



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 17665:2022**  
**01-november-2022**

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**Sterilizacija izdelkov za zdravstveno nego - Vlažna toplota - Zahteve za razvoj, validacijo in rutinsko kontrolo sterilizacijskih postopkov za medicinske pripomočke (ISO/DIS 17665:2022)**

Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO/DIS 17665:2022)

Sterilisation von Produkten für die Gesundheitsfürsorge - Feuchte Hitze - Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO/DIS 17665:2022)

Stérilisation des produits de santé - Chaleur humide - Exigences pour le développement, la validation et le contrôle de routine d'un procédé de stérilisation des dispositifs médicaux (ISO/DIS 17665:2022)

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**ICS:**

11.080.01 Sterilizacija in dezinfekcija na splošno Sterilization and disinfection in general

**oSIST prEN ISO 17665:2022**

**en,fr,de**



# DRAFT INTERNATIONAL STANDARD

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## Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices

ICS: 11.080.01

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## 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](http://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](http://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 of 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 [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

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

This second edition cancels and replaces ISO 17665-1, ISO/TS 17665-2 and ISO/TS 17665-3, which have been technically revised and merged into a single document.

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

- combined ISO 17665-1, ISO/TS 17665-2 and ISO/TS 17665-3 into a single standard.

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](http://www.iso.org/members.html).

## ISO/DIS 17665:2022(E)

### 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, could, 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 generally can best be described by an exponential relationship between the number 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 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 organisms exist during treatment. It follows that the sterility of any one product in a population subjected to sterilization processing cannot be ensured and the expression of sterility of a processed population is defined in terms of the probability of there being a viable microorganism present on a product item.

The process variables for a moist heat sterilization process, i.e. those which contribute towards microbial lethality, are exposure to adequate temperature for a prerequisite time in the presence of moisture. Moist heat sterilization can be utilised as a saturated steam process, where saturated steam is allowed to directly contact all surfaces to be sterilized or as a contained product sterilization process, where steam, steam mixed with air or other gas, or hot water under pressure are used as the heating medium in order to generate moist heat within the sealed contained product. The term saturated steam describes a theoretical state in which water and vapour are in equilibrium and that no other gases are present so in practice saturated steam is not used in production steam sterilizers. Mixtures of steam and non-condensable gases, albeit in very low levels, will be supplied to the sterilizer and employed as the sterilizing agent, moist heat.

ISO 17665 describes requirements that, if met, will provide a moist heat sterilization process intended to sterilize medical devices, which has appropriate microbicidal activity. Furthermore, conformance with the requirements, ensures 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 every sterilization process is complete. Specification of this probability is a matter for regulatory authorities and can 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, monitored and recorded sterilization process is not the only factor associated with the provision of reliable assurance that the product is sterile and, in this regard, suitable for its intended use. Attention is therefore given to a number of factors 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.

The type of contamination on a product to be sterilized varies and this has an impact upon the effectiveness of a sterilization process. It is preferable that products that have been used in a health care setting and that are being presented for sterilization in accordance with the instructions for use (see ISO 17664-1) be regarded as special cases. There is the potential for such products to possess a wide range of contaminating microorganisms and residual inorganic and/or organic contamination in spite of the application of a cleaning process. Hence, particular attention is given to the validation and control of the cleaning and disinfection processes used during processing. The ISO 15883 series provides requirements for and information on automated cleaning and disinfection processes.

This document describes the requirements for ensuring that the activities associated with the process of moist heat sterilization are performed properly. The requirements are the normative parts of this document with which conformance is claimed supported by appropriate normative Annexes. The guidance given in the informative Annexes is not intended as checklists for assessing conformance with the requirements of this document. The guidance in the informative Annexes is intended to assist in obtaining a uniform understanding and implementation of the requirements in this document by providing explanations, rationales, examples and methods that are regarded as being suitable means for conforming with the requirements. Methods other than those given in the guidance may be used if they are effective in achieving conformance with the requirements of this document.

The development, validation and routine control of a sterilization process comprise a number of discrete but interrelated activities, e.g. calibration, equipment maintenance, product definition, process definition, installation qualification, operational qualification and performance qualification. While the activities required by this document have been grouped together and are presented in a particular order, the standard 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 document does not specify the particular individuals or organizations who are responsible for carrying out the activities. 949b2fec8c0f/osist-pren-iso-17665-2022

The requirements of this document are applicable to all settings where moist heat sterilization of medical devices is carried out. However, this standard or part of it can be applied to the moist heat sterilization of other products.

