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English Version

**Sterilization of health care products - Moist heat - Part 2:  
Guidance on the application of 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)

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

This Technical Specification (CEN/TS) was approved by CEN on 23 November 2008 for provisional application.

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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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### Endorsement notice

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

# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>2</b>
<b>4 Quality management system elements</b> .....	<b>2</b>
<b>5 Sterilizing agent characterization</b> .....	<b>2</b>
5.1 Sterilizing agent.....	2
5.2 Microbicidal effectiveness.....	2
5.3 Material effects.....	3
5.4 Environmental considerations.....	3
<b>6 Process and equipment characterization</b> .....	<b>3</b>
6.1 Process.....	3
6.2 Equipment.....	6
<b>7 Product definition</b> .....	<b>7</b>
<b>8 Process definition</b> .....	<b>8</b>
<b>9 Validation</b> .....	<b>10</b>
9.1 General.....	10
9.2 Installation qualification (IQ).....	11
9.3 Operational qualification (OQ).....	11
9.4 Performance qualification (PQ).....	13
9.5 Review and approval of the validation.....	14
<b>10 Routine monitoring and control</b> .....	<b>15</b>
<b>11 Product release from sterilization</b> .....	<b>16</b>
<b>12 Maintaining process effectiveness</b> .....	<b>17</b>
12.1 Demonstration of continued effectiveness.....	17
12.2 Recalibration.....	17
12.3 Maintenance of equipment.....	17
12.4 Requalification.....	17
12.5 Assessment of change.....	18
<b>Annex A (informative) Evaluation of a sterilization process primarily based on the measurement of physical parameters</b> .....	<b>19</b>
<b>Annex B (informative) Evaluation of a sterilization process primarily based on biological inactivation and an accompanying mechanical air removal procedure</b> .....	<b>27</b>
<b>Annex C (informative) Temperature and pressure of saturated steam for use in moist heat sterilization</b> .....	<b>30</b>
<b>Annex D (informative) Special considerations for health care settings</b> .....	<b>32</b>
<b>Annex E (informative) Index of normative clauses/subclauses of ISO 17665-1 and cited references or related guidance given in ISO 17665-1 and ISO/TS 17665-2</b> .....	<b>41</b>
<b>Bibliography</b> .....	<b>44</b>

## 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<sup>[23]</sup>) 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<sup>[19-22]</sup>). 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<sup>[8]</sup> and ISO 11607-2<sup>[9]</sup>.

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<sup>[6],[7]</sup> series specifies a number of microbiological methods used during this process. Health care facilities would not normally utilize this approach for process validation.