AS ISO 10993.1—2002
ISO 10993-1:1997

Australian Standard™

Biological evaluation of medical devices

Part 1: Evaluation and testing

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 College of Operating Room Nurses
Australian Dental Association
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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 10993-1:1997, *Biological evaluation of medical devices — Part 1: Evaluation and testing.*

The objective of this Standard is to describe the principles governing biological evaluation and testing of medical devices.

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.

CONTENTS

INTRODUCTION

This part of ISO 10993 is a combination/harmonization of numerous International and national Standards and guidelines concerning the biological evaluation of medical devices. It is intended to be the overall guidance document for the selection of tests enabling evaluation of biological responses relevant to the safety of medical devices and materials.

The role of this part of ISO 10993 is to serve as a framework in which to plan such a biological evaluation which minimizes the number and exposure of test animals.

The protection of humans is the primary goal of ISO 10993.

The appropriate selection and interpretation of biological evaluation tests requires an understanding of the rationale behind such testing. An informative rationale for the use of this part of ISO 10993 is provided in annex A. Annex B contains a flow chart to aid in the systematic approach to the biological evaluation of medical devices. Annex C contains an informative bibliography.

AUSTRALIAN STANDARD

Biological evaluation of medical devices

Part 1: Evaluation and testing

1 Scope

This part of ISO 10993 describes

a) the general principles governing the biological evaluation of medical devices;

b) the categorization of devices based on the nature and duration of their contact with the body;

c) the selection of appropriate tests.

This part of ISO 10993 does not cover testing of materials and devices that do not come into direct or indirect contact with the patient's body, nor does it cover biological hazards arising from any mechanical failure. Other parts of ISO 10993 cover specific tests as indicated in the foreword. (See also the rationale in A.2.)

2 Definitions

For the purposes of this part of ISO 10993, the following definitions apply.

2.1 medical device: Any instrument, apparatus, appliance, material or other article, including software, whether used alone or in combination, intended by the manufacturer to be used for human beings solely or principally for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or handicap;

— investigation, replacement or modification of the anatomy or of a physiological process;

— control of conception.

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

NOTES

1 Devices are different from drugs, and their biological evaluation requires a different approach.

2 Use of the term “medical device” includes dental devices.

2.2 material: Any synthetic or natural polymer, metal, alloy, ceramic, or other nonviable substance, including tissue rendered nonviable, used as a medical device or any part thereof.

2.3 final product: Medical device in its “as-used” state.