

AS/NZS 4187:2014
(Incorporating Amendment Nos 1 and 2)

AS/NZS 4187:2014

Australian/New Zealand Standard™

**Reprocessing of reusable medical
devices in health service organizations**



AS/NZS 4187:2014

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 18 November 2014 and on behalf of the Council of Standards New Zealand on 26 November 2014. This Standard was published on 15 December 2014.

The following are represented on Committee HE-023:

Australasian College for Infection Prevention and Control
Australian Chamber of Commerce and Industry
Australian College of Operating Room Nurses
Australian Day Surgery Nurses Association
Australian Dental Association
Australian Dental Industry Association
Australian Industry Group
Australian Institute of Packaging
Australian Nursing and Midwifery Federation
Department of Health, SA
Department of Human Services Victoria
Department of Health, WA
Federation Sterilizing Research and Advisory Council of Australia
Gastroenterological Nurses College of Australia
Institute of Hospital Engineering Australia
Medical Technology Association of Australia
New Zealand Nurses Organisation
New Zealand Sterile Services Association
NSW Ministry of Health
Queensland Health
Royal College of Pathologists of Australasia
Therapeutic Goods Administration

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about joint Australian/New Zealand Standards can be found by visiting the Standards Web Shop at www.saiglobal.com or Standards New Zealand web site at www.standards.govt.nz and looking up the relevant Standard in the on-line catalogue.

For more frequent listings or notification of revisions, amendments and withdrawals, Standards Australia and Standards New Zealand offer a number of update options. For information about these services, users should contact their respective national Standards organization.

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 Standards Australia or the New Zealand Standards Executive at the address shown on the back cover.

This Standard was issued in draft form for comment as DR 100397.

AS/NZS 4187:2014
(Incorporating Amendment Nos 1 and 2)

Australian/New Zealand Standard™

Reprocessing of reusable medical devices in health service organizations

Originated in Australia as AS 4187—1994.
Previous and first joint edition AS/NZS 4187:2003.
Fourth edition 2014.
Reissued incorporating Amendment No. 1 (July 2015).
Reissued incorporating Amendment No. 2 (May 2019).

COPYRIGHT

© Standards Australia Limited

© The Crown in right of New Zealand, administered by the New Zealand Standards Executive

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher, unless otherwise permitted under the Copyright Act 1968 (Australia) or the Copyright Act 1994 (New Zealand).

PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-023, Processing of Medical and Surgical Instruments, to supersede AS/NZS 4187:2003, Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.

This Standard incorporates Amendment No. 1 (July 2015) and Amendment No. 2 (May 2019). The changes required by the Amendments are indicated in the text by a marginal bar and amendment number against the clause, note, table, figure or part thereof affected.

Prevention of health care associated infection in patients undergoing dental, medical or surgical procedures is an essential component of patient safety in the delivery of high quality health care. It avoids unnecessary pain and suffering for patients and lessens health care costs. Effective and safe reprocessing of reusable medical devices (RMDs) in health service organizations (HSOs) is a critical aspect in the prevention of health care associated infection.

The objective of this Standard is to ensure that HSOs correctly clean, disinfect and sterilize RMDs prior to and between patient uses in order to produce RMDs that are able to be used safely without risk of transmission of infectious agents.

There are significant differences in the structure, content and terminology of this edition of the Standard and that of the previous 2003 edition, as follows:

- (a) The structure and clause headings of this Standard mirror that of the International Organization for Standardization, Technical Committee 198 (ISO/TC 198), Sterilization of health care products, suite of Standards.
- (b) It is necessary to read this Standard in conjunction with relevant national and International Standards and guideline documents (see Clause 1.3, normative references).
- (c) This Standard does not reiterate all the technical requirements already identified in national or International Standards. For example, this Standard refers directly to ISO 17665-1, Sterilization of health care products—Moist heat, Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices, for the requirements concerning moist heat sterilization processes.
- (d) This Standard is not written as a procedural document. Therefore, it is necessary for HSOs to develop their own workplace procedures based on the requirements of this Standard.

Committee HE-023 recommends that HSOs implement the requirements of this Standard within 2 years of date of publication.

Statements expressed in mandatory terms in notes to tables are deemed to be requirements of this Standard.

The terms ‘normative’ and ‘informative’ have been used in this Standard to define the application of the Appendix to which they apply. A ‘normative’ Appendix is an integral part of a Standard, whereas an ‘informative’ Appendix is only for information and guidance.

CONTENTS

	<i>Page</i>
FOREWORD.....	5
 SECTION 1 SCOPE AND GENERAL	
1.1 SCOPE.....	7
1.2 EXCLUSIONS.....	7
1.3 NORMATIVE REFERENCES	8
1.4 ABBREVIATIONS	10
1.5 DEFINITIONS.....	11
 SECTION 2 QUALITY MANAGEMENT	
2.1 GENERAL.....	21
2.2 DOCUMENTATION.....	21
2.3 MANAGEMENT RESPONSIBILITY	23
2.4 PRODUCT REALIZATION.....	24
2.5 MEASUREMENT, ANALYSIS AND IMPROVEMENT	27
 SECTION 3 REPROCESSING AGENT CHARACTERIZATION	
3.1 GENERAL.....	30
3.2 CLEANING AGENTS.....	31
3.3 DISINFECTANTS.....	31
3.4 STERILIZING AGENTS.....	32
3.5 MICROBICIDAL EFFECTIVENESS	32
3.6 EFFECTS ON RMD MATERIALS	32
3.7 PERSONNEL AND ENVIRONMENTAL SAFETY	33
 SECTION 4 PROCESS CHARACTERIZATION AND EQUIPMENT CHARACTERIZATION	
4.1 GENERAL.....	34
4.2 PROCESS CHARACTERIZATION.....	34
4.3 EQUIPMENT CHARACTERIZATION	35
 SECTION 5 PRODUCT DEFINITION	
5.1 GENERAL.....	37
5.2 PRODUCT FAMILIES.....	39
5.3 LIMITING VALUES	40
5.4 PRE-DISINFECTION AND PRE-STERILIZATION CLEANLINESS OF RMDs....	40
5.5 PACKAGING SYSTEM.....	40
5.6 REPROCESSING ENVIRONMENT.....	40
 SECTION 6 PROCESS DEFINITION	
6.1 GENERAL.....	43
6.2 CLEANING PROCESS DEFINITION	44
6.3 DISINFECTING PROCESS DEFINITION	45
6.4 PACKAGING PROCESS DEFINITION	46
6.5 STERILIZING PROCESS DEFINITION	47

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

-
- Looking for additional Standards? Visit Intertek Inform Infostore
 - Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation
-