Medical devices processed in an industrial setting can, in certain circumstances, be manufactured using standardised processes that result in product with a known and controlled bioburden prior to sterilization. Medical devices processed, such as in health care facilities can include a wide variety of product with varying levels of bioburden. Appropriate and thorough cleaning and, where necessary for safe handling, decontamination processes are used prior to presenting product for sterilization. Mixed product loads are common in facilities reprocessing medical devices with throughput volumes dictated by historical and predicted demand for sterile product.

[Annex A](#) provides guidance on the principles of moist heat sterilization and provides a rationale for the requirements. Specific guidance for health care facilities is given in [Annex F](#) and for industrial applications, in [Annex H](#). The numbering and structure of the clauses in [Annex F](#) and [Annex H](#) correspond to the numbering and structure of the clauses in the normative requirements section of this document.



# Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices

## 1 Scope

This document provides requirements for the development, validation and routine control of moist heat sterilization processes for medical devices. The standard also contains guidance which is intended to explain the requirements set forth in the normative sections. The guidance given is intended to promote good practice related to moist heat sterilization processes according to this document. The application within industrial and health care settings is considered.

### 1.1 Inclusions

**1.1.1** Moist heat sterilization processes covered by this document include but are not limited to:

- a) Saturated steam sterilization in which air is removed by venting;
- b) Saturated steam sterilization in which air is removed by active air removal;
- c) Contained product sterilization in which heat transfer is achieved by steam-air mixtures;
- d) Contained product sterilization in which heat transfer is achieved by water sprays.
- e) Contained product sterilization in which heat transfer is achieved by water immersion.

NOTE 1 See [Annex D](#) where the processes are explained further.

NOTE 2 Although the scope of this document is limited to medical devices, it specifies requirements and provides guidance that can be applicable to other health care products and industrial applications.

### 1.2 Exclusions

**1.2.1** This document 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 Creutzfeldt-Jakob disease.

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

**1.2.2** This document does not apply to those sterilization processes that are based on a combination of moist heat with other biocidal agents (e.g. formaldehyde) as the sterilizing agent.

**1.2.3** This document does not detail a specified requirement for designating a medical device as “sterile.”

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

**1.2.4** This document does not specify requirements for occupational safety associated with the design and operation of moist heat sterilization facilities.

NOTE There could be applicable national or regional regulations for operational safety.

## ISO/DIS 17665:2022(E)

### 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 11138-1, *Sterilization of health care products — Biological indicators — Part 1: General requirements*

ISO 11138-3, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes*

ISO 11140-1, *Sterilization of health care products — Chemical indicators — Part 1: General requirements*

ISO 11140-3, *Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test*

ISO 11140-4, *Sterilization of health care products — Chemical indicators — Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration*

ISO 11140-5, *Sterilization of health care products — Chemical indicators — Part 5: Class 2 indicators for Bowie and Dick-type air removal tests*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

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

ISO 11737-2, *Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*

### 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:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

**3.1**  
**air detector**  
device designed to detect the presence of non-condensable gases in the chamber or in a stream of steam and condensate

[SOURCE: ISO 11139:2018, 3.9]

**3.2**  
**automatic controller**  
device that directs the equipment sequentially through required stages of the cycle in response to programmed cycle parameters

[SOURCE: ISO 11139:2018, 3.18]

**3.3****bioburden**

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

[SOURCE: ISO 11139:2018, 3.23]

**3.4****biological indicator**

test system containing viable microorganisms providing a defined resistance to a specified sterilization process

[SOURCE: ISO 11139:2018, 3.29]

**3.5****calibration**

operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by the measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

[SOURCE: ISO/IEC Guide 99:2007, 2.39, modified — The notes to entry have been deleted]

**3.6****chamber**

part of equipment in which a load is processed

[SOURCE: ISO 11139:2018, 3.36]

**3.7****chemical indicator**

test system that reveals change in one or more pre-specified process variables based on a chemical or physical change resulting from exposure to a process

[SOURCE: ISO 11139:2018, 3.43]

**3.8****contained product**

load for which the ambient media within a chamber do not come into direct contact with the item to be processed

Note 1 to entry: The environment within the sterilizer is used for heating and cooling purposes only, not for achieving the sterilization effect; e.g. a solution in a sealed bottle.

