Australian/New Zealand 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 Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-023, Processing of Medical and Surgical Instruments and Equipment. It was approved on behalf of the Council of Standards Australia on 9 December 2002 and on behalf of the Council of Standards New Zealand on 13 December 2002. It was published on 28 January 2003.

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Additional interests participating in the preparation of this Standard:

Australian Association of Practice Managers
Infection Control Review and Certification Service, N.S.W.

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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 and Equipment, to supersede AS 4187—1998, *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.*

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 infection transmission.

The principal differences between this edition and the 1998 edition are as follows:

(a) Table 7.1 has been modified.

(b) A new appendix (Appendix A) has been included to provide a rationale for some of the requirements of the Standard. Relevant clauses are indicated by a footnote to the clause title.

(c) An appendix on validation protocol for moist heat sterilization process has been included (Appendix H) as well as a new appendix on handwashing (Appendix J).

(d) The appendix on care and handling of flexible and rigid endoscopes has been rewritten.

(e) The appendix on the method for measurement of temperature and pressure in steam sterilizers, or temperature only in any heat sterilizers, has been expanded.

Persons having responsibility for the safe delivery of sterile health care products should be aware of available sterilization processes, methods of control, and physical characteristics of the product to be sterilized. Even when products are produced under controlled conditions, they 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 9001:2000, *Quality management systems—Requirements*, 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 controlled, 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.

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 K 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.