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Sterilization — Steam sterilizers — Large sterilizers

This British Standard is the UK implementation of EN 285:2015. It supersedes BS EN 285:2006+A2:2009 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Sterilization - Steam sterilizers - Large sterilizers

Stérilisation - Stérilisateurs à la vapeur d'eau - Grands stérilisateurs

Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren

This European Standard was approved by CEN on 15 November 2015.

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European foreword

This document (EN 285:2015) has been prepared by Technical Committee CEN/TC 102 "Sterilizers for medical purposes", the secretariat of which is held by DIN.

This document supersedes EN 285:2006+A2:2009.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2016, and conflicting national standards shall be withdrawn at the latest by December 2018.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

The standard is a full technical revision of the previous version. The following amendments have been made in comparison with EN 285:2006+A2:2009:

— introduction has been implemented;

— scope was modified to differentiate small and large sterilizer by chamber size and to exclude equipment intended to use, contain or be exposed to flammable substances or substances which could cause combustion, and equipment intended to process pathogenic substances or human tissues;

— normative references and bibliography have been updated;

— terms and definitions improved, deleted or new definitions such as, "cycle parameter", "fault", "maintenance", "measuring chain" "operating cycle stage", "pressure", "risk assessment", "risk control", "services", "sterilization process", "software validation" and "verification" added;

— new subclauses 4.3.1.3 *Protection at moving door*, 4.5 *Loading equipment*, 4.6 *Transport* and 7.3 *Software verification and validation* added;

— Clause 6 on measuring system, indicating and recording devices completely redrafted;

— requirements on sound power and vibration completely redrafted;

— requirements on safety, risk control and usability (Clause 11) completely redrafted including normative Annex F and reference to EN ISO 14971;

— requirements on packaging and marking (Clause 12) revised and extended;

— requirements on service and working environment (Clause 13) extended, e.g. 13.4 *Lighting* added, 13.7 *Electromagnetic interference* improved;

— clause on sound power test deleted;

— requirements on test measurement equipment redrafted;

— clauses on documentation and information revised and extended;

— Annex A on environmental aspects redrafted;

— Annex C on recommended material deleted;

— normative Annex F on protective measures added;

— Annex ZA relationship with the essential requirements of the Directive 93/42/ECC on Medical Devices including Tables ZA.1 and ZA.2 completely revised

— editorial revision of whole document.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This European Standard specifies test procedures and acceptance criteria to confirm whether the sterilizer is safe and can deliver an operating cycle for sterilizing the range of medical devices and loading configurations used in healthcare. It can also be used in other manufacturing sectors and industries. In addition, national regulations can necessitate consideration of the impact the sterilizer could have on the environment.

A steam sterilization process uses water in its liquid and vaporous state to penetrate as steam into the load and to condense on the surfaces of a device. The distribution of moisture and temperature throughout the sterilization load and the process of sterilization itself cannot be measured directly for each routine sterilization process. This is done by comparison of measurement results with cycle parameters shown previously by validation to deliver an efficient sterilization process to the exposed medical devices.

An instruction manual supplied with the sterilizer is required to have comprehensive information on the sterilizer, programmed operating cycles and safe operation. Requirements for the validation and routine control of sterilization are not addressed as they are specified EN ISO 17665-1.

Medical devices used in health care can differ in properties such as materials, mass, shape, volume and packaging. Each sterilizer load can comprise a variable number of packages each containing different types of variably distributed medical devices.

The reproducibility of the sterilization process can be affected by this variability and also by other changes which can include:

— deviation of the defined cycle parameters,

— retention of air in the load, air leakage and non-condensable gases in the steam,

— excessive accumulation of non-condensable gases and/or condensate,

— overheating of the steam,

— selection of an inappropriate operating cycle, and

— orientation of the load.

The state “sterile” is specified in EN 556-1. For the steam sterilization in health care national regulations and the European Pharmacopoeia require or recommend combinations of minimum process parameters to produce a substantial overkill. This European Standard identifies combinations of sterilization temperatures and holding times, with tolerances, recommended by the “Working Party on Pressure-steam Sterilisers”[1)]. The use of these values is justified when also considering the variable characteristics of sterilizer loads in healthcare.

