# SLOVENSKI STANDARD
# oSIST prEN ISO 11737-1:2026

**01-maj-2026**

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**Sterilizacija izdelkov za zdravstveno nego - Mikrobiološke metode - 1. del: Določevanje populacije mikroorganizmov na izdelkih (ISO/DIS 11737-1:2026)**

Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO/DIS 11737-1:2026)

Sterilisation von Produkten für die Gesundheitsfürsorge - Mikrobiologische Verfahren - Teil 1: Bestimmung der Population von Mikroorganismen auf Produkten (ISO/DIS 11737-1:2026)



Stérilisation des produits de santé - Méthodes microbiologiques - Partie 1: Détermination d'une population de microorganismes sur des produits (ISO/DIS 11737-1:2026)



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| 07.100.10 | Medicinska mikrobiologija | Medical microbiology |
| 11.080.01 | Sterilizacija in dezinfekcija na splošno | Sterilization and disinfection in general |

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# DRAFT International Standard

# ISO/DIS 11737-1

# Sterilization of health care products — Microbiological methods —

## Part 1: Determination of a population of microorganisms on products

*Stérilisation des produits de santé — Méthodes microbiologiques —*

*Partie 1: Détermination d'une population de microorganismes sur des produits*

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# Foreword

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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).

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This document was prepared by Technical Committee ISO/TC *198,Sterilization of health care products* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 204, *Sterilization of medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).



This fourth edition cancels and replaces the third edition (ISO 11737-1:2018), which has been technically revised.

The main changes are as follows:

— incorporation of the amendment content.

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

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

# 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 population of microorganisms by physical 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, ISO 13004, ISO 17665, ISO 14160, ISO 20857, ISO 22441 and ISO 25424). 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 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;

— evaluation of change in a manufacturing process or location;

— an overall environmental monitoring programme.

Bioburden is the sum of the microbial contributions from a number of sources, including people, 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 precisely and, in practice, a determination of bioburden is relative to the defined method used. 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 extraction

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.

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

NOTE 2 Guidance on inactivating viruses and prions can be found in ISO 22442-3, ICH Q5A(R1) and ISO 13022.

NOTE 3 ISO/TS 22456 provides specific guidance for bioburden testing for biologics and tissue-based products where this testing is conducted in relation to product sterilization.

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



## 2 Normative references

There are no normative references in this document.

## 3 Terms and definitions

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

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

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

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

**3.1**
**action level**
value from monitoring that necessitates immediate intervention

[SOURCE: ISO 11139:2018, 3.5]

**3.2**
**alert level**
value from monitoring providing early warning of deviation from specified conditions

[SOURCE: ISO 11139:2018, 3.11]

**3.3**
**batch**
defined quantity of a *product* (3.18) intended or purported to be uniform in character and quality produced during a specified cycle of manufacture

[SOURCE: ISO 11139:2018, 3.21]

**3.4**
**bioburden**
population of viable microorganisms on or in a *product* (3.18) and/or *sterile barrier system* (3.24)

[SOURCE: ISO 11139:2018, 3.23]

**3.5**
**bioburden correction factor**
numerical value applied to a viable count to compensate for incomplete removal of microorganisms from a *product* (3.18) and/or failure to culture microorganisms

[SOURCE: ISO 11139:2018, 3.24]

**3.6**
**bioburden estimate**
value *established* (3.11) by applying a *bioburden correction factor* (3.5) to a *bioburden* (3.4) count

Note 1 to entry: The recovery efficiency can also be used to determine the bioburden estimate.

[SOURCE: ISO 11139:2018, 3.25, modified — "bioburden" has been added to the referenced term "correction factor."]



**3.7**
**bioburden method suitability**
<microbiological> assessment of the test method to demonstrate its ability to allow microbial growth

[SOURCE: ISO 11139:2018, 3.168, modified — "bioburden" has been added to the term.]



**3.8**
**bioburden spike**
individual *bioburden* (3.4) value that is significantly greater than other bioburden values in a set

[SOURCE: ISO 11139:2018, 3.26]

**3.9**
**corrective action**
action to eliminate the cause of a nonconformity and to prevent recurrence

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action is taken to prevent recurrence whereas *preventive action* (3.17) is taken to prevent occurrence.

[SOURCE: ISO 9000:2015, 3.12.2, modified — Note 3 to entry has been deleted.]

**3.10**
**culture condition**
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 11139:2018, 3.70]

**3.11**
**establish**
determine by theoretical evaluation and confirm by experimentation

[SOURCE: ISO 11139:2018, 3.107]

**3.12**
**excursion**
data exceeding an established level

Note 1 to entry: Bioburden results are typically evaluated as averages of a number of individual values.

