AS ISO 10993.8—2003
ISO 10993-8:2000

Australian Standard™

Biological evaluation of medical devices

Part 8: Selection and qualification of reference materials for biological tests

Standards Australia

This Australian Standard was prepared by Committee HE-012, Surgical Implants and Committee HE-009, Hypodermic Equipment—General Medical. It was approved on behalf of the Council of Standards Australia on 29 May 2003 and published on 30 June 2003.

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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/ Standards New Zealand Committees HE-012, Surgical Implants and HE-009, Hypodermic Equipment—General Medical. 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 10993-8:2000, *Biological evaluation of medical devices—Part 8: Selection and qualification of reference materials for biological tests.*

The objective of this Standard is to specify requirements on the use of reference materials or certified reference materials used to determine the biological response of a material. This Standard specifies the selection and qualification of reference materials for biological tests and the characteristics of reference materials for the use of reference materials as experimental controls.

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.

(b) In the source text 'this International Standard' should read 'this Australian Standard'.

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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 ISO	
10993	Biological evaluation of medical devices	10993	Biological evaluation of medical devices
10993-12	Part 12: Sample preparation and reference materials	10993.12	Part 12: Sample preparation and reference materials
ISO		HB	
Guide 30	Terms and definitions used in connection with reference materials	19-30	Reference materials—Guide 30 — Terms and definitions used in connection with reference materials

AS ISO 10993, Biological evaluation of medical devices, consists of the following parts:

Part 1: Evaluation and testing
Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
Part 4: Selection of tests for interactions with blood
Part 5: Tests for in vitro cytotoxicity
Part 6: Tests for local effects after implantation
Part 7: Ethylene oxide sterilization residuals
Part 8: Selection and qualification of reference materials for biological tests (this Standard)
Part 9: Framework for identification and quantification of potential degradation products
Part 10: Tests for irritation and delayed-type hypersensitivity

Part 11: Tests for systematic toxicity
Part 12: Sample preparation and reference materials
Part 13: Identification and quantification of degradation products from polymeric medical devices
Part 14: Identification and quantification of degradation products from ceramics
Part 15: Identification and quantification of degradation products from metals and alloys
Part 16: Toxicokinetic study design for degradation products and leachables

INTRODUCTION

The information given in this part of ISO 10993 should be considered as a supplement to ISO 10993-12 which specifies requirements and gives guidance on procedures to be followed in the preparation of samples of medical devices for testing in biological systems in accordance with one or more parts of the ISO 10993 series. In clause 4 of ISO 10993-12:1996, there is a discussion of the use of reference materials as experimental controls. Annex A of ISO 10993-12:1996 provides specific information regarding current sources of commercially available reference materials.

AUSTRALIAN STANDARD

Biological evaluation of medical devices

Part 8: Selection and qualification of reference materials for biological tests

1 Scope

This part of ISO 10993 specifies requirements on the use of reference materials or certified reference materials used to determine the biological response of a material. It specifies the selection and qualification of reference materials for biological tests and the characteristics of reference materials for the use of reference materials as experimental controls.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 10993. 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 10993 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 10993-12, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials.*

ISO Guide 30:1992, *Terms and definitions used in connection with reference materials.*

3 Terms and definitions

For the purposes of this part of ISO 10993, the terms and definitions given in ISO 10993-12, ISO Guide 30 and the following apply.

3.1
certified reference material
CRM
reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence

[ISO Guide 30:1992, 2.2]

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