SLOVENSKI STANDARD
oSIST prEN ISO 11737-2:2018

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Sterilizacija medicinskih pripomočkov - Mikrobiološke metode - 2. del: Preskusi sterilnosti pri definiciji, validaciji in vzdrževanju sterilizacijskih postopkov (ISO/DIS 11737-2:2018)

Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO/DIS 11737-2:2018)

Sterilisation von Medizinprodukten - Mikrobiologische Verfahren - Teil 2: Prüfungen der Sterilität bei der Definition, Validierung und Aufrechterhaltung eines Sterilisationsverfahrens (ISO/DIS 11737-2:2018)

Stérilisation des dispositifs médicaux - Méthodes microbiologiques - Partie 2: Contrôles de stérilité pratiqués au moment de la définition, de la validation et de la maintenance d'un procédé de stérilisation (ISO/DIS 11737-2:2018)

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Sterilization of medical devices — Microbiological methods —

Part 2:
Tests of sterility performed in the definition, validation and maintenance of a sterilization process

Stérilisation des dispositifs médicaux — Méthodes microbiologiques —

Partie 2: Contrôles de stérilité pratiqués au moment de la définition, de la validation et de la maintenance d'un procédé de stérilisation

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Contents

Page

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 11737-2:2009), which has been technically revised.

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

— addition of a requirement concerning the test samples and the interval of time between the manufacture of product and the exposure to the sterilizing agent being reflective of routine manufacturing;

— addition of a requirement about the samples staying immersed in the media and providing a rationale where this is not possible;

— addition of a requirement regarding tests where microorganisms are eluted from product for the test of sterility, to address a risk assessment to determine the appropriateness of the removal process and well as stating that it has to be demonstrated that all microorganisms are recoverable using this method;

— provision of additional guidance regarding performing tests of sterility on packaging, clarifying that package testing is not typically done except when it is an integral part of the product;

— provision of additional guidance regarding what is meant by “controlled environment” for performing tests of sterility;

— provision of additional guidance to discuss circumstances where the method suitability test does not give acceptable results, stating that after multiple attempts to eliminate inhibitory substances, it is appropriate to accept a reduction of inhibitory substances, with an accompanying rationale and risk assessment;

— provision of guidance regarding identification of microbial growth in a test of sterility, saying generally for positive growth the microorganism(s) should be identified;

— provision of guidance regarding method suitability, saying that consideration should be given to periodically demonstrating ongoing method suitability in order to ensure that an accumulation of minor changes over time has not occurred;

— addition of a table to clarify where typical responsibilities reside for the manufacturer or the laboratory.

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

Introduction

A sterile medical device is one that is free from 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 from all sources 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. 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 item 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[16] 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.

International Standards specifying procedures for the development, validation and routine control of the processes used for sterilization of medical devices have been prepared (see ISO 11135,[1] ISO 11137-1,[2] ISO 14937,[11] ISO 14160,[7] ISO 17665-1[12] and ISO 20857[13]). An element of validation might consist of exposing medical devices to the sterilizing agent with the extent of treatment being reduced relative to that which will be used in routine sterilization 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 document. Examples of the use of such tests are in:

a) establishing a dose for sterilization by radiation, and

b) demonstrating the continued validity of an established sterilization dose.

Annex A of this document gives guidance on the techniques used and on practical aspects of the requirements.

Sterilization of medical devices — Microbiological methods —

Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

1 Scope

1.1 This document specifies the general criteria for tests of sterility on medical devices that have been exposed to a treatment with the sterilizing agent reduced relative to that anticipated to be used in routine sterilization processing. These tests are intended to be performed when defining, validating or maintaining a sterilization process.

1.2 This document is not applicable to:

a) sterility testing for routine release of product that has been subjected to a sterilization process,

b) performing a test for sterility (see 3.12), and

NOTE 1 The performance of a) or b) is not a requirement of ISO 11135, ISO 11137-1, ISO 14160, ISO 14937, ISO 17665-1 or ISO 20857.

c) culturing of biological indicators or inoculated products.

NOTE 2 Guidance on culturing biological indicators is included in ISO 11138-7[5].

