



**ISO 17665**

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

*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*

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<b>Foreword</b> .....	<b>v</b>
<b>Introduction</b> .....	<b>vi</b>
<b>1 Scope</b> .....	<b>1</b>
1.1 Inclusions.....	1
1.2 Exclusions.....	1
<b>2 Normative references</b> .....	<b>2</b>
<b>3 Terms and definitions</b> .....	<b>2</b>
<b>4 General</b> .....	<b>12</b>
<b>5 Sterilizing agent characterization</b> .....	<b>13</b>
5.1 Sterilizing agent.....	13
5.2 Microbicidal effectiveness.....	14
5.3 Effects on materials.....	14
5.4 Environmental consideration.....	14
<b>6 Process and equipment characterization</b> .....	<b>14</b>
6.1 General.....	14
6.2 Process characterization.....	14
6.3 Saturated steam sterilization processes.....	15
6.4 Contained product sterilization processes.....	16
6.5 Equipment.....	17
<b>7 Product definition</b> .....	<b>18</b>
<b>8 Process definition</b> .....	<b>20</b>
<b>9 Validation</b> .....	<b>22</b>
9.1 General.....	22
9.2 Installation qualification (IQ).....	23
9.3 Operational qualification (OQ).....	23
9.4 Performance qualification (PQ).....	24
9.5 Review and approval of validation.....	26
<b>10 Routine monitoring and control</b> .....	<b>26</b>
10.1 Routine monitoring.....	26
10.2 Operational status.....	26
10.3 Process verification.....	27
10.4 Evaluation of additional data for saturated steam sterilization processes.....	27
10.5 Evaluation of additional data for contained product sterilization processes.....	27
10.6 Record retention.....	28
<b>11 Product release from sterilization</b> .....	<b>28</b>
<b>12 Maintaining process effectiveness</b> .....	<b>28</b>
12.1 Purpose.....	28
12.2 Demonstration of continued effectiveness.....	28
12.3 Recalibration.....	29
12.4 Equipment maintenance.....	29
12.5 Requalification.....	29
12.6 Assessment of change.....	30
<b>Annex A (informative) Guidance on the principles of moist heat sterilization and rationales for requirements</b> .....	<b>31</b>
<b>Annex B (informative) Establishment and evaluation of a sterilization process primarily based on microbiological inactivation</b> .....	<b>59</b>
<b>Annex C (informative) Establishment and evaluation of a sterilization process primarily based on the measurement of physical parameters</b> .....	<b>73</b>

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<b>Annex E</b> (informative) <b>Temperature and pressure of saturated steam for use in moist heat sterilization</b> .....	<b>89</b>
<b>Annex F</b> (informative) <b>Guidance on the application of the normative requirements in health care facilities</b> .....	<b>93</b>
<b>Annex G</b> (informative) <b>Guidance on the designation of a medical device to a product family and processing category for sterilization by moist heat</b> .....	<b>118</b>
<b>Annex H</b> (informative) <b>Guidance on the application of the normative requirements in industrial settings</b> .....	<b>126</b>
<b>Bibliography</b> .....	<b>150</b>

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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 document 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)).

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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 first edition cancels and replaces ISO 17665-1:2006, ISO/TS 17665-2:2009 and ISO/TS 17665-3:2013, which have been technically revised.

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.

A list of all parts in the ISO 17665 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](http://www.iso.org/members.html).

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, can, 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. In practice theoretical saturated steam state conditions are not achieved. Mixtures of steam and NCGs, albeit in very low levels, will be supplied to the sterilizer and employed as the sterilizing agent, moist heat.

This document 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 either incoming raw materials or components, or both;
- 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;

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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 (bioburden) and either residual inorganic or organic contamination, or both, 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. 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 can 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 (IQ), OQ and PQ, during which, along with other characteristics, compatibility of product and materials will be ascertained. While the activities required by this document have been grouped together and are presented in a particular order, this document 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 can be iterative. It is possible that performing these different activities will involve a number of either separate individuals or organizations, or both, 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.

The requirements of this document are applicable to all settings where moist heat sterilization of medical devices is carried out. However, this document 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 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.

An overview of the purpose of each normative section is provided at the beginning of [Clauses 5](#) to [12](#) (see ISO 14937). [Table A.1](#) summarises the purpose of each normative section and suggests the roles and responsibilities for the organisations and personnel involved in each element of the development, validation and routine control of a moist heat sterilization process and moist heat sterilizer.