Singapore Standards Council

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SINGAPORE STANDARD

Sterilisation of health care products — Microbiological methods —

Part 1: Determination of a population of microorganisms on products

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Part 1: Determination of a population of microorganisms on products

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This Singapore Standard was approved on 3 December 2018 by the Biomedical and Health Standards Committee under the purview of the Singapore Standards Council.

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The National Mirror Working Group on ISO/TC 210, appointed by the Technical Committee to assist in the preparation of this standard, comprises the following experts who contribute in their individual capacity:

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Access-2-Healthcare
BioPharmaSpec UK Ltd
Sanmina Corporation Singapore
Singapore Manufacturing Federation (Medical Technology Industry Group)
SysteMED Pte Ltd
TüV SüD PSB Pte Ltd
Wise Consultants and Services Pte Ltd

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National Foreword

This Singapore Standard was prepared by the National Mirror Working Group on ISO/TC 210 appointed by the Technical Committee on Quality Management Systems under the direction of the Biomedical and Health Standards Committee.

This standard is identical with ISO 11737-1:2018, "Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products", published by the International Organization for Standardization.

Attention is drawn to the following:

1. The references to International Standards shall be replaced by the following Singapore Standards:

International Standard	Corresponding Singapore Standard
ISO 13485	SS ISO 13485
ISO 15189	SS ISO 15189
ISO/IEC 17025	SS ISO/IEC 17025

2. The comma has been used throughout as a decimal marker whereas in Singapore Standards it is a practice to use a full point on the baseline as the decimal marker.

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

NOTE

1. *Singapore Standards (SSs) and Technical References (TRs) are reviewed periodically to keep abreast of technical changes, technological developments and industry practices. The changes are documented through the issue of either amendments or revisions.*

2. *An SS or TR is voluntary in nature except when it is made mandatory by a regulatory authority. It can also be cited in contracts making its application a business necessity. Users are advised to assess and determine whether the SS or TR is suitable for their intended use or purpose. If required, they should refer to the relevant professionals or experts for advice on the use of the document. Enterprise Singapore shall not be liable for any damages whether directly or indirectly suffered by anyone or any organisation as a result of the use of any SS or TR.*

3. *Compliance with a SS or TR does not exempt users from any legal obligations*

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, Sterilization of health care products.

This third edition cancels and replaces the second edition (ISO 11737-1:2006), which has been technically revised. It also incorporates the Technical Corrigendum ISO 11737-1:2006/ Cor.1:2007.

The main changes compared to the previous edition are as follows:

— the term “bioburden spikes” has been introduced as a normal and consistent part of the bioburden, and examples of data have been provided;

— clarification has been added that package testing is not typically done except when it is an integral part of the product;

— more information has been provided on the most probable number (MPN) technique and its applications;

— details have been provided on ways to improve limit of detection (LOD) and correct use of the data;

— some discussion has been deleted of statistical methods for the evaluation of bioburden data where information was not typical or not required;

— a table has been added with criteria for selection of a bioburden recovery efficiency approach, the use of the correction factor (CF) has been explained, and the bioburden recovery efficiency value of < 50 % mentioned for technique modifications has been eliminated;

— more information has been provided on the application and performance of a bioburden method suitability test;

— a section has been added to detail rules for direct plate counts, estimated counts and counts beyond the ideal range;

— a table has been added to clarify where typical responsibilities reside for the manufacturer or the laboratory;

— the focus on a risk-based approach has been increased, including the purpose for which bioburden data will be used.

A list of all parts in the ISO 11737 series can be found on the ISO website.

Introduction

A sterile health care product is one that is free of viable microorganisms. International Standards that specify requirements for the validation and routine control of sterilization processes require, when it is necessary to supply a sterile health care product, that adventitious microbiological contamination of a health care product prior to sterilization be minimized. 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 health care products 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 there is always a finite probability that a microorganism can 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 microorganisms 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 health care products have been prepared (see, for example, ISO 14937, ISO 11135, the ISO 11137 series, the ISO 17665 series and ISO 14160). 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 a product and/or a sterile barrier system. A knowledge of bioburden can be used in a number of situations as part of the following:

— validation and requalification 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 products. To control bioburden, attention should be given to the microbiological status of these sources.

It is not possible to enumerate bioburden exactly and, in practice, a determination of bioburden is made using a defined method. Definition of a single method for use in determining bioburden in all situations is not practicable because of the wide variety of designs and materials of construction of health care products. 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 culture conditions for enumeration of microorganisms will be influenced by the types of microorganism likely to be present on or in health care products.

This document specifies the requirements to be met for the determination of bioburden. In addition, it gives guidance in the annexes to provide explanations and methods that are deemed suitable to conform with the requirements. Methods other than those given in the guidance may be used, if they are effective in achieving conformity with the requirements of this document.

Sterilization of health care products — Microbiological methods —

Part 1: Determination of a population of microorganisms on products

1 Scope

This document specifies requirements and provides guidance on the enumeration and microbial characterization of the population of viable microorganisms on or in a health care product, component, raw material or package.

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

NOTE 2 See Annex A for guidance on Clauses 1 to 9.

This document does not apply to the enumeration or identification of viral, prion or protozoan contaminants. This includes the removal and detection of the causative agents of spongiform encephalopathies, such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease.

NOTE 3 Guidance on inactivating viruses and prions can be found in ISO 22442-3, ICH Q5A(R1) and ISO 13022.

This document does not apply to the microbiological monitoring of the environment in which health care products are manufactured.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 15189, *Medical laboratories — Requirements for quality and competence*

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