AS ISO 14160—2002
ISO 14160:1998



Australian Standard™

# Sterilization of single-use medical devices incorporating materials of animal origin—Validation and routine control of sterilization by liquid sterilants

Standards Australia

This Australian Standard was prepared by Committee HE-023, Processing of medical and surgical instruments. It was approved on behalf of the Council of Standards Australia on 26 June 2002 and published on 28 June 2002.

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# PREFACE

This Standard has been developed to assist in the process of implementation of the Australian Medical Device legislation.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard, through the Joint Standards Australia/Standards New Zealand Committee HE-023 on Processing of medical and surgical instruments.

This Standard is identical with and has been reproduced from ISO 14160:1998, *Sterilization of single-use medical devices incorporating materials of animal origin — Validation and routine control of sterilization by liquid sterilants.*

The objective of this Standard is to specify requirements for the development, validation, process control and monitoring of the sterilization, by the use of liquid chemical sterilants, of single-use medical devices comprising, in whole or in part, materials of animal origin.

At the time of publication, the 1994 editions of AS/NZS ISO 9001, AS/NZS ISO 9002 and AS/NZS ISO 9003 have been superseded by AS/NZS ISO 9001:2000, *Quality management systems — Requirements,* but will remain available as superseded standards until December 2003. The use of the superseded standards beyond that date is endorsed for applications covered by the Australian Medical Device legislation.

This Standard provides for the use of the following Australian/New Zealand Standards as equivalents to the ISO Standards referenced herein:

| *Reference to International Standard or other publication* | | *Equivalent Australian/New Zealand Standard* | |
|---|---|---|---|
| ISO | | AS/NZS ISO | |
| 9001 | Quality management systems — Requirements | | Quality management systems — Requirements |

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(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text ‘this International Standard’ should read ‘this Australian Standard’.

(c) A full point substitutes for a comma when referring to a decimal marker.

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# INTRODUCTION

A sterile product item is one which is free of viable microorganisms. International Standards require, when it is necessary to supply a sterile product item, that adventitious microbiological contamination of a medical device from all sources prior to sterilization be minimized by all practical means. Even so, product items produced under defined manufacturing conditions in accordance with the requirements for quality systems for medical devices (see ISO 13485 and ISO 13488) can, prior to sterilization, have microorganisms on them, albeit in low numbers. Such product items are non-sterile. The purpose of sterilization processing is to inactivate the microbiological contaminants and thereby transform the non-sterile items into sterile ones.

The inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices often approximates an exponential relationship; inevitably this means that there is always a finite probability that a microorganism can survive regardless of the extent of treatment applied. For a given treatment, the probability of survival is determined by the number and types of microorganisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one item in a population of items subjected to sterilization processing cannot be guaranteed and the sterility of the processed population of items has to be defined in terms of the probability of there being a viable microorganism present on the device.

Generic requirements for the quality system for the design/development, production, installation and servicing are given in the ISO 9000 family of standards and in ISO 13485 and ISO 13488. The ISO 9000 series of standards designates certain processes used in manufacture as "special" if the results cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of a special process because process efficacy cannot be verified by inspection and testing of the product. For this reason, sterilization processes have to be validated before use, the performance of the process monitored routinely and the equipment maintained.

It is important to be aware that the exposure to a properly validated and accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the product is sterile and in this respect suitable for its intended use. Attention has also to be given to a number of factors, including the microbiological status (bioburden) of incoming raw materials and/or components, their subsequent storage, and to the control of the environment in which the product is manufactured, assembled and packaged.

The agents for sterilization used most frequently for medical devices are moist heat, dry heat, irradiation and ethylene oxide. While some devices containing animal tissues may be compatible with these commonly applied methods of sterilization (for example catgut sutures are usually sterilized by irradiation), other devices, such as biological heart valves or tissue patches, are not compatible with conventional sterilization processes. It has been recognized that other sterilizing agents might have to be used in these exceptional circumstances. Liquid chemical sterilants have been widely used in such instances and, in common with the other sterilization methods, the efficacy of the process needs to be demonstrated and recorded before it is adopted for routine use.

This International Standard contains requirements for the validation and routine monitoring of sterilization of single-use medical devices containing materials of animal origin by exposure to liquid chemical sterilants; guidance on the application of this International Standard is given in annex A. Manufacturing processes for medical devices containing animal tissues frequently include exposure to chemical agents which can in themselves reduce significantly the bioburden on the medical device. Following the manufacturing process, a medical device is exposed to a defined sterilization process; the requirements for validation and routine control described in this International Standard apply only to this defined sterilization process and do not take account of the lethal effects of other bioburden reduction steps.

NOTE — The guidance given in annex A is not obligatory and it is not provided as a check list for auditors.

NOTES

AUSTRALIAN STANDARD

# Sterilization of single-use medical devices incorporating materials of animal origin—Validation and routine control of sterilization by liquid sterilants

## 1 Scope

This International Standard specifies requirements for the development, validation, process control and monitoring of the sterilization, by the use of liquid chemical sterilants, of single-use medical devices comprising, in whole or in part, materials of animal origin.

This International Standard does not apply to material of human origin.

This International Standard does not describe a quality assurance system for the control of all stages of manufacture.

NOTE 1 Attention is drawn to the standards for quality systems (see ISO 9001 and ISO 13485 or ISO 9002 and ISO 13488) which can be used in the control of all stages of manufacture including the sterilization process.

This International Standard does not describe tests to establish the effects of any chosen sterilization method upon the fitness for use of the medical device.

NOTE 2 Such testing is a crucial part of the design and development of a medical device.

This International Standard does not describe methods for the validation of the inactivation of viruses.

NOTE 3 In developing a method for processing medical devices containing materials of animal origin, consideration of the effects of liquid chemical sterilization on potential viral contaminants will also be necessary because of the source of materials used in the manufacture of these particular medical devices. The importance of validation of viral inactivation for processes within the scope of this International Standard is recognized. This aspect is excluded from this International Standard; a separate European Standard is in preparation (EN 12442-3).

NOTE 4 Liquid chemical sterilants traditionally employed to sterilize animal tissues in medical devices may not be effective in inactivating the causative agents of transmissable spongiform encephalopathies such as bovine spongiform encephalopathy (BSE), or scrapie. Satisfactory validation in accordance with this International Standard should not be assumed to demonstrate inactivation of infective agents of this type.

This International Standard does not cover the level of residual sterilant within medical devices.

NOTE 5 ISO 14538 is concerned with this issue.

## 2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.


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