

Australian Standard™

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

**Part 3: Guide to the methods for
validation of microbiological techniques**

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 College of Operating Room Nurses
Australian Dental Association
Australian Dental Industry Association Inc
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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 1174-3:1996, *Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 3: Guide to the methods for validation of microbiological techniques*

The objective of this Standard is to provide guidance by describing approaches which may be taken when validating techniques 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

This Part of EN 1174 describes approaches that may be used for the validation of a technique for the estimation of bioburden. These general approaches are intended to provide guidance on the implementation of the requirements of EN 1174-1. Approaches other than those outlined here may be used.

The judgement of suitably trained and qualified personnel needs to be applied in the correct application of these approaches and, in particular, it is important to take account of product configuration and situations in which certain contaminants are sought amongst the bioburden.

AUSTRALIAN STANDARD

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

Part 3: Guide to the methods for validation of microbiological techniques

1 Scope

This Part of EN 1174 gives guidance by describing approaches which may be taken when validating techniques for bioburden estimation.

This guidance is not intended to be exhaustive but is intended to highlight important aspects of methodology to which attention should be given.

This document is informative and does not contain requirements.

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 : 1996 Sterilization of medical devices - Estimation of the population of micro-organisms on product - Part 1: Requirements