

Australian Standard™

Biological evaluation of medical devices

**Part 4: Selection of tests for
interactions with blood**

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.

The following are represented on Committee HE-012:

HE-012 and (HE-009):

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Biological evaluation of medical devices

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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 10993-4:2002, *Biological evaluation of medical devices—Part 4: Selection of tests for interactions with blood*.

This second edition cancels and replaces the first edition (AS ISO 10993.4—2002), which has been technically revised.

The objective of this Standard is to specify general requirements for evaluating the interactions of medical devices with blood. This Standard describes a classification of medical and dental devices that are intended for use in contact with blood, based on the intended use and duration of contact, the fundamental principles governing the evaluation of the interaction of devices with blood, and the rationale for structured selection of tests according to specific categories, together with the principles and scientific basis of these tests.

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:

<i>Reference to International Standard</i>	<i>Australian Standard</i>
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

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 (this Standard)
- 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

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

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INTRODUCTION

The selection and design of test methods for the interactions of medical devices with blood should take into consideration device design, materials, clinical utility, usage environment and risk benefit. This level of specificity can only be covered in vertical standards.

The initial source for developing this part of ISO 10993 was the publication, *Guidelines for blood/material interactions*, Report of the National Heart, Lung, and Blood Institute [29]; chapters 9 and 10. This publication has since been revised [32].

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AUSTRALIAN STANDARD

Biological evaluation of medical devices

Part 4: Selection of tests for interactions with blood

1 Scope

This part of ISO 10993 provides general requirements for evaluating the interactions of medical devices with blood.

It describes

- a classification of medical and dental devices that are intended for use in contact with blood, based on the intended use and duration of contact as defined in ISO 10993-1,
- the fundamental principles governing the evaluation of the interaction of devices with blood,
- the rationale for structured selection of tests according to specific categories, together with the principles and scientific basis of these tests.

Detailed requirements for testing cannot be specified because of limitations in the knowledge and precision of tests for interactions of devices with blood. This part of ISO 10993 describes biological evaluation in general terms and may not necessarily provide sufficient guidance for test methods for a specific device.

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

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

3 Terms and definitions

For the purposes of this part of ISO 10993, the terms and definitions given in ISO 10993-1 and the following apply.

3.1 Blood device interaction

any interaction between blood or any component of blood and a device resulting in effects on the blood, or on any organ or tissue, or on the device

NOTE Such effects may or may not have clinically significant or undesirable consequences. Annex A contains further information on these interactions.