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Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1 (ISO 17665-2:2009)

Sterilisation von Produkten für die Gesundheitsfürsorge - Feuchte Hitze - Teil 2: Leitfaden für die Anwendung von ISO 17665-1 (ISO 17665-2:2009)

Stérilisation des produits de santé - Chaleur humide - Partie 2: Directives relatives à l'application de l'ISO 17665-1 (ISO 17665-2:2009)

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Foreword

This document (CEN ISO/TS 17665-2:2009) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" of the International Organization for Standardization (ISO) and has been taken over as CEN/TS ISO 17665-2:2009 by Technical Committee CEN/TC 204 “Sterilization of medical devices” the secretariat of which is held by BSI.

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The text of ISO 17665-2:2009 has been approved by CEN as a CEN/TS ISO 17665-2:2009 without any modification.

TECHNICAL SPECIFICATION

ISO/TS 17665-2

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Sterilization of health care products — Moist heat —

Part 2: Guidance on the application of ISO 17665-1

Stérilisation des produits de santé — Chaleur humide —

Partie 2: Directives relatives à l'application de l'ISO 17665-1

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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.

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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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/TS 17665-2 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

ISO 17665 consists of the following parts, under the general title *Sterilization of health care products — Moist heat*:

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

— *Part 2: Guidance on the application of ISO 17665-1* [Technical Specification]

Introduction

The guidance given in this Technical Specification is not intended as a checklist for assessing compliance with ISO 17665-1. This guidance is intended to assist in obtaining a uniform understanding and implementation of ISO 17665-1 by providing explanations and acceptable methods for achieving compliance with specified requirements. It highlights important aspects and provides examples. Methods other than those given in this guidance may be used. However, the use of alternative methods has to be demonstrated to be effective in achieving compliance with ISO 17665-1.

The main body of this document is applicable to all settings where moist heat sterilization is carried out. The annexes to this guidance document also specify detailed means of implementing the requirements of ISO 17665-1 and represent current best practices.

The numbering of the clauses in the main body of this Technical Specification corresponds to that in ISO 17665-1.

Medical devices reprocessed in health care facilities include a wide variety of product with varying levels of bioburden. Appropriate and thorough cleaning and, where necessary for safe handling, decontamination processes are essential prior to presenting product for sterilization. Mixed product loads are common in healthcare facilities with throughput volumes dictated by historical and predicted demand for sterile product.

Health care facilities do not normally specify sterilization processes for any individual medical device. Also, it is impractical for health care facilities to determine bioburden on a medical device. It is important that specified instruments be disassembled before decontamination and thoroughly inspected after completion of the sterilization process. Reassembly and assessment of functionality are also needed. Therefore, the medical device manufacturer's instructions (see ISO 17664[23]) should be followed for all aspects of cleaning, disinfection, packaging and sterilization. Many devices can be fully immersed and can be washed and disinfected in automated equipment (see ISO 15883[19-22]). For devices that cannot be fully immersed and that cannot tolerate thermal decontamination, alternative methods of disinfection should be used to ensure safe handling. Such procedures and policies should be in place to ensure that medical devices undergo appropriate reprocessing. Particular attention needs to be paid to the drying and storage of sterile medical devices. Requirements for packaging of medical devices are covered in ISO 11607-1[8] and ISO 11607-2[9].

If multiple sterilization cycles can lead to degradation and limit the useful life of a medical device, the manufacturer will specify the number of reprocessing cycles that can normally be tolerated.

When selecting a medical device, priority should be given to properties such as ease of cleaning and disassembly.

Additional guidance specific to health care is offered in Annex D of this Technical Specification.

Sterilization of health care products — Moist heat —

Part 2: Guidance on the application of ISO 17665-1

1 Scope

This Technical Specification provides general guidance on the development, validation and routine control of moist heat sterilization processes and is intended to explain the requirements set forth in ISO 17665-1. The guidance given in this Technical Specification is provided to promote good practice related to moist heat sterilization processes and to assist those developing and validating a moist heat sterilization process according to ISO 17665-1.

NOTE 1 The structure of the main body of this ISO Technical Specification (Clauses 1 to 12) corresponds to the structure of ISO 17665-1, so that the guidance given under a particular clause or subclause of this part of ISO 17665 applies to the requirements given in the corresponding clause or subclause of ISO 17665-1. For example, guidance for subclause 5.2 of ISO 17665-1:2006 is given in 5.2. This guidance is provided in addition to the guidance given in ISO 17665-1:2006, Annex A. See also Annexe E.

NOTE 2 Special considerations specific to sterilization processes performed in health care facilities are given in Annex D.

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 17665-1:2006, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

NOTE The normative references in ISO 17665-1 refer to published standards, the content of which should be used to assist in demonstrating compliance to the clause in which they are cited. Some are required mainly for moist heat sterilization in industry or for manufacturers of moist heat sterilizers and could go beyond typical practice for those performing sterilization in health care facilities.