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 11737-1:2018, *Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

ISO 13485:2016, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 15189:2012, *Medical laboratories — Requirements for quality and competence*

ISO/IEC 17025:2017, *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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
aerobic organism
microorganism that requires oxygen for metabolism

3.2
anaerobic organism
microorganism that does not require oxygen for metabolism

3.3
bacteriostasis/fungistasis test
technical operation performed to detect the presence of substances that inhibit microbial multiplication

[SOURCE: ISO 11139:201X, 3.20]

3.4
bioburden
population of viable microorganisms on or in product and/or sterile barrier system

[SOURCE: ISO 11139:201X, 3.23]

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

Note 1 to entry: The manner of incubation can include the temperature, time, and any other conditions specified for incubation.

[SOURCE: ISO 11139:201X, 3.69]

3.6
facultative organism
microorganism capable of both aerobic and anaerobic metabolism

[SOURCE: ISO 11139:201X, 3.113]

3.7
growth promotion test
technical operation performed to demonstrate that a growth medium will support microbial multiplication

[SOURCE: ISO 11139:201X, 3.127]

3.8
health care product
medical device, including *in vitro* diagnostic medical device, or medicinal product, including biopharmaceutical

[SOURCE: ISO 11139:201X, 3.131]

3.9
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, or , software material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical 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 by means of *in vitro* examination of specimens derived from the human body;

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

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions, but not in others include:

— items specifically intended for cleaning or sterilization of medical devices;

— pouches, reel goods, sterilization wrap, and reusable containers for packaging of medical devices for sterilization;

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for *in vitro* fertilization or assisted reproduction technologies.

[SOURCE: ISO 13485:2016, 3.11, modified — The first two list items in the Note 1 to entry have been added]

3.10
product
tangible result of a process

EXAMPLE Raw material(s), intermediate(s), sub-assembly(ies), health care product(s).

[SOURCE: ISO 11139:201X, 3.216]

3.11
sample item portion
SIP
specified part of a health care product that is tested

[SOURCE: ISO 11139:201X, 3.239]

3.12
sterile
free from viable microorganisms

[SOURCE: ISO 11139:201X, 3.270]

3.13
test for sterility
technical operation specified in a pharmacopoeia performed on product following an aseptic process or exposure to a sterilization process

[SOURCE: ISO 11139:201X, 3.298]

3.14
test of sterility
technical operation performed as part of development, validation or requalification to determine the presence or absence of viable microorganisms on product or portions thereof

[SOURCE: ISO 11139:201X, 3.299]

4 Quality management system elements

4.1 Documentation

4.1.1 Procedures for the performance of tests of sterility shall be specified.

4.1.2 Documents and records required by this document shall be reviewed and approved by designated personnel (see 4.2.1). Documents and records shall be controlled in accordance with applicable standards (e.g. ISO 13485, ISO/IEC 17025, or ISO 15189). Records retained shall include all original observations, calculations, derived data and final reports. The records shall include the identity of all personnel involved in sampling, preparation and testing.

4.1.3 Calculations and data transfers shall be subjected to appropriate verification.

4.2 Management responsibility

4.2.1 The responsibility and authority for implementing and performing the procedures described in this document shall be specified. Responsibility shall be assigned to competent personnel in accordance with applicable standards (e.g. ISO 13485, ISO/IEC 17025, or ISO 15189).

4.2.2 If the requirements of this document are undertaken by organizations with separate quality management systems, the responsibility and authority of each party shall be specified.

4.2.3 All equipment required for correct performance of the specified tests and measurements shall be available.

4.3 Product realization

4.3.1 Procedures for purchasing shall be specified. These procedures shall comply with applicable standards (e.g. ISO 13485, ISO/IEC 17025, or ISO 15189).

4.3.2 A documented system complying with ISO 13485, ISO/IEC 17025 or ISO 10012 shall be specified for the calibration of all equipment, including instrumentation for test purposes, used in meeting the requirements of this document.

4.3.3 Equipment or parts thereof or materials that come into contact with product during testing shall be sterile.

4.3.4 Methods shall be specified for the preparation and sterilization of materials used in the tests of sterility, including appropriate quality tests.

4.4 Measurement, analysis and improvement

For the purpose of tests of sterility and results, measurement uncertainty, precision and bias do not apply and therefore this type of data analysis is not necessary, except in evaluating the overall competency of the laboratory.

Procedures for investigation of unusual or unexpected results, results not meeting acceptance criteria, and for correction, corrective action or preventive action should be specified. These procedures shall comply with applicable standards (e.g. ISO 13485, ISO/IEC 17025, or ISO 15189).

