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AS ISO 10993.12—2004

Australian Standard™

Biological evaluation of medical devices

Part 12: Sample preparation and reference materials

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Australian Standard™

Biological evaluation of medical devices

Part 12: Sample preparation and reference materials

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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, to supersede AS ISO 10993.12—2002, *Biological evaluation of medical device,* Part 12: *Sample preparation and reference materials*. 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 10993-12:2002, *Biological evaluation of medical devices,* Part 12*: Sample preparation and reference materials.*

The objective of this Standard is to specify requirements and provide guidance on the procedures to be followed in the preparation of samples and the selection of reference materials for medical devices testing in biological systems in accordance with other AS ISO 10993 series Standards.

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.

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 part of ISO 10993' should read 'this Australian Standard'.

(c) A full point substitutes for a comma when referring to a decimal marker.

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
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 (this Standard)
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.
Part 17: Establishment of allowable limits for leachable substances

References to International Standards and European Standards should be replaced by references to Australian or Australian/New Zealand Standards as follows:

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
14971	Medical devices—Application of risk management to medical devices	AS/NZS 4810 4810.1	Medical devices—Risk management Part 1: Application of risk analysis

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INTRODUCTION

This part of ISO 10993 specifies methods of sample preparation and the selection of reference materials in the biological evaluation of medical devices. Because ISO 10993 describes many different biological assay systems, the individual parts should be consulted to ascertain if these recommendations are appropriate for specific test systems.

Sample preparation methods should be appropriate for both the biological evaluation methods and the materials being evaluated. Each biological test method requires the selection of materials, extraction solvents and conditions.

This part of ISO 10993 is based on existing national and international specifications, regulations and standards wherever possible. It is periodically reviewed and revised.

AUSTRALIAN STANDARD

Biological evaluation of medical devices —

Part 12:
Sample preparation and reference materials

1 Scope

This part of ISO 10993 specifies requirements and gives guidance on the procedures to be followed in the preparation of samples and the selection of reference materials for medical devices testing in biological systems in accordance with one or more parts of the ISO 10993 series.

Specifically, this part of ISO 10993 addresses:

— test material selection;

— selection of representative portions from a device;

— test sample preparation;

— experimental controls;

— selection of and requirements for reference materials; and

— preparation of extracts.

The applicability of this part of ISO 10993 to absorbable materials, materials that polymerize *in situ*, tissue-engineered medical products and materials of biological origin should be carefully evaluated.

2 Normative references

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

ISO 10993-1:1997, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
accelerated extraction
extraction that provides a measure of the hazard potential of the device or material using conditions that shorten the time for leaching of the substances into the medium

NOTE 1 Examples of accelerated extraction conditions are elevated temperature, agitation, changing medium, etc.

NOTE 2 Accelerated extraction will not result in a chemical change in the substances being extracted.