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EN 1174-1:1996

Australian Standard™

Sterilization of medical devices — Estimation of the population of micro-organisms on product

Part 1: Requirements

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.

The following are represented on Committee HE-023:

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Australian Dental Association
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Australian General Practice Accreditation
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Australian Healthcare 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 1174-1:1996, *Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 1: Requirements.*

The objective of this Standard is to specify requirements for the estimation of the population of viable micro-organisms on a medical device or on a component, raw material or package.

Users in Australia should be aware that, where reference is made to EN 29001, EN 29002 and/or EN 29003, they are identical with the 1994 editions of AS/NZS ISO 9001, AS/NZS ISO 9002 and AS/NZS ISO 9003 respectively. These Standards provide three quality assurance models that represent three distinct forms of quality system requirements suitable for the purpose of a supplier demonstrating its capability, and for the assessment of the capability of a supplier by external parties.

At the time of publication, the 1994 editions of AS/NZS ISO 9001, AS/NZS ISO 9002 and AS/NZS ISO 9003 have been superseded by AS/NZS ISO 9001:2000, *Quality management systems — Requirements*, but will remain available as superseded standards until December 2003. The use of the superseded standards and their EN equivalents beyond that date is endorsed for applications covered by the Australian Medical Device legislation.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

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. The 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 the requirements for quality systems for medical devices (see EN 46001 or EN 46002) 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 there is always a finite probability that a micro-organism may survive regardless of the extent of treatment applied. 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 in a population of items subjected to sterilization processing cannot be guaranteed and the sterility of the processed population of items is defined in terms of the probability of the existence of a non-sterile item in that population.

Requirements for the quality system for the design/development, production, installation and servicing of *medical devices* are given in EN 46001 and EN 46002 which supplement the EN ISO 9000 series of European Standards. The EN 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 need to be validated before use, the performance of each process monitored routinely and the equipment properly maintained.

European standards specifying procedures for the validation and routine control of the processes used for the sterilization of *medical devices* have been prepared (see EN 550, EN 552 and EN 554). However, 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 is sterile and, in this respect, suitable for its intended use. Indeed for the effective *validation* and routine control of a sterilization process, it is also important to be aware of the microbiological challenge which is presented to that process, both in terms of number, identities and properties of micro-organisms.

The pre-sterilization microbiological contamination is the sum of contributions from a number of sources: therefore it is important also to give attention to factors including the microbiological status of incoming raw materials and/or components, their subsequent storage and the control of the environment in which the product is manufactured, assembled and packaged.

AUSTRALIAN STANDARD

Sterilization of medical devices — Estimation of the population of micro-organisms on product

Part 1: Requirements

1 Scope

1.1 This Part of EN 1174 specifies general criteria to be applied in the estimation of the population of viable micro-organisms on a *medical device* or on a component, raw material or package. This estimation consists of both enumeration and characterization of the population.

NOTE 1: Prior to routine use, a technique for estimating the population of micro-organisms on *product* is validated. The level to which, during characterization, identification is necessary is dependent on the use to be made of the data generated.

NOTE 2: Parts 2 and 3 of this European Standard will provide guidance on selection of a technique and outline method(s) which may be used to validate the technique selected.

NOTE 3: A bibliography of useful standards is given in annex A.

1.2 This Part of EN 1174 is not applicable to the enumeration or identification of viral contamination.

1.3 This Part of EN 1174 is not applicable to the microbiological monitoring of the environment in which *medical devices* are manufactured (see Note 1).

NOTE 1: Standards on environmental monitoring are being prepared by CEN/TC 243.

NOTE 2: Attention is drawn to the standards for quality systems (see EN 46001 or EN 46002) which control all stages of manufacture including the sterilization process. It is not a requirement of this standard to have a complete quality system during manufacture but certain elements of such a system are required and these are normatively referenced at appropriate places in the text.

2 Normative references

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

EN ISO 9001 : 1994	Quality systems - Model for quality assurance in design, development, production, installation and servicing (ISO 9001:1994)
EN 46001 : 1993	Quality systems - Medical devices - Particular requirements for the application of EN 29001