This is a free page sample. Access the full version online.

National Standards Authority of Ireland

IRISH STANDARD

I.S. EN ISO 11737-1:2006

ICS 07.100.10
11.080.01

STERILIZATION OF MEDICAL DEVICES - MICROBIOLOGICAL METHODS - PART 1: DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS (ISO 11737-1:2006)

National Standards
Authority of Ireland
Glasnevin, Dublin 9
Ireland

Tel: +353 1 807 3800
Fax: +353 1 807 3838
http://www.nsai.ie

Sales
http://www.standards.ie

This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on:
June 16, 2006

NO COPYING WITHOUT NSAI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW

© NSAI 2006

Price Code M

Údarás um Chaighdeáin Náisiúnta na hÉireann

This is a free page sample. Access the full version online.

This is a free page sample. Access the full version online.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11737-1:2006/AC

April 2009
Avril 2009
April 2009

ICS 07.100.10; 11.080.01

English version
Version Française
Deutsche Fassung

Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006/Cor 1:2007)

Stérilisation des dispositifs médicaux - Méthodes microbiologiques - Partie 1: Détermination d'une population de micro-organismes sur des produits (ISO 11737-1:2006/Cor 1:2007)

Sterilisation von Medizinprodukten - Mikrobiologische Verfahren - Teil 1: Bestimmung der Population von Mikroorganismen auf Produkten (ISO 11737-1:2006/Cor 1:2007)

This corrigendum becomes effective on 8 April 2009 for incorporation in the three official language versions of the EN.

Ce corrigendum prendra effet le 8 avril 2009 pour incorporation dans les trois versions linguistiques officielles de la EN.

Die Berichtigung tritt am 8.April 2009 zur Einarbeitung in die drei offiziellen Sprachfassungen der EN in Kraft.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

© 2009 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.
Tous droits d'exploitation sous quelque forme et de quelque manière que ce soit réservés dans le monde entier aux membres nationaux du CEN.
Alle Rechte der Verwertung, gleich in welcher Form und in welchem Verfahren, sind weltweit den nationalen Mitgliedern von CEN vorbehalten.

Ref. No.:EN ISO 11737-1:2006/AC:2009 D/E/F

This is a free page sample. Access the full version online.

Endorsement notice

The text of ISO 11737-1:2006/Cor.1:2007 has been approved by CEN as a European Corrigendum without any modification.

This is a free page sample. Access the full version online.

I.S. EN ISO 11737-1:2006/AC:2009
INTERNATIONAL STANDARD ISO 11737-1:2006
TECHNICAL CORRIGENDUM 1

Published 2007-05-15

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Sterilization of medical devices — Microbiological methods —

Part 1:
Determination of a population of microorganisms on products

TECHNICAL CORRIGENDUM 1

Stérilisation des dispositifs médicaux — Méthodes microbiologiques —

Partie 1: Détermination d'une population de micro-organismes sur des produits

RECTIFICATIF TECHNIQUE 1

Technical Corrigendum 1 to ISO 11737-1:2006 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*

Page 17

Subclause A.7.2

In paragraph 2, the last sentence shall read:

> However, this approach can be used for products with low levels of bioburden.

(The verb form “cannot be” has been corrected to “can be”.)

ICS 07.100.10; 11.080.01 **Ref. No. ISO 11737-1:2006/Cor.1:2007(E)**

© ISO 2007 – All rights reserved

Published in Switzerland

This is a free page sample. Access the full version online.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11737-1

April 2006

ICS 07.100.10; 11.080.01

Supersedes EN 1174-1:1996, EN 1174-2:1996, EN 1174-3:1996

English Version

Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)

Stérilisation des dispositifs médicaux - Méthodes microbiologiques - Partie 1: Détermination d'une population de micro-organismes sur des produits (ISO 11737-1:2006)

Sterilisation von Medizinprodukten - Mikrobiologische Verfahren - Teil 1: Bestimmung der Population von Mikroorganismen auf Produkten (ISO 11737-1:2006)

This European Standard was approved by CEN on 23 March 2006.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

© 2006 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. EN ISO 11737-1:2006: E

This is a free page sample. Access the full version online.

