Singapore Standards Council

SS ISO 11137-1 : 2018

ISO 11137-1 : 2006, IDT

(ICS 11.080.01)

SINGAPORE STANDARD

Sterilisation of health care products — Radiation

– Part 1 : Requirements for development, validation and routine control of a sterilisation process for medical devices

Published by

Enterprise Singapore

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ISBN 978-981-48-3546-6

This Singapore Standard was approved on 9 November 2018 by the Biomedical and Health Standards Committee under the purview of the Singapore Standards Council.

First published, 2019

The Biomedical and Health Standards Committee, appointed by the Standards Council, consists of the following members:

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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 11137-1:2006 “Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices” incorporating Amendments 1 and 2, 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 9000	SS ISO 9000
ISO 9001	SS ISO 9001
ISO 10993-1	SS ISO 10993-1
ISO 11737-1	SS ISO 11737-1
ISO 13485	SS ISO 13485
ISO 14001	SS ISO 14001
ISO 14040	SS ISO 14040

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 legl 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.

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 11137-1 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care product*.

This first edition, together with ISO 11137-2 and ISO 11137-3, cancels and replaces ISO 11137:1995.

ISO 11137 consists of the following parts, under the general title *Sterilization of health care products — Radiation*:

— *Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

— *Part 2: Establishing the sterilization dose*

— *Part 3: Guidance on dosimetric aspects*

Introduction

A sterile medical device is one that is free of viable microorganisms. International Standards, which 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 medical devices are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile medical devices 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 medical device 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 medical device.

This part of ISO 11137 describes requirements that, if met, will provide a radiation sterilization process intended to sterilize medical devices, that has appropriate microbicidal activity. Furthermore, compliance with the requirements ensures that this activity is both reliable and reproducible so that predictions can be made, with reasonable confidence, that there is a low level of probability of there being a viable microorganism present on product after sterilization. Specification of this probability is a matter for regulatory authorities and may vary from country to country (see, for example, EN 556-1 and ANSI/AAMI ST67).

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 recognise 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.

Exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the products are sterile and, in this regard, suitable for its intended use. Attention is therefore given to a number of considerations including:

a) the microbiological status of incoming raw materials and/or components;

b) the validation and routine control of any cleaning and disinfection procedures used on the product;

c) the control of the environment in which the product is manufactured, assembled and packaged;

d) the control of equipment and processes;

e) the control of personnel and their hygiene;

f) the manner and materials in which the product is packaged;

g) the conditions under which product is stored.

This part of ISO 11137 describes the requirements for ensuring that the activities associated with the process of radiation sterilization are performed properly. These activities are described in documented work programmes designed to demonstrate that the radiation process will consistently yield sterile products on treatment with doses falling within the predetermined limits.

The requirements are the normative parts of this part of ISO 11137 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 11137.

The development, validation and routine control of a sterilization process comprise a number of discrete but interrelated activities; e.g. calibration, maintenance, product definition, process definition, installation qualification, operational qualification and performance qualification. While the activities required by this part of ISO 11137 have been grouped together and are presented in a particular order, this part of ISO 11137 does not require that the activities be performed in the order that they are presented. The activities required are not necessarily sequential, as the programme of development and validation may be iterative. It is possible that performing these different activities will involve a number of separate individuals and/or organizations, each of whom undertake one or more of these activities. This part of ISO 11137 does not specify the particular individuals or organizations to carry out the activities.

Sterilization of health care products — Radiation —

Part 1:
Requirements for development, validation and routine control of a sterilization process for medical devices

1 Scope

1.1 This part of ISO 11137 specifies requirements for the development, validation and routine control of a radiation sterilization process for medical devices.

NOTE Although the scope of this part of ISO 11137 is limited to medical devices, it specifies requirements and provides guidance that may be applicable to other products and equipment.

This part of ISO 11137 covers radiation processes employing irradiators using,

a) the radionuclide ^{60}Co or ^{137}Cs,

b) a beam from an electron generator

or

c) a beam from an X-ray generator.

1.2 This part of ISO 11137 does not specify requirements for development, validation and routine control of a process for inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeld-Jakob disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.

NOTE See, for example, ISO 22442-1, ISO 22442-2 and ISO 22442-3.

1.2.1 This part of ISO 11137 does not detail specified requirements for designating a medical device as sterile.

NOTE Attention is drawn to regional and national requirements for designating medical devices as “sterile.” See, for example, EN 556-1 or ANSI/AAMI ST67.

1.2.2 This part of ISO 11137 does not specify a quality management system for the control of all stages of production of medical devices.

NOTE It is not a requirement of this part of ISO 11137 to have a complete quality management system during manufacture, but the elements of a quality management system that are the minimum necessary to control the sterilization process are normatively referenced at appropriate places in the text (see, in particular, Clause 4). Attention is drawn to the standards for quality management systems (see ISO 13485) that control all stages of production of medical devices, including the sterilization process. Regional and national regulations for the provision of medical devices might require implementation of a complete quality management system and the assessment of that system by a third party.

1.2.3 This part of ISO 11137 does not require that biological indicators be used for validation or monitoring of radiation sterilization, nor does it require that a pharmacopoeial test for sterility be carried out for product release.

1.2.4 This part of ISO 11137 does not specify requirements for occupational safety associated with the design and operation of irradiation facilities.

NOTE Attention is also drawn to the existence, in some countries, of regulations laying down safety requirements for occupational safety related to radiation.

1.2.5 This part of ISO 11137 does not specify requirements for the sterilization of used or reprocessed devices.

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 10012-1, *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment*

ISO 11137-2:2006, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11737-1, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

ISO 11737-2, *Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the validation of a sterilization process* *As amended, ISO Amd 1*

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