AS ISO 11135—2002
ISO 11135:1994

Australian Standard™

Medical devices—Validation and routine control of ethylene oxide sterilization

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 11135:1994, *Medical devices — Validation and routine control of ethylene oxide sterilization* and Technical Corrigendum 1 has been incorporated.

The objective of this Standard is to specify the requirements and guidance for validation and routine control of ethylene oxide sterilization processes for medical devices.

As this Standard is reproduced from an International Standard, the following applies:

(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

International Standards require, when it is necessary to supply a sterile product item, that adventitious microbiological contamination of medical devices from all sources is minimized by all practical means. Even so, product items produced under standard manufacturing conditions in accordance with ISO Quality Systems Standards may well, prior to sterilization, have microorganisms on them, albeit in low numbers. Such product items are nonsterile. The purpose of sterilization processing is to deactivate the microbiological contaminants and thereby transform the nonsterile items into sterile ones.

The deactivation of microorganisms by physical and chemical agents used to sterilize medical devices follows an exponential law; inevitably, this means that there is always a finite probability that a microorganism may 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 the environment in which the organisms exist before and during treatment. It follows that the sterility of any one item in a population of items subjected to sterilization can only be expressed in terms of the probability of the existence of a nonsterile item in that population.

Requirements for the quality system for the design/development, production, supply, installation and servicing are given in the ISO 9000 series.

The ISO 9000 series of Standards designates certain processes used in manufacture as "special" in that 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 need to be validated before use and the performance of the process needs to be monitored routinely. The manufacture of a sterile medical device requires attention to product and package characteristics, and to sterilization methods, facilities and controls.

It is important to be aware that 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 suitable for its intended use. Attention should also be given to a number of factors including the microbiological status (bioburden) of incoming raw materials and their subsequent storage, and to the control of the environment in which the product is manufactured, assembled and packaged.

This International Standard contains requirements and offers guidance (as given in the annexes) for the validation and routine monitoring of sterilization by gaseous ethylene oxide. The validation of sterilization procedures presupposes that the sterilization equipment complies with appropriate specifications.

NOTE 1 The requirements are the obligatory parts of this Standard with which compliance has to be achieved. The guidance given in the informative annexes is not obligatory and it is **not** provided as a check-list for auditors.

The guidance included in the annexes provides explanations as well as methods which are accepted as being suitable for achieving compliance with the requirements. This guidance is provided in order to assist in obtaining a uniform understanding and implementation of this International Standard. Methods other than those given in the guidance may be used. However, these methods need to be demonstrated to be effective in achieving compliance with the requirements of this International Standard.

AUSTRALIAN STANDARD

Medical devices—Validation and routine control of ethylene oxide sterilization

1 Scope

1.1 This International Standard establishes requirements and guidance for validation and routine control of ethylene oxide sterilization processes for medical devices.

Particular attention is drawn to the need for specific testing for safety, quality and efficacy, possibly exceeding the requirements of 4.2, which may be necessary for a specific product.

NOTE 2 Although this International Standard has been written for medical device sterilization, it may also apply to other health care products.

1.2 It does not cover the quality assurance system which is essential to control all stages of manufacture which include the sterilization process.

1.3 It does not cover operator safety (for further information, see IEC 1010-2).

Ethylene oxide is toxic, flammable and explosive. Attention is drawn to the existence in some countries of regulations laying down safety requirements for handling ethylene oxide and for premises in which it is used.

Attention is drawn to the existence in some countries of statutory regulations laying down limits for the level of ethylene oxide residues within medical devices and products.

1.4 It does not cover sterilization either by the technology of injecting ethylene oxide or its mixtures directly into individual product packages or continuous sterilization processes.

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1) To be published.

1.5 It does not cover analytical methods for determining levels of residual ethylene oxide and/or its reaction products (see ISO 10993-7).

1.6 It does not cover products that are affected adversely by ethylene oxide or by other ethylene oxide residuals produced in the processes described.

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, and parties to 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.

ISO 9001:1987, *Quality systems — Model for quality assurance in design/development, production, installation and servicing.*

ISO 9002:1987, *Quality systems — Model for quality assurance in production and installation.*

ISO 9004:1987, *Quality management and quality system elements — Guidelines.*

ISO 10993-7:—[1], *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals.*

ISO 11138-1:—[1], *Sterilization of health care products — Biological indicators — Part 1: General.*