Foreword

This document (EN ISO 11737-1:2006) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with 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 October 2006, and conflicting national standards shall be withdrawn at the latest by October 2006.

This document supersedes EN 1174-1:1996, EN 1174-2:1996 and EN 1174-3:1996.

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

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

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

Endorsement notice

The text of ISO 11737-1:2006 has been approved by CEN as EN ISO 11737-1:2006 without any modifications.

This is a free page sample. Access the full version online.

ANNEX ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directives 90/385/EEC concerning active implantable medical devices, 93/42/EEC concerning medical devices and 98/79/EC concerning *in vitro* diagnostic medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directives 90/385/EEC concerning active implantable medical devices, 93/42/EEC concerning medical devices and 98/79/EC concerning *in vitro* diagnostic medical devices.

Once this standard is cited in the Official Journal of the European Communities under thos Directives and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of those Directives and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directives 90/385 EEC concerning active implantable medical devices, 93/42/EEC concerning medical devices and 98/79/EC concerning in vitro diagnostic medical devices

Clause(s)/Sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 90/385/EEC	Essential Requirements (ERs) of Directive 93/42/EEC	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/Notes
4, 5, 6, 7, 8, 9, 10, 11, 12	7	8.3	2.3	In part
4, 5, 6, 7, 8, 9, 10, 11, 12		8.4	2.4	In part

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

This is a free page sample. Access the full version online.

This is a free page sample. Access the full version online.

This is a free page sample. Access the full version online.

INTERNATIONAL STANDARD

ISO 11737-1

Second edition
2006-04-01

Sterilization of medical devices — Microbiological methods —

Part 1: Determination of a population of microorganisms on products

Stérilisation des dispositifs médicaux — Méthodes microbiologiques —

Partie 1: Détermination d'une population de micro-organismes sur des produits

Reference number
ISO 11737-1:2006(E)

© ISO 2006

This is a free page sample. Access the full version online.

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

© ISO 2006

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

This is a free page sample. Access the full version online.

Contents

Page

Foreword ... iv

Introduction ... v

1 Scope ... 1

2 Normative references ... 1

3 Terms and definitions ... 2

4 Quality management system elements ... 4
4.1 Documentation ... 4
4.2 Management responsibility ... 4
4.3 Product realization ... 4
4.4 Measurement, analysis and improvement — Control of nonconforming product ... 5

5 Selection of product ... 5
5.1 General ... 5
5.2 Sample item portion (SIP) ... 5

6 Methods of determination and microbial characterization of bioburden ... 6
6.1 Determination of bioburden ... 6
6.2 Microbial characterization of bioburden ... 7

7 Validation of method for determining bioburden ... 7

8 Routine determination of bioburden and interpretation of data ... 7

9 Maintenance of the method of determination of bioburden ... 8
9.1 Changes to the product and/or manufacturing process ... 8
9.2 Changes to the method of determination of bioburden ... 8
9.3 Revalidation of the method of determination of bioburden ... 8

Annex A (informative) **Guidance on determination of a population of microorganisms on product** ... 9

Annex B (informative) **Guidance on methods of determination of bioburden** ... 22

Annex C (informative) **Validation of bioburden methods** ... 31

Bibliography ... 34

© ISO 2006 – All rights reserved

This is a free page sample. Access the full version online.

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 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11737-1 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11737-1:1995) which has been technically revised and ISO 11737-3:2004 whose contents it now incorporates.

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

— *Part 1: Determination of a population of microorganisms on products*

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

 © ISO 2006 – All rights reserved

This is a free page sample. Access the full version online.

Introduction

A sterile medical device is one that is free of viable microorganisms. International standards that specify requirements for validation and routine control of sterilization processes, require, when it is necessary to supply a sterile medical device, that adventitious microbiological contamination of a medical device prior to sterilization be minimized. Even so, medical devices produced under standard manufacturing conditions in accordance with the requirements for quality management systems (see, for example, ISO 13485) may, prior to sterilization, have microorganisms on them, albeit in low numbers. Such products are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile products into sterile ones.

