electrical systems
60601-1-2	Part 1-2: General requirements for safety—Collateral standard: Electromagnetic compatibility—Requirements and tests	3200.1.2	Part 1.2: General requirements for safety—Collateral Standard: Electromagnetic compatibility—Requirements and tests
60601-1-4	Part 1: General requirements for safety—4. Collateral standard: Programmable electrical medical systems	3200.1.4	Part 1.4: General requirements for safety—Collateral Standard: Programmable electrical medical systems
60601-2-27	Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment	3200.2.27	Part 2.27: Particular requirements for safety—Electrocardiographic monitoring equipment
61000	Electromagnetic compatibility (EMC)	61000	Electromagnetic compatibility (EMC)
61000-4-2	Part 4: Testing and measurement techniques—Section 2: Electrostatic discharge immunity test. Basic EMC Publication	61000.4.2	Part 4.2: Testing and measurement techniques—Electrostatic discharge immunity test

CONTENTS

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.

This part of ISO 14708 is based on the fundamental principles in ISO/TR 14283, which closely parallel the essential requirements of the European Directives applicable to medical devices.

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 For particular types of active implantable medical devices, these general requirements are supplemented or modified by the requirements of particular standards which form additional parts of ISO 14708. Special care is required in applying this part of ISO 14708 to active implantable medical devices where no particular standard exists.

The tests that are specified in this part of ISO 14708 are type tests intended to be carried out on samples of a device to show compliance, and are not intended to be used for the routine testing of manufactured products.

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 gas pressure or springs).

This part of ISO 14708 is also applicable to some non-implantable parts and accessories of the devices (see 3.3).

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 14708. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 14708 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times*.

ISO 11607:1997, *Packaging for terminally sterilized medical devices.*

ISO 14155:1996, *Clinical investigation of medical devices*.

ISO 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*.

IEC 60068-2-14:1986, *Environmental testing — Part 2: Tests. Test N: Change of temperature*.

IEC 60068-2-32:1990, *Environmental testing — Part 2: Tests. Test Ed: Free fall (Procedure 1)*.

IEC 60068-2-47:1999, *Environmental testing — Part 2-47: Test methods — Mounting of components, equipment and other articles for vibration, impact and similar dynamic tests.*