



## Expert commentary

**BS EN ISO 17665:2024**, *Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

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## 1 Overview

Moist heat sterilization, also termed steam sterilization, is one of the earliest recorded sterilization processes. The process employs steam at high pressures and temperatures and is used to sterilize a wide variety of materials and products. Some example application areas include:

- medical and pharmaceutical industries for the sterilization of medical devices, pharmaceutical and health care products;
- health care facilities for the sterilization of reusable surgical instruments including sets used in community dentistry and general medical practice;
- laboratory facilities for the preparation of microbiological growth media and the decontamination of microbiological waste; and
- food industries for the sterilization of canned food products.

BS EN ISO 17665:2024 is the international standard for the development, validation and routine control of moist heat (steam) sterilization processes used to produce medical devices and health care products. The standard is applicable to both health care facilities such as hospital surgical instrument decontamination departments and industrial organizations responsible for the production of sterile medical devices and pharmaceutical products. The standard was developed by ISO/TC 198 working group 3, moist heat sterilization.

The standard covers all moist heat sterilization processes used in the production of medical devices and health care products including those which employ saturated steam sterilization in which the steam entering the chamber impinges on the surfaces requiring sterilization and those for contained products in which the steam entering the chamber acts as a heating medium and which can be mixed with air or inert gases to provide a ballasting overpressure to prevent container breakage. Hot water spray and hot water immersion processes are also covered.

The first edition of BS EN ISO 17665 was published in 2006 and included normative requirements with minimal guidance. This was followed by publication of supplementary comprehensive guidance as a technical specification in 2009. The third part, another technical specification published in 2013, was primarily aimed at health care facilities who mostly process variable mixed loads of re-usable medical devices. This third part covered guidance on the designation of medical devices into product families and processing categories for steam sterilization and was aimed at enabling health care facilities to rationalise sterilizer load configurations so that validation could be carried out more efficiently.

BS EN ISO 17665:2024 is the first revision of the BS EN ISO 17665 series and, in line with the policy of ISO/TC 198 to combine normative requirements and guidance into single documents, is a combination of the three previously published parts. The new standard covers up to date thinking and state of the art moist heat sterilization principles. When harmonized to EU medical device regulations (MDR), BS EN ISO 17665:2024 will provide manufacturers with a possible route to conformity assessment to the Essential Safety and Quality Requirements of the MDR.

In combining the three parts of BS EN ISO 17665, considerable changes have been made in light of newer innovations and global changes in health care and industrial practice. Those managerially responsible for moist heat sterilization in either health care facilities or industrial settings should make themselves familiar with the new 2024 version in order to understand any changes to processes and procedures which could be needed to allow continued compliance.

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## 2 Main commentary

The standard is an extensive document of over 150 pages. The key elements of the standard are listed below including the changes which have been made. (In describing the changes made to BS EN ISO 17665:2024, the author has used the term "small changes" to indicate minor changes in text and content but essential principles are still followed. The author also uses the term "significant changes" to indicate major remodelling to the section along with several new clauses.)

The normative clauses are broadly aligned to the requirements of BS EN ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*.

### 2.1 Scope

The scope is a description of the areas of application for the standard and has some small changes. The moist heat sterilization processes covered include:

- a) saturated steam sterilization in which air is removed by passive purging (gravity displacement principle);

- b) saturated steam sterilization in which air is removed by active air removal (dynamic air removal, pre-vacuum/fractionated vacuum principle);
- c) contained product sterilization in which heat transfer is achieved by steam or 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.

## 2.2 Normative references

Normative References are those references cited by the normative sections. Some small changes have been made to update dated normative references to the current versions.

## 2.3 Terms and definitions

The terms and definitions used in BS EN ISO 17665-1:2006 predate the development of BS EN ISO 11139:2018. In revising the standard, terms and definitions have, as far as possible, been aligned with those found in BS EN ISO 11139:2018 and BS EN ISO 11139:2018+A1:2024 with additional notes provided to further explain the context in which the more generic terms are used. Significant changes have been made and users are advised to become fully familiar with the terms and definitions in order to understand and make sense of their use within the document. It is important to understand that the internationally agreed definitions can sometimes be counterintuitive and must be understood in terms of the context of their use. Two important definitions relate to the nature of the process. Thus, saturated steam sterilization processes are those in which the steam entering the chamber becomes the sterilizing agent by impinging on cold surfaces, condensing forming liquid water and releasing energy. Contained product sterilization processes are those where the steam entering the chamber, or the water contained within is used as a heating medium. The sterilizing agent, moist heat, is generated from the aqueous fluid inside the sealed containers as it is heated to microbicidal temperatures.

## 2.4 General

ISO have implemented a policy whereby standards cannot mandate the use of a specified quality system. As a consequence, significant changes have been made to Clause 4 and the chair and secretary of ISO/TC 198 developed some common text that discusses general areas including the advantages of implementing a formal quality system.

## 2.5 Sterilizing agent characterization

The sterilizing agent in a moist heat sterilization process is moist heat, and this clause includes a discussion on what moist heat is and its microbicidal effectiveness, along with its effects on materials and, being an energy intensive process, environmental considerations. This clause has been expanded with small changes. An important point to note is that moist heat sterilization does not require the presence of saturated steam but rather thermal energy in the presence of sufficient moisture to effect microbial inactivation. This has implications for process design. Similarly, the standard recognizes that moist heat can be used at temperatures below those commonly cited (e.g. 121°C for 15 minutes). Under such circumstances the onus for proving sterilizing capability rests with the user.

## 2.6 Process and equipment characterization

Process and equipment characterization is divided into general requirements and then specific requirements for saturated steam sterilization processes and contained product sterilization processes. Clause 6 is core to the standard and many of the further requirements are built on its content. It is recommended that existing users of BS EN ISO 17665 study this clause carefully and compare its content with the previous versions to take into account the significant changes made.

It is worth noting that ISO/TC 198 is in the process of developing a new standard for contained product sterilizers (ISO 19253) which will be published as a CD in April 2024 and as a finished standard in 2026. This standard will replace BS 3970 in due course.

## 2.7 Product definition

Product definitions outline the specification for the product which will be sterilized. Clause 7 has some small changes.