AS EN 1174.2—2002
EN 1174-2:1996

Australian Standard™

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

Part 2: Guidance

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 EN 1174-2:1996, *Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 2: Guidance.*

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

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

Requirements for the estimation of the population of micro-organisms on product (this population is commonly known as the bioburden) during the manufacture of medical devices are specified in EN 1174-1. This Part of EN 1174 contains guidance on the implementation of EN 1174-1. Methods other than those given in the guidance can be used but these alternative methods should be demonstrated as being effective in achieving compliance with the requirements of EN 1174-1.

AUSTRALIAN STANDARD

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

Part 2: Guidance

1 Scope

This Part of this European Standard provides guidance on the implementation of the requirements specified in EN 1174-1. It is aimed at providing a better understanding of EN 1174-1 as well as assisting in implementing its requirements. The guidance given is not intended to be exhaustive, but to highlight important aspects to which attention should be given.

NOTE: This Part of EN 1174-1 is informative and does not contain requirements.

This Part of this European standard is not intended as a checklist for assessing compliance with EN 1174-1.

2 Normative reference

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.

EN 1174-1: 199c Sterilization of medical devices - Estimation of the population of micro-organisms on product - Part 1: Requirements