ISO 17665-1 specifies a number of methods and procedures that can be used to monitor sterilization processes. The equipment required will normally be commercially available. A number of the normative references cited describe the specification and test methods used by commercial suppliers to qualify their products. The user of such products should ensure that purchased products comply with these standards, but will not normally need to refer to the standards.

ISO 17665-1 specifies the use of packaging complying with ISO 11607-1 and ISO 11607-2. Healthcare facilities should purchase packaging complying with these International Standards.

One method of process validation specified in ISO 17665-1 is based on the determination of bioburden. The ISO 11737[6],[7] series specifies a number of microbiological methods used during this process. Health care facilities would not normally utilize this approach for process validation.

3 Terms and definitions

For the purposes of this Technical Specification, the terms and definitions given in ISO 17665-1 and the following apply.

3.1
tests for sterility
technical operation defined in pharmacopoeia performed on product following exposure to a sterilization process

4 Quality management system elements

The guidance offered in Annex A of ISO 17665-1:2006 applies.

NOTE For additional considerations specific to health care facilities, see Clause D.2.

5 Sterilizing agent characterization

5.1 Sterilizing agent

5.1.1 Moist heat is water at elevated temperatures. Moist heat may be provided as saturated steam or can be generated in situ by applying thermal energy to water already present in the product. Moisture acts as the medium for transferring thermal energy to microorganisms.

5.1.2 Contaminants suspended in the sterilizing agent can be both toxic and corrosive and may generate a barrier between the microorganism and the sterilizing agent. They originate from water, that is heated or evaporated into steam or from contact between materials and the sterilizing agent during generation and transport to the sterilizer (see Clause 6, Clause 7 and Annex A). If the level of contaminants in the sterilizing agent can be affected by the quality of the feed water to the steam generation system, the feed water quality should be specified.

5.2 Microbicidal effectiveness

The microbicidal activity of moist heat is based on the temperature and the duration of contact between water molecules and microorganisms.

For the purpose of moist heat sterilization there are a number of acceptable time and temperature combinations recognised by some pharmacopoeias. These combinations include but are not limited to those listed in Table 1. All combinations listed are based on the concept of overkill with a safety factor that has been established for saturated steam or water in contact with the microorganism. Superheated steam behaves more like a dry gas and has a low microbicidal effectiveness compared with saturated steam. Superheated steam can result from pressure reduction and/or thermodynamic compression of saturated steam. It can also occur from the rehydration of parts of the sterilization load, particularly those parts containing natural fibres. Superheated steam conditions can be minimized by engineering of the steam supply system, for example by:

a) having a series of pressure reduction stages from the supply pipe to the sterilizer chamber and ensuring the pressure reduction ratio for each stage does not exceed 2:1;

b) ensuring steam velocity does not exceed 25 m/s;

c) ensuring materials made from natural fibres are pre-conditioned to a humidity greater than 40 % RH prior to sterilization.

Table 1 — Examples of minimum temperatures and times established for adequate levels of microbial lethality in sterilization processes

Temperature °C	Time min
121	15
126	10
134	3

5.3 Material effects

Material effects are generally limited to deformation and fracture caused by the temperatures and pressures of the sterilizing agent.

5.4 Environmental considerations

Principles of an environmental management system can be applied to a moist heat sterilization process. ISO 14001[11] provides a specification for an environmental management system. ISO 14040[12] provides guidance on designing a life cycle assessment study. The presence of noxious substances in the exhausts from the sterilizer should be considered. Further guidance on this clause is given in E.3 of ISO 14937:—[15].

6 Process and equipment characterization

NOTE The purpose of this activity is to characterize the entire sterilization process and the equipment necessary to deliver the sterilization process safely and reproducibly.

6.1 Process

6.1.1 General

A sterilization process should be specified for each product family and/or load configuration presented for sterilization.

Process parameters should apply to the equipment used. They should be optimised to ensure that for defined product families specified exposure conditions will be routinely obtained throughout the sterilizer chamber, and the maximum temperatures and rates of change of process variable (e.g. temperature and pressure) will not cause damage or degradation to the product.

The sterilization process specification should include all the process parameters that define the exposure profile throughout the operating cycle. It should also include the ones used to verify reproducibility. The portion of the operating cycle over which lethality is established should be identified, and the upper and lower limits of each process parameter that can affect both this lethality and the performance of the medical device should be defined.

Provision should be made to record data for judging the effectiveness and suitability of a routine sterilization process. The accuracy of measurement should be related to the tolerances of the process parameters.

If it is proposed to use an existing sterilization process to treat a new medical device, the existing sterilization process should be detailed and contain information and data sufficient to enable process definition (see Clause 8) to be carried out for the proposed new medical device(s) or loading configuration. The challenge identified for the new medical device or loading condition should be less than or equal to the challenge from the existing sterilization load(s). For some product families, assurance that defined exposure conditions will be reproduced might only be possible if the size of the sterilization load and the load configuration have been clearly defined.