

Australian Standard™

Biological evaluation of medical devices

**Part 14: Identification and quantification
of degradation products from ceramics**



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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Australian Dental Association
Australian Industry Group
Australian Orthopaedic Association
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This Standard was issued in draft form for comment as DR 03176.

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First published as AS ISO 10993.14—2003.

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Published by Standards Australia International Ltd
GPO Box 5420, Sydney, NSW 2001, Australia

ISBN 0 7337 5372 8

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 10993-14:2001, *Biological evaluation of medical devices—Part 14: Identification and quantification of degradation products from ceramics*.

The objective of this Standard is to specify two methods of obtaining solutions of degradation products from ceramics (including glasses) for the purposes of quantification, together with guidance on the analysis of these solutions in order to identify the degradation products. This Standard considers only those degradation products generated by a chemical dissociation of ceramics during in vitro testing.

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
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

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
- Part 13: Identification and quantification of degradation products from polymeric medical devices

Part 14: Identification and quantification of degradation products from ceramics (this Standard)

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

This part of ISO 10993 consists of two tests for the biological evaluation of medical devices: an extreme solution test and a simulation solution test. The extreme solution test is developed as a worst-case environment and the simulation test is developed as a very common environment.

Degradation products covered by this part of ISO 10993 are formed primarily by dissolution in an aqueous environment. It is recognized that additional biological factors such as enzymes and proteins can alter the rate of degradation. Degradation by such outside factors is not addressed in this part of ISO 10993.

It should be kept in mind that a ceramic device might have extraneous chemical phases and/or elements in extremely minor amounts. Whilst these components might not be named in the original specification, they can often be suspected by the relationship that the material in question has to other materials and the expected history of the material's processing.

Once identified and quantified, the chemical composition of the degradation products form the basis for risk assessment and, if appropriate, biological safety studies according to the principles of ISO 10993-1.

