

Australian Standard™

Biological evaluation of medical devices

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



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):

Australian Chamber of Commerce and Industry (HE-009)
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Australian Dental Association
Australian Industry Group
Australian Orthopaedic Association
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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.
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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
10993-12	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