The kinetics of inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices can generally best be described by an exponential relationship between the numbers of microorganisms surviving and the extent of treatment with the sterilizing agent; 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 product in a population subjected to sterilization processing cannot be guaranteed and the sterility of a processed population is defined in terms of the probability of there being a viable microorganism present on a product item.

Generic requirements of the quality management system for design and development, production, installation and servicing are given in ISO 9001 and particular requirements for quality management systems for medical device production are given in ISO 13485. The standards for quality management systems recognize that, for certain processes used in manufacturing, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process is monitored routinely and the equipment is maintained.

International Standards specifying procedures for the validation and routine control of the processes used for the sterilization of medical devices have been prepared (see, for example, ISO 11135, ISO 11137 series and ISO 17665). However, it is important to be aware that exposure to a properly validated and accurately controlled sterilization process is not the only factor associated with the provision of assurance that the product is sterile and, in this respect, suitable for its intended use. Furthermore, for the effective validation and routine control of a sterilization process, it is important to be aware of the microbiological challenge that is presented in the process, in terms of number, characteristics and properties of microorganisms.

The term bioburden is used to describe the population of viable microorganisms present on or in product and/or a sterile barrier system. A knowledge of bioburden can be used in a number of situations as part of:

— validation and revalidation of sterilization processes;

— routine monitoring for control of manufacturing processes;

— monitoring of raw materials, components or packaging;

— assessment of the efficiency of cleaning processes;

— an overall environmental monitoring programme.

Bioburden is the sum of the microbial contributions from a number of sources, including raw materials, manufacturing of components, assembly processes, manufacturing environment, assembly/manufacturing aids (e.g., compressed gases, water, lubricants), cleaning processes and packaging of finished product. To control bioburden, attention must be given to the microbiological status of these sources.

© ISO 2006 – All rights reserved

This is a free page sample. Access the full version online.

It is not possible to enumerate the bioburden exactly and, in practice, a determination of bioburden is made using a defined method. Definition of a single method for use in the determination of bioburden in all situations is not practicable because of the wide variety of designs and materials of construction of medical devices. Nor is it possible to define a single technique to be used in all situations for the removal of microorganisms in preparation for enumeration. Furthermore, the selection of conditions for enumeration of microorganisms will be influenced by the types of microorganism likely to be present on or in medical devices.

This part of ISO 11737 specifies the requirements to be met in the determination of bioburden. The requirements are the normative parts of this part of ISO 11737 with which compliance is claimed. The guidance given in the informative annexes is not normative and is not provided as a checklist for auditors. The guidance provides explanations and methods that are regarded as being a suitable means for complying with the requirements. Methods other than those given in the guidance may be used, if they are effective in achieving compliance with the requirements of this part of ISO 11737.

© ISO 2006 – All rights reserved

This is a free page sample. Access the full version online.

Sterilization of medical devices — Microbiological methods —

Part 1: Determination of a population of microorganisms on products

1 Scope

This part of ISO 11737 specifies requirements and provides guidance for the enumeration and microbial characterization of the population of viable microorganisms on or in a medical device, component, raw material or package.

NOTE 1 The nature and extent of microbial characterization is dependent on the intended use of the bioburden data.

This part of ISO 11737 does not specify requirements for the enumeration or identification of viral or protozoan contaminants.

NOTE 2 Furthermore, the requirements specified in this part of ISO 11737 are not intended to address the removal and detection of the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease.

This part of ISO 11737 does not specify requirements for the microbiological monitoring of the environment in which medical devices are manufactured.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

ISO 13485:2003, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

© ISO 2006 – All rights reserved

SAI GLOBAL

This is a free preview. Purchase the entire publication at the link below:

Product Page

Looking for additional Standards? Visit Intertek Inform Infostore

Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation