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Australian Standard™

Biological evaluation of medical devices

Part 17: Establishment of allowable limits for leachable substances

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Australian College of Operating Room Nurses
Australian Dental Association
Australian Industry Group
Australian Orthopaedic Association
Commonwealth Department of Health and Ageing
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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. 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 10993-17:2002, *Biological evaluation of medical devices,* Part 17: *Establishment of allowable limits for leachable substances.*

The objective of this Standard is to specify a method for the determination of allowable limits for substances leachable from medical devices. It describes a systematic process through which identified risks arising from toxicologically hazardous substances present in medical devices can be quantified.

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
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 (this Standard)

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

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