AS ISO 5840—2003
ISO 5840:1996

Australian Standard™

Cardiovascular implants—Cardiac valve prostheses

Standards Australia

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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 5840:1996, *Cardiovascular implants—Cardiac valve prostheses.*

The objective of this Standard is to specify tests to be performed and requirements for test apparatus to be used in determining the physical, biological and mechanical properties of heart valve substitutes of all types, and of the materials and components of which they are made.

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.

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(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

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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	
10993	Biological evaluation of medical devices	10993	Biological evaluation of medical devices
10993-1	Part 1: Evaluation and testing	10993.1	Part 1: Evaluation and testing
10993-3	Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	10993.3	Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
10993-4	Part 4: Selection of tests for interactions with blood	10993.4	Part 4: Selection of tests for interactions with blood
10993-5	Part 5: Tests for in vitro cytotoxicity	10993.5	Part 5: Tests for in vitro cytotoxicity
10993-6	Part 6: Tests for local effects after implantation	10993.6	Part 6: Tests for local effects after implantation
10993-7	Part 7: Ethylene oxide sterilization residuals	10993.7	Part 7: Ethylene oxide sterilization residuals
10993-9	Part 9: Framework for identification and quantification of potential degradation products	10993.9	Part 9: Framework for identification and quantification of potential degradation products

Reference to International Standard		*Australian Standard*	
ISO		AS ISO	
10993	Biological evaluation of medical devices	10993	Biological evaluation of medical devices
10993-10	Part 10: Tests for irritation and delayed-type hypersensitivity	10993.10	Part 10: Tests for irritation and delayed-type hypersensitivity
10993-11	Part 11: Tests for systematic toxicity	10993.11	Part 11: Tests for systematic toxicity
10993-12	Part 12: Sample preparation and reference materials	10993.12	Part 12: Sample preparation and reference materials
11134	Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization	11134	Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization
11135	Medical devices—Validation and routine control of ethylene oxide sterilization	11135	Medical devices—Validation and routine control of ethylene oxide sterilization
11137	Sterilization of health care products—Requirements for validation and routine control—Radiation sterilization	11137	Sterilization of health care products—Requirements for validation and routine control—Radiation sterilization
14155	Clinical investigation of medical devices	14155	Clinical investigation of medical devices

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INTRODUCTION

There is, as yet, no heart valve substitute which can be regarded as ideal.

This International Standard has been prepared by a group well aware of the problems associated with heart valve substitutes and their development. In several areas, the provisions of this International Standard have been deliberately left open as there has been no wish to inhibit development and innovation. For these reasons, this International Standard intentionally does not attempt to specify performance requirements for finished products. It does specify types of tests, test methods and/or requirements for test apparatus, and requires disclosure of test methods and results. The areas with which this International Standard is concerned are those which will facilitate quality assurance, aid the surgeon in choosing a heart valve substitute, and ensure that the device will be presented at the operating table in a convenient form. Emphasis has been placed on specifying types of *in vitro* testing, on preclinical *in vivo* and clinical evaluations, on reporting of all *in vitro,* preclinical *in vivo* and clinical evaluations and on the labelling and packaging of the device. Such a process involving *in vitro,* preclinical *in vivo* and clinical evaluations is intended to clarify the required procedures prior to market release and to enable prompt identification and management of subsequent problems.

With regard to *in vitro* testing and reporting, apart from basic material testing for mechanical, physical, chemical and biocompatibility characteristics, this International Standard also covers important hydrodynamic and accelerated fatigue characteristics of heart valve substitutes. The exact test methods for hydrodynamic and accelerated fatigue testing have not been specified, but requirements for the test apparatus are given.

This International Standard is incomplete in several areas. It is intended to be revised, updated, and/or amended, as knowledge and techniques in heart valve substitute technology improve.

NOTES

AUSTRALIAN STANDARD

Cardiovascular implants—Cardiac valve prostheses

1 Scope

1.1 This International Standard specifies tests to be performed and requirements for test apparatus to be used in determining the physical, biological and mechanical properties of heart valve substitutes of all types, and of the materials and components of which they are made.

1.2 Requirements are provided for preclinical *in vivo* evaluation, for clinical evaluation, and for reporting the results of all types of testing and evaluation covered in this International Standard. These requirements do not purport to comprise a complete test programme.

1.3 Specifications are also given for packaging and labelling of heart valve substitutes.

1.4 This International Standard is not applicable to heart valve substitutes comprised in whole or in part of human tissue.

NOTE — A rationale for the provisions of this International Standard is given in annex A.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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

ISO 10993-1:—[1)], *Biological evaluation of medical devices — Part 1: Evaluation and testing.*

ISO 10993-2:1992, *Biological evaluation of medical devices — Part 2: Animal welfare requirements.*

ISO 10993-3:1992, *Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.*

ISO 10993-4:1992, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood.*

ISO 10993-5:1992, *Biological evaluation of medical devices — Part 5: Tests for cytotoxicity: in vitro methods.*

ISO 10993-6:1994, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation.*

ISO 10993-7:1995, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals.*

ISO/TR 10993-9:1994, *Biological evaluation of medical devices — Part 9: Degradation of materials related to biological testing.*

1) To be published. (Revision of ISO 10993-1:1992)

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