[SOURCE: AAMI TIR106:2024, 3.2]

**3.13**
**facultative microorganism**
microorganism capable of both aerobic and anaerobic metabolism

[SOURCE: ISO 11139:2018, 3.114]

**3.14**
**health care product**
medical device, including *in vitro* diagnostic medical device, or medicinal *product* (3.18), including biopharmaceutical

[SOURCE: ISO 11139:2018, 3.132]

**3.15**
**microbial characterization**
process by which microorganisms are grouped into categories



Note 1 to entry: Categories can be broadly based, for example, on the use of selective media, colony or cellular morphology, staining properties, or other characteristics.



[SOURCE: ISO 11139:2018, 3.170]

**3.16**
**obligate anaerobe**
organism that only lives and grows in the absence of molecular oxygen

[SOURCE: ISO 11139:2018, 3.186]

**3.17**
**preventive action**
action to eliminate the cause of a potential nonconformity or other potential undesirable situation

Note 1 to entry: There can be more than one cause for a potential nonconformity.

Note 2 to entry: Preventive action is taken to prevent occurrence whereas *corrective action* (3.10) is taken to prevent recurrence.

[SOURCE: ISO 9000:2015, 3.12.1]

**3.18**
**product**
tangible result of a process

EXAMPLE Raw material(s), intermediate(s), sub-assembly(ies), *health care product(s)* (3.15).

[SOURCE: ISO 11139:2018, 3.217]

**3.19**
**product family**
group or subgroup of *product* (3.18) characterized by similar attributes determined to be equivalent for evaluation and processing purposes

[SOURCE: ISO 11139:2018, 3.218]

**3.20**
**recovery efficiency**
<bioburden> measure of the ability of a specified technique to remove, collect, and/or culture microorganisms from a *product* (3.18)

[SOURCE: ISO 11139:2018, 3.225]

**3.21**
**requalification**
repetition of part or all of *validation* (3.25) for the purpose of confirming the continued acceptability of a specified process

[SOURCE: ISO 11139:2018, 3.220.5]

**3.22**
**sample item portion**
**SIP**
specified part of a *health care product* (3.14) that is tested

[SOURCE: ISO 11139:2018, 3.240, modified — acronym SIP has been added.]



**3.23**
**sterile**
free from viable microorganisms

[SOURCE: ISO 11139:2018, 3.271]



**3.24**
**sterile barrier system**
**SBS**
minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the *sterile* (3.23) contents at the point of use

[SOURCE: ISO 11139:2018, 3.272]

**3.25**
**terminally sterilized**
condition of a *product* (3.18) that has been exposed to a sterilization process in its sterilized barrier system

[SOURCE: ISO 11139:2018, 3.296]

**3.26**
**validation**
confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word “validated” is used to designate the corresponding status.

Note 3 to entry: The use conditions for validation can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13, modified — “process” has been added to the definition.]

# 4 General

**4.1** The development, validation and routine control of bioburden are critical elements in the realization of some types of health care products. To ensure the consistent implementation of the requirements specified in this document, the necessary processes shall be established, implemented and maintained. Processes of particular importance in relation to the development, validation and routine bioburden control of a process include but are not limited to:

— control of documentation, including records;

— assignment of management responsibility;

— provision of adequate resources, including competent human resources and infrastructure;

— control of product provided by external parties;

— identification and traceability of product throughout the process; and

— control of non-conforming product.

NOTE 1 ISO 13485 covers all stages of the lifecycle of medical devices in the context of quality management systems for regulatory purposes. National or regional regulatory requirements for the provision of health care product can require the implementation of a full quality management system and the assessment of that system by a recognized conformity assessment body.

NOTE 2 See Annex G for information on typical assignment of responsibilities.

**4.2** A process shall be specified for the calibration of equipment, as applicable, used in meeting the requirements of this document (e.g. instrumentation for test purposes).



# 5 Selection of products



## 5.1 General

**5.1.1** The procedures for the selection and handling of products for the determination of bioburden shall ensure that the selected product is representative of routine production, including primary packaging materials and processes, but prior to the terminal sterilization process, if applicable. Terminally sterilized product should not be used for bioburden testing.

**5.1.2** If product(s) are grouped in a product family for the purpose of the determination of bioburden, the rationale for inclusion of a product within a product family shall be documented. The rationale shall include criteria to ensure that bioburden determined for a product selected from the product family is representative for the whole product family.

**5.1.3** Consideration shall be given to the timing of the determination of bioburden relative to manufacturing because bioburden can change with the passage of time.

## 5.2 Sample item portion (SIP)

**5.2.1** The determination of bioburden may be performed on:

a) the entire product (SIP = 1,0);

b) a portion of the product, e.g. half of the product for an SIP of 0,5, or;

c) the sterile fluid path for which sterility is claimed (SIP = 1,0).