AS ISO 10993.12—2002
ISO 10993-12:1996

Australian Standard™

Biological evaluation of medical devices

Part 12: Sample preparation and reference materials

Standards Australia

This Australian Standard was prepared by Committee HE-012, Surgical Implants. It was approved on behalf of the Council of Standards Australia on 26 June 2002 and published on 28 June 2002.

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Australian Chamber of Commerce and Industry

Australian College of Operating Room Nurses

Australian Dental Association

Australian Industry Group

Australian Orthopaedic Association

Commonwealth Department of Health and Ageing

Department of Defence (Australia)

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PREFACE

This Standard has been developed to assist in the process of implementation of the Australian Medical Device legislation.

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, through the Joint Standards Australia/Standards New Zealand Committee HE-012 on Surgical Implants.

This Standard is identical with and has been reproduced from ISO 10993-12:1996, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials.*

The objective of this Standard is to specify requirements and provide guidance on procedures for sample preparation of medical devices for testing in biological systems.

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.

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INTRODUCTION

This part of ISO 10993 gives guidance on methods of sample preparation and on the use of reference materials for use in biological evaluation. Because of the many different biological assay systems described in ISO 10993, the individual standards should be consulted to ascertain the appropriateness of these recommendations for a specific test system.

Sample preparation methods should consider both the biological evaluation methods and the materials being evaluated. Each biological test restricts selection of solid samples and extraction solvents or conditions by its own methodology.

This part of ISO 10993 is based on existing national and international specifications, regulations and standards wherever possible. It is open to regular review whenever new research work is presented to improve the state of scientific knowledge.

AUSTRALIAN STANDARD

Biological evaluation of medical devices

Part 12: Sample preparation and reference materials

1 Scope

This part of ISO 10993 specifies requirements and gives guidance on procedures to be followed in the preparation of samples of medical devices for testing in biological systems in accordance with one or more other parts of ISO 10993. These include:

a) test material selection;

b) selection of representative portions from a device;

c) test sample preparation;

d) the selection of reference materials to demonstrate the suitability of the test system and/or to enable relative comparison of the biological activity of the test sample; and,

e) preparation of extracts.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10993. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10993 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 9000-1:1994, *Quality management and quality assurance standards — Part 1: Guidelines for selection and use.*

ISO 9000-2:1993, *Quality management and quality assurance standards — Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003.*

ISO 9000-3:1991, *Quality management and quality assurance standards — Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software.*

ISO 9000-4:1993, *Quality management and quality assurance standards — Part 4: Guide to dependability programme management.*

ISO Guide 25:1990, *General requirements for competence of calibration and testing laboratories.*

ISO Guide 30:1992, *Terms and definitions used in connection with reference materials.*

3 Definitions

For the purposes of this part of ISO 10993, the definitions given in ISO Guide 30 and the following definitions apply.

3.1 blank liquid: Liquid treated in the same manner as that for preparing extract liquid but without test material, and used for comparison with extract liquid.

3.2 extract liquid: Liquid resulting from the extraction of the test material.

3.3 negative control: Material or substance which, when tested by the procedure described, demonstrates the suitability of the procedure to yield a reproducible, appropriate negative, nonreactive or background response in the test system.