AS ISO 10993.4—2003
ISO 10993-4:2002

Australian Standard™

Biological evaluation of medical devices

Part 4: Selection of tests for interactions with blood

Standards Australia

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)
Australian College of Operating Room Nurses (HE-009)
Australian Dental Association
Australian Industry Group
Australian Orthopaedic Association
Australian Society for Biomaterials
Commonwealth Department of Health and Ageing (HE-009)
Department of Defence (Australia)
Medical Industry Association of Australia Inc (HE-009)
Neurological Society of Australasia
Royal Australasian College of Surgeons
Royal Perth Hospital
University of New South Wales
University of Sydney

HE-009 only:
Australian Infection Control Association
Australian Medical Association
Certification Bodies (Australia)
Department of Human Services (Victoria)
Federation of Sterilizing Research and Advisory Council of Australia
Hunter Area Health Service
NSW Health Department
Queensland Health
Royal Australian College of General Practitioners
Royal College of Pathologists of Australasia
Royal Melbourne Hospital

This Standard was issued in draft form for comment as DR 03172.

Australian Standard™

Biological evaluation of medical devices

Part 4: Selection of tests for interactions with blood

Originated as AS ISO 10993.4—2002.
Second edition 2003.

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

ISBN 0 7337 5368 X

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:

Reference to International Standard		*Australian Standard*	
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

CONTENTS

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].

NOTES

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) 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,

b) the fundamental principles governing the evaluation of the interaction of devices with blood,

c) 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.