AS/NZS ISO 11137.3:2006
ISO 11137-3:2006
Reconfirmed 2017

Australian/New Zealand Standard™

Sterilization of health care products—Radiation

Part 3: Guidance on dosimetric aspects

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-023, Processing of Medical and Surgical Instruments. It was approved on behalf of the Council of Standards Australia on 17 October 2006 and on behalf of the Council of Standards New Zealand on 17 November 2006.
This Standard was published on 19 December 2006.

The following are represented on Committee HE-023:

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Australian Chamber of Commerce and Industry
Australian College of Operating Room Nurses
Australian Dental Association
Australian Dental Industry Association
Australian General Practice Accreditation
Australian Infection Control Association
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Detailed information about joint Australian/New Zealand Standards can be found by visiting the Standards Web Shop at www.standards.com.au or Standards New Zealand web site at www.standards.co.nz and looking up the relevant Standard in the on-line catalogue.

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We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia or Standards New Zealand at the address shown on the back cover.

This Standard was issued in draft form for comment as DR 06399.

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

RECONFIRMATION

OF

AS/NZS ISO 11137.3:2006
Sterilization of health care products—Radiation
Part 3: Guidance on dosimetric aspects

RECONFIRMATION NOTICE

Technical Committee HE-023 has reviewed the content of this publication and in accordance with Standards Australia procedures for reconfirmation, it has been determined that the publication is still valid and does not require change.

Certain documents referenced in the publication may have been amended since the original date of publication. Users are advised to ensure that they are using the latest versions of such documents as appropriate, unless advised otherwise in this Reconfirmation Notice.

Approved for reconfirmation in accordance with Standards Australia procedures for reconfirmation on 06 December 2016.

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Australian/New Zealand Standard™

Sterilization of health care products—Radiation

Part 3: Guidance on dosimetric aspects

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-023, Processing of Medical and Surgical Instruments, to supersede (in part) AS ISO 11137:2002, *Sterilization of health care products—Requirements for validation and routine control—Radiation Sterilization.*

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

This Standard is identical with, and has been reproduced from IISO 11137-3:2006SO 11137-3:2006, *Sterilization of health care products—Radiation* —Part 3: *Guidance on dosimetric aspects.*

The objective of this Standard is to specify the dosimetric procedures related to the development, validation and routine control of a radiation sterilization process.

There are three parts in the series for AS/NZS 11137, *Sterilization of health care products—Radiation* as follows:

Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
Part 2: Establishing the sterilization dose
Part 3: Guidance on dosimetric aspects

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 11137’ should read ‘this Australian/New Zealand Standard’

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References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

Reference to International Standard ISO		*Australian or Australian/New Zealand Standard* AS/NZS ISO	
11137	Sterilization of health care products—Radiation	11137	Sterilization of health care products—Radiation
11137-1	Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	11137.1	Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
11137-2	Part 2: Establishing the sterilization dose	11137.2	Part 2: Establishing the sterilization dose
		AS ISO	
13485	Medical devices—Quality management systems—Requirements for regulatory purposes	13485	Medical devices—Quality management systems—Requirements for regulatory purposes

Only international references that have been adopted as Australian or Australian/New Zealand Standards have been listed.

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.

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