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Utgåva 1

Sterilisering av medicintekniska produkter – Mikrobiologiska metoder –
Del 1: Skattning av antalet mikroorganismer på produkter (ISO 11737-1:2006)

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

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The European Standard EN ISO 11737-1:2006 has the status of a Swedish Standard. This document contains the official English version of EN ISO 11737-1:2006.

This standard supersedes the Swedish Standards SS-EN 1174-1, edition 1, SS-EN 1174-2, edition 1 and SS-EN 1174-3, edition 1.

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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.

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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of an identical text or by endorsement, at the latest by October 2006, and conflicting national standards shall be withdrawn at the latest by October 2006.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.

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.

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.

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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
bioburden
population of viable microorganisms on or in product and/or sterile barrier system

[ISO/TS 11139:2006, definition 2.2]

3.2
correction
action to eliminate a detected nonconformity

NOTE A correction can be made in conjunction with a **corrective action** (3.4).

[ISO 9000:2005, definition 3.6.6]

3.3
correction factor
numerical value applied to compensate for incomplete removal from product and/or culture of microorganisms

3.4
corrective action
action to eliminate the cause of a detected nonconformity or other undesirable situation

NOTE 1 There can be more than one cause for a nonconformity.

NOTE 2 Corrective action is taken to prevent recurrence whereas **preventive action** (3.9) is taken to prevent occurrence.

NOTE 3 There is a distinction between **correction** (3.2) and corrective action.

[ISO/TS 11139:2006, definition 2.8]

3.5
culture conditions
combination of growth media and manner of incubation used to promote germination, growth and/or multiplication of microorganisms

NOTE The manner of incubation may include the temperature, time and any other conditions specified for incubation.

[ISO/TS 11139:2006, definition 2.10]

3.6
establish
determine by theoretical evaluation and confirm by experimentation

[ISO/TS 11139:2006, definition 2.17]

3.7
medical device
instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

— investigation, replacement, modification or support of the anatomy or of a physiological process;

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

— providing information for medical purposes by means of in vitro examination of specimens derived from the human body;

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

NOTE This definition from ISO 13485:2003 has been developed by the Global Harmonization Task Force (GHTF 2002).

[ISO 13485:2003]

3.8
microbial characterization
process by which microorganisms are grouped into categories

NOTE Categories may be broadly based, for example, on the use of selective media, colony or cellular morphology, staining properties or other characteristics.

[ISO/TS 11139:2006, definition 2.25]

3.9
preventive action
action to eliminate the cause of a potential nonconformity or other undesirable potential situation

NOTE 1 There can be more than one cause for a potential nonconformity.

NOTE 2 Preventive action is taken to prevent occurrence whereas **corrective action** (3.4) is taken to prevent recurrence.

[ISO 9000:2005, definition 3.6.4]

3.10
product
result of a process

NOTE For the purposes of sterilization standards, the product is tangible and can be raw material(s), intermediate(s), sub-assembly(ies) and health care products.

[ISO 9000:2005, definition 3.4.2]

3.11
recognized culture collection
depository authority under the Budapest Treaty on “The International Recognition of the Deposit of Microorganisms for the Purposes of Patent and Procedure”

[ISO/TS 11139:2006, definition 2.38]

3.12
recovery efficiency
measure of the ability of a specified technique to remove and/or culture microorganisms from product

3.13
sample item portion
SIP
defined part of a medical device that is tested