AS/NZS ISO 11137.2:2006
ISO 11137-2:2006

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Australian/New Zealand Standard™

Sterilization of health care products—Radiation

Part 2: Establishing the sterilization dose

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.
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The following are represented on Committee HE-023:

Australian Association of Practice Managers
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
Australian Nursing Federation
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Australian/New Zealand Standard™

Sterilization of health care products—Radiation

Part 2: Establishing the sterilization dose

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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 ISO 11137-2:2006ISO 11137-2:2006, *Sterilization of health care products—Radiation* —Part 2: *Establishing the sterilization dose.*

The objective of this Standard is to specify the methods of determining the minimum dose of radiation sterilization of medical devices.

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

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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
13485	Medical devices—Quality management systems—Requirements for regulatory purposes	AS ISO 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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