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EN 556-1:2001

Australian Standard™

Sterilization of medical devices — Requirements for medical devices to be designated "STERILE"

Part 1: Requirements for terminally sterilized medical devices

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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Australian Dental Association
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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 EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices.*

The objective of this Standard is to specify requirements for a terminally-sterilized medical device to be designated 'sterile'.

As this Standard is reproduced from a European 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 European 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 micro-organisms. European Standards for *medical devices* require, when it is necessary to supply a *sterile* product item, that adventitious microbiological contamination of a *medical device* from all sources is minimized by all practical means. Even so, product items produced under standard manufacturing conditions in accordance with their requirements for quality systems for medical devices (see EN ISO 13485:2000 or EN ISO 13488:2000) may, prior to sterilization, have micro-organisms 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 micro-organisms by physical and/or chemical agents used to sterilize *medical devices* often approximates to an exponential relationship; inevitably this means that, regardless of the extent of treatment applied, there is always a finite probability that a micro-organism will survive. For a given treatment, the probability of survival is determined by the number and resistance of micro-organisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one item subjected to sterilization processing cannot be guaranteed and the sterility of the processed items has to be defined in terms of the probability of the existence of a surviving micro-organism on/in an item. The standards for quality management systems recognize that there are processes used which cannot be fully verified by subsequent inspection and testing of product. Sterilization is an example of such a process. 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 exposure to a properly validated and accurately controlled sterilization process is not the only factor associated with the provision of assurance that the product item 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.

AUSTRALIAN STANDARD

Sterilization of medical devices — Requirements for medical devices to be designated "STERILE"

Part 1: Requirements for terminally sterilized medical devices

1 Scope

This European Standard specifies the requirements for a terminally-sterilized *medical device* to be designated *'STERILE'*. Part 2 of this European Standard specifies the requirements for an aseptically processed medical device to be designated "*STERILE*".

NOTE For the purpose of the EU Directive(s) for medical devices (see Bibliography), designation of a medical device as *'STERILE'* is only permissible when a validated sterilization process has been applied. Requirements for validation and routine control of processes for the sterilization of *medical devices* are specified in EN 550, EN 552, EN 554, EN ISO 14160 and EN ISO 14937.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN ISO 13485:2000, *Quality systems - Medical devices - Particular requirements for the application of EN/ISO 9001 (revision of EN 46001:1996) (identical to ISO 13485:1996)*

EN ISO 13488:2000, *Quality systems - Medical devices - Particular requirements for the application of EN/ISO 9002 (revision of EN 46002:1996) (identical to ISO 13488:1996)*

3 Terms and definitions

For the purposes of this standard, the following terms and definitions apply.

NOTE Terms defined in this clause are set in Italic type throughout the text of this standard.