

Sterilization of medical devices — Microbiological methods —

Part 2: Tests of sterility performed in the validation of a sterilization process

The European Standard EN ISO 11737-2:2000 has the status of a
British Standard

ICS 07.100.10;11.080.01

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW



Document Sharing Hub

National foreword

This British Standard is the official English language version of EN ISO 11737-2:2000. It is identical with ISO 11737-2:1998.

The UK participation in its preparation was entrusted to Technical Committee CH/67, Sterilization of medical devices, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

Attention is drawn to the fact that CEN and CENELEC Standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

The Bibliography refers to ISO 11737-1, Sterilization of medical devices — Microbiological methods — Part 1: Estimation of the population of micro-organisms on products, the contents of which has been published in the United Kingdom as:

BS EN 1174-1 Sterilization of medical devices — Estimation of the population of micro-organisms on product

Part 1: Requirements;

BS EN 1174-2 Sterilization of medical devices — Estimation of the population of micro-organisms on product

Part 2: Guidance;

BS EN 1174-3 Sterilization of medical devices — Estimation of the population of micro-organisms on product

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

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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, the EN ISO title page, the EN ISO foreword page, the ISO title page, pages ii to iv, pages 1 to 13, the annex ZA page, an inside back cover and a back cover.

The BSI copyright notice displayed in this document indicates when the document was last issued.

Amendments issued since publication

Amd. No.	Date	Comments

This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 May 2000

© BSI 05-2000

ISBN 0 580 34033 3

English version

**Sterilization of medical devices - Microbiological methods - Part
2: Tests of sterility performed in the validation of a sterilization
process (ISO 11737-2:1998)**

Stérilisation des dispositifs médicaux - Méthodes
microbiologiques - Partie 2: Essais de stérilité pratiqués en
cours de validation d'un procédé de stérilisation (ISO
11737-2:1998)

Sterilisation von Medizinprodukten - Mikrobiologische
Verfahren - Teil 2: Sterilitätsprüfungen bei der Validierung
eines Sterilisationsverfahrens (ISO 11737-2:1998)

This European Standard was approved by CEN on 17 December 1999.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. 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.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Foreword

The text of the International Standard from Technical Committee ISO/TC 198 "Sterilization of health care products" of the International Organization for Standardization (ISO) has been taken over as an European Standard by Technical Committee CEN/TC 204 "Sterilization of medical devices", the secretariat of which is held by BSI.

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 August 2000, and conflicting national standards shall be withdrawn at the latest by August 2000.

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

Endorsement notice

The text of the International Standard ISO 11737-2:1998 has been approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

INTERNATIONAL STANDARD

ISO
11737-2

First edition
1998-07-01

Sterilization of medical devices — Microbiological methods —

Part 2:

Tests of sterility performed in the validation of
a sterilization process

Stérilisation des dispositifs médicaux — Méthodes microbiologiques

*Partie 2: Essais de stérilité pratiqués en cours de validation d'un procédé de
stérilisation*



Contents

	Page
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General.....	2
5 Selection and preparation of product units for testing	3
6 Tests of sterility	4
7 Assessment of method for test of sterility.....	4
Annex A (informative) Guidance on tests of sterility performed in validation of a sterilization process.....	5
Bibliography	12

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 11737-2 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

ISO 11737 consists of the following parts, under the general title *Sterilization of medical devices — Microbiological methods*:

- *Part 1: Estimation of the population of microorganisms on product*
- *Part 2: Tests of sterility performed in the validation of a sterilization process*

Annex A of this International Standard is for information only.

Introduction

A sterile product item is one which is free of viable microorganisms. The International Standards for sterilization of medical devices require, when it is necessary to supply a sterile product item, that adventitious microbiological contamination of a medical device from all sources be 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 may, prior to sterilization, have microorganisms 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 microorganisms by physical and/or chemical agents used to sterilize medical devices often approximates an exponential relationship; inevitably this means that there is always a finite probability that a microorganism 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 microorganisms 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 has to be 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 ISO 9001 and ISO 9002 in conjunction with ISO 13485 and ISO 13488, respectively.

The 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 have to be validated before use, the performance of the process monitored routinely and the equipment maintained.

International Standards specifying procedures for the validation and routine control of the processes used for sterilization of medical devices have been prepared (see ISO 11134, 11135 and 11137). An element of this validation may consist of exposing medical devices to the sterilizing agent when the extent of treatment has been reduced relative to that which will be used in routine processing in order to provide a knowledge of the resistance to the agent of the microbial contamination as it occurs naturally on medical devices. Subsequent to this exposure, medical devices are subjected individually to tests of sterility as described in this part of ISO 11737. An example of the use of such a test is in establishing a sterilizing dose for sterilization by radiation and for demonstrating the continued validity of this sterilization dose (see ISO 11137, Annex B).

Annex A of this part of ISO 11737 gives guidance on the techniques used and on practical aspects of the requirements.