AS EN 1174.3—2002
EN 1174-3:1996

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

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:

Australian Chamber of Commerce and Industry
Australian College of Operating Room Nurses
Australian Dental Association
Australian Dental Industry Association Inc
Australian General Practice Accreditation
Australian Health Industry Inc
Australian Healthcare Association
Australian Industry Group
Australian Infection Control Association
Australian Medical Association
Australian Nursing Federation
Australian Veterinary Association
Commonwealth Department of Health and Ageing
Council of Textile and Fashion Industries of Australia Ltd
Dental Assistants Association of Australia Inc
Department of Defence (Australia)
Department of Human Services (South Australia)
Department of Human Services (Victoria)
Federation of Sterilizing Research and Advisory Councils of Australia
Gastroenterological Nurses College of Australia
Health Department of Western Australia
Institute of Hospital Engineering Australia
Medical Industry Association of Australia Inc
NSW Health Department
Queensland Health
Royal Australasian College of Surgeons
Royal Australian College of General Practitioners
Royal College of Pathologists of Australasia
Rural Doctors Association of Australia
The Chiropody Board of South Australia

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about Standards can be found by visiting the Standards Australia web site at www.standards.com.au and looking up the relevant Standard in the on-line catalogue.

Alternatively, the printed Catalogue provides information current at 1 January each year, and the monthly magazine, *The Australian Standard*, has a full listing of revisions and amendments published each month.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.com.au, or write to the Chief Executive, Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001.

This Standard was issued in draft form for comment as DR 02172.

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

First published as AS EN 1174.3—2002.

Published by Standards Australia International Ltd
GPO Box 5420, Sydney, NSW 2001, Australia

ISBN 0 7337 4694 2

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.

CONTENTS

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