

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

Part 2. Guidance

The European Standard EN 1174-2 : 1996 has the status of a
British Standard

ICS 07.100.10; 11.080

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/67, Sterilization of medical devices, upon which the following bodies were represented:

- Association of British Health-Care Industries
- Association of Contact Lens Manufacturers
- Association of the British Pharmaceutical Industry
- British Anaesthetic and Respiratory Equipment Manufacturers Association
- British Surgical Trades Association
- Central Sterilising Club
- Department of Health
- Hospital Infection Society
- Institute of Sterile Services Management
- Medical Sterile Products Association
- National Physical Laboratory
- Panel on Gamma and Electron Irradiation
- Parenteral Society
- Royal College of Pathologists
- Royal Pharmaceutical Society of Great Britain
- Sterilised Suture Manufacturers Association

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 July 1997

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National foreword

This Part of BS EN 1174 has been prepared by Technical Committee CH/67, and is the English language version of EN 1174-2 : 1996 *Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 2: Guidance*, published by the European Committee for Standardization (CEN).

Cross-reference

Publication referred to	Corresponding British Standard
EN 1174-1 : 1996	BS EN 1174 <i>Sterilization of medical devices — Estimation of the population of micro-organisms on product</i> Part 1 : 1996 <i>Requirements</i>

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 14, an inside back cover and a back cover.

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Descriptors: Medical equipment, sterilization, quality, estimation, contamination, designation, micro-organisms, microbiological analysis

English version

Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 2: Guidance

Stérilisation des dispositifs médicaux — Estimation de la population de micro-organismes sur un produit — Partie 2: Lignes directrices

Sterilisation von Medizinprodukten — Schätzung der Population von Mikroorganismen auf einem Produkt — Teil 2: Leitfaden

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 204, Sterilization of medical devices, the secretariat of which is held by BSI.

Annex A is informative.

This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directives(s), see informative Annex ZA, which is an integral part of this standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 1997, and conflicting national standards shall be withdrawn at the latest by May 1997.

This standard has been considered by CEN/TC 204 as one of a sequence of European standards concerned with the estimation of the population of micro-organisms (bioburden) on product to be sterilized or after sterilization. EN 1174 has been prepared in three Parts, as follows:

- EN 1174 *Sterilization of medical devices — Estimation of the population of micro-organisms on product*
- Part 1: *Requirements*
- Part 2: *Guidance*
- Part 3: *Guide to the methods for validation of microbiological techniques.*

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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