AS ISO 10993.3—2002
ISO 10993-3:1992

AS ISO 10993.3

Australian Standard™

Biological evaluation of medical devices

Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

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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)

Medical Industry Association of Australia Inc

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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 10993-3:1992, *Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.*

The objective of this Standard is to specify the requirements for tests of genotoxicity, carcinogenicity and reproductive toxicity for biological evaluation of medical devices.

As this Standard is reproduced from an international Standard, the following applies:

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INTRODUCTION

The basis for biocompatibility evaluation of medical devices is often empirical and driven by the relevant concerns for human safety. Not all test methods for the assessment of genotoxicity, carcinogenicity or reproductive toxicity are equally well developed, nor is their validity well established for the testing of medical devices.

Significant issues in test sample size and preparation, scientific understanding of disease processes and test validation can be cited as limitations of available methods. For example the biological significance of solid state carcinogenesis is poorly understood. It is expected that ongoing scientific and medical advances will alter our understanding and approaches to these important toxicity test methods. At the time the document was prepared, the test methods proposed were those most acceptable. Sound scientific alternatives to the proposed testing should be acceptable insofar as they address relevant matters of safety assessment.

In the selection of tests needed to evaluate a particular device, there is no substitute for a careful assessment of expected human uses and potential interactions of the device with various biological systems. These considerations will be particularly important in such areas as reproductive and developmental toxicology.

This part of ISO 10993 presents test methods for the detection of specific biological hazards, and therefore maximum test sensitivity is required. The interpretation of findings and implications for human health effects are beyond the scope of this part of ISO 10993. Because of the multitude of possible outcomes and the importance of such factors as extent of exposure, species differences and mechanical or physical considerations, risk assessment has to be performed on a case-by-case basis.

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