**3.9****contained product sterilization**

A validated process which involves the indirect contact of steam as a heating medium on the external surfaces of contained product to create moist heat as the sterilizing agent internally to achieve the specified requirements for sterility within the contained product.

Note 1 to entry: The environment within the sterilizer is used for heating and cooling purposes only, not for achieving the sterilization effect, e.g. a solution in a sealed bottle.

**3.10****correction**

action to eliminate a detected nonconformity

Note 1 to entry: A correction can be made in advance of, in conjunction with, or after a corrective action.

[SOURCE: ISO 9000:2015, 3.12.3, modified — Note 2 to entry has been deleted]

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### 3.11

#### **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 is taken to prevent occurrence.

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

### 3.12

#### **cycle parameter**

value of a cycle variable including its tolerance used for control, monitoring, indication, and recording of an operating cycle

[SOURCE: ISO 11139:2018, 3.72]

### 3.13

#### **cycle variable**

property used to control, monitor, indicate, or record an operating cycle

[SOURCE: ISO 11139:2018, 3.74]

### 3.14

#### ***D* value**

#### ***D*<sub>10</sub> value**

time or dose required under stated conditions to achieve inactivation of 90 % of a population of the test microorganism

Note 1 to entry: For the purposes of ISO 17665 *D* value refers to the exposure period necessary to achieve 90 % reduction.

Note 2 to entry: The definition of *D* value assumes that a plot of log<sub>10</sub> of population versus time of exposure is linear within accepted tolerances.

[SOURCE: ISO 11139:2018, 3.75, modified — Notes to entry have been added]

### 3.15

#### **development**

act of elaborating a specification

[SOURCE: ISO 11139:2018, 3.79]

### 3.16

#### **equilibration time**

period between the attainment of defined sterilization process parameters at the reference measurement point and the attainment of the specified sterilization process parameters at all points within the load

Note 1 to entry: For the purposes of this document the process parameter to which this definition refers is temperature.

Note 2 to entry: Equilibration time is also known as sterilization time lag.

[SOURCE: ISO 11139:2018, 3.105, modified — Note to entry has been added]

### 3.17

#### **equipment maintenance**

combination of all technical and associated administrative actions intended to keep equipment at a state in which it can perform its required function, or restore it to such a state

[SOURCE: ISO 11139:2018, 3.106]

**3.18****establish**

determine by theoretical evaluation and confirm by experimentation

[SOURCE: ISO 11139:2018, 3.107]

**3.19****evaluation**

a systematic and objective comparison of the measured results either with one another or with a specification to be met in initial, intermediate and final tests.

Note 1 to entry: Evaluation analyses the level of achievement of both expected and unexpected results by examining the results chain, processes, contextual factors and causality using appropriate criteria. An evaluation should provide credible, useful evidence-based information that enables the timely incorporation of its findings, recommendations and lessons into the decision-making processes of organizations and stakeholders.

[SOURCE: ISO 9022-1:2016, 2.10, modified – Note to entry has been added]

**3.20****exposure phase**

cycle stage between the introduction of the sterilizing or disinfecting agent into the chamber and when the agent is removed

Note 1 to entry: For the purposes of this document the exposure phase only includes that part of the process for which microbial lethality is claimed.

[SOURCE: ISO 11139:2018, 3.111]

**3.21** **$F_o$  value**

measure of microbiological lethality delivered by a moist heat sterilization process expressed in terms of the equivalent time, in minutes, at a temperature of 121,1 °C with reference to microorganisms with a z value of 10 K

[SOURCE: ISO 11139:2018, 3.113.1]

**3.22** **$F_{BI0}$  value**

term used to describe the delivered lethality, measured in terms of actual kill of microorganisms on or in a BI challenge system

**3.23****fault**

situation in which one or more of the process or cycle parameters is/are outside its/their specified tolerance(s)

[SOURCE: ISO 11139:2018, 3.116]

**3.24****health care facility**

dedicated setting where health care professionals deliver services for care of patients

EXAMPLE Hospitals, free standing ambulatory surgical centres, nursing homes, extended care facilities, medical, dental and physician offices or clinics and other specialized treatment facilities.

**3.25****health care product**

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

[SOURCE: ISO 11139:2018, 3.132]