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AS 4187—1998

Australian Standard®

Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities

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This Australian Standard was prepared by Committee HT/30, Cleaning and Sterilization of Medical and Surgical Equipment. It was approved on behalf of the Council of Standards Australia on 17 November 1997 and published on 5 January 1998.

The following interests are represented on Committee HT/30:

Australian Chamber of Commerce and Industry

Australian Chamber of Manufactures

Australian Confederation of Operating Room Nurses

Australian Dental Association

Australian Dental Industry Association

Australian Healthcare Association

Australian Infection Control Association

Australian Medical Association

Australian Veterinary Association

Commonwealth Department of Health and Family Services

Dental Assistants Association of Australia

Department of Defence

Federation of Sterilizing Research and Advisory Councils of Australia

Gastroenterological Nurses Society of Australia

Health Department, W.A.

Institute of Hospital Engineering, Australia

Medical Industry Association of Australia

New Zealand Sterile Services Association

N.S.W. Health Department

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Royal College of Pathologists of Australasia

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Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/30, Cleaning and Sterilization of Medical and Surgical Equipment to supersede AS 4187—1994, *Code of practice for cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities*.

This Standard is the result of a consensus among representatives on the Joint Committee to produce it as an Australian Standard.

The objective of this Standard is to ensure that items intended for reprocessing are cleaned, disinfected or sterilized so that they can be safely reused without risk of cross-contamination.

This edition incorporates, inter alia, Amendment No.1—1995 and Amendment No.2—1997. Where Amendment No.1 is incorporated, a marginal bar is placed alongside the text. Where Amendment No.2 is incorporated, parallel marginal bars are placed alongside the text.

It is believed that this arrangement will assist in ascertaining the differences between the 1994 edition and this edition, and will also make the Standard user-friendly.

The principal differences between this edition and the 1994 edition are as follows:

(a) The thrust of the Scope Clause has been altered, with the emphasis on process validation.

(b) More definitions have been included.

(c) More information on liquid chemical sterilants has been included.

(d) Section 7 has been clarified, and Table 7.1 has been modified.

(e) Appendix C has been updated.

Persons having responsibility for safe sterile health care products should be aware of available sterilization processes, methods of control, and physical characteristics of the product to be sterilized. Products produced under controlled conditions will have microorganisms on them and are, by definition, non-sterile. The purpose of sterilization is to destroy these microbiological contaminants. After sterilization, however, there is always a finite probability that a microorganism could survive regardless of the treatment applied. As a consequence, sterility of a processed item is defined in terms of the probability of the occurrence of a single viable microorganism surviving on the item.

Quality system requirements covering the various aspects for design, development, production, supply, installation and servicing are given in AS/NZS ISO 9001, AS/NZS ISO 9002 and AS/NZS ISO 9003, and these requirements can be applied to health care products.

Certain processes used in the manufacture of health care products are considered to be 'special' (as described in the AS/NZS ISO 9000 series of Standards) in that the result cannot be fully verified by subsequent inspection or testing of the product. Sterilization is an example of a special process because efficacy cannot be verified by inspection or testing of the product. For this reason, sterilization processes must be validated before use, the process routinely monitored and the equipment maintained.

There are many references in this Standard to using the manufacturer's written instructions. However, there are occasions when such instructions may still be inadequate and it is recommended that on-site testing be undertaken. Further clarification of these instructions should be sought from the manufacturer.

Sterilization of items that may be contaminated with unconventional infectious agents, e.g. Creutzfeldt-Jakob, is currently being investigated. Current knowledge suggests that these unconventional agents resist processes specified in this Standard.

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

In addition to the referenced documents appearing in Clause 1.2, Appendix I lists additional documents which are considered useful sources of information on the subject of this Standard.

|| Mandatory statements in footnotes to Tables are deemed to be requirements of this Standard.

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