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

Australian/New Zealand Standard™

Reprocessing of reusable medical devices in health service organizations

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.
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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
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Federation Sterilizing Research and Advisory Council of Australia
Gastroenterological Nurses College of Australia
Institute of Hospital Engineering Australia
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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 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.

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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 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.

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