

Australian/New Zealand Standard™

**Sterilization of health care products—
Radiation**

**Part 2: Establishing the sterilization
dose**



AS/NZS ISO 11137.2:2006

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.

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AS/NZS ISO 11137.2:2006

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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 11137-2:2006 ISO 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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	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.

CONTENTS

	<i>Page</i>
1	Scope1
2	Normative references1
3	Abbreviations, terms and definitions1
3.1	Abbreviations1
3.2	Terms3
4	Definition and maintenance of product families for dose setting, dose substantiation and sterilization dose auditing4
4.1	General.....4
4.2	Defining product families.....4
4.3	Designation of product to represent a product family for performance of a verification dose experiment or sterilization dose audit5
4.4	Maintaining product families6
4.5	Effect of failure of establishment of sterilization dose or of a sterilization dose audit on a product family7
5	Selection and testing of product for establishing and verifying the sterilization dose7
5.1	Nature of product.....7
5.2	Sample item portion (SIP)8
5.3	Manner of sampling8
5.4	Microbiological testing.....9
5.5	Irradiation9
6	Methods of dose establishment9
7	Method 1: dose setting using bioburden information10
7.1	Rationale.....10
7.2	Procedure for Method 1 for product with an average bioburden $\geq 1,0$ for multiple production batches.....11
7.3	Procedure for Method 1 for product with an average bioburden $\geq 1,0$ for a single production batch.....16
7.4	Procedure for Method 1 for product with an average bioburden in the range 0,1 to 0,9 for multiple or single production batches.....18
8	Method 2: Dose setting using fraction positive information from incremental dosing to determine an extrapolation factor.....18
8.1	Rationale.....18
8.2	Procedure for Method 2A.....19
8.3	Procedure for Method 2B.....22
9	Method VD_{max} — Substantiation of 25 kGy or 15 kGy as the sterilization dose.....25
9.1	Rationale.....25
9.2	Procedure for Method VD_{max}^{25} for multiple production batches26
9.3	Procedure for Method VD_{max}^{25} for a single production batch29
9.4	Procedure for Method VD_{max}^{15} for multiple production batches30
9.5	Procedure for Method VD_{max}^{15} for a single production batch33
10	Auditing sterilization dose34
10.1	Purpose and frequency34

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