Process variables and process parameters as defined in EN ISO 17665-1 characterize the microbicidal effectiveness of the sterilization process. Cycle parameters are associated with the control of the operating cycle and have implications on the attainment of process parameters, the uniformity of steam penetration, the removal of air, drying and deterioration of medical devices and their packaging.

1) Working Party on Pressure-steam Sterilisers (JW Howie, Allison VD, JH Bowie, Darmady EM, Knox R, EJK Penikett, Shone JAV, Sykes G, Weir CD, Wells CA, Wyllie CAP, Kelsey JC): Sterilization by Steam Under Increased Pressure, The Lancet (1959), p. 425-435.

This European Standard specifies test loads and test pieces designed to present a specific challenge to the operating cycle. The results from each test collectively contribute to a presumption that the sterilizer and the operating cycles are suitable for use in health care facilities. A test load does not necessarily mimic a configuration of medical devices. The suitability of an operating cycle for a particular product will require validation (see EN ISO 17665-1). By specifying numeric pass and fail-conditions the tests are used to confirm that the cycle parameters of the operating cycle are attained and maintained.

Limiting values for the properties and the purity of the services are related to the characteristics of the medical devices, therefore this European Standard does not include specific requirements on services. However, it does provide guidance and information on recommended properties, limit values and test methods.

Condensate derived from the sterilizer chamber will include additional impurities from the load and as a consequence is not representative of the quality of the supplied steam. Recommended limits for the purity of feed water and condensate are different from the requirements of the European Pharmacopeia for purified water. This difference is to compensate for increased corrosion to the sterilizer chamber and instruments resulting from a higher condensate temperature. The level of bacterial endotoxins contained in the steam will depend on the quality of feed water and the steam generation equipment[2)].

To minimize human errors during routine use this European Standard specifies automatic control of the operating cycle and a fault detection system designed to automatically detect changes to both services and operating cycle significant to affect sterility assurance. An air detector is an optional provision which when set and tested according to this European Standard will routinely challenge the operating cycle and register a pass/failure. Other methods for routinely assessing specific performance aspects can be used, such as chemical or biological indicators, providing their performance is determined and verified using validated test procedures.

Software can only be used in combination with hardware. The tests described in this standard can be used for the verification and final validation of the repeatability, reliability and performance of the control system. The requirements of this European Standard are intended to prevent products being considered “sterile” whenever a single fault condition occurs in the control and measuring system. In addition, this European standard specifies the provision of an electronic or permanent record of the operating cycle.

This European Standard refers to sections in the all risks safety standard EN 61010-1 and specific safety standard for sterilizers EN 61010-2-040 and offers as alternatives EN ISO 12100 and other harmonized safety standards listed in the Official Journal of the European Union under the Medical Devices Directive or Machinery Directive. Information on the relationship of this European Standard and the Essential Requirements of the Directives on medical devices and machinery is provided in the Tables ZA.1 and ZA.2.

The European Directive on pressure equipment applies to sterilizers and this is addressed by reference to harmonized standards on pressure equipment. Outside the EU other pressure equipment specifications can apply.

This European Standard contains no specific requirements for the sterilization of liquids or test methods to assess the heat transfer into a liquid. The sterilization of a liquid or the sterilization of contained product requires specific means for monitoring the temperature profile in the liquid or by reference to a challenge device.

2) A. Steeves*, R.M. Steeves: Endotoxin and Reprocessing of Medical Devices, ZentrSteril 2006 (5), 364-368 and D. Goullet, V. Flocard & J. Freney: Evaluation of the endotoxin risk posed by use of contaminated water during sterilisation of surgical instruments, WFHSS Conference 2007.

The performance requirements specified in this document are not intended for the process to be effective in inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease. However, some national regulations require the use of modified steam processes as part of a general prion decontamination programme.

1 Scope

This European Standard specifies requirements and the relevant tests for large steam sterilizers primarily used in health care for the sterilization of medical devices and their accessories contained in one or more sterilization modules. The test loads described in this European Standard are selected to represent the majority of loads (i.e. wrapped goods consisting of metal, rubber and porous materials) for the evaluation of general purpose steam sterilizers for medical devices. However, specific loads (e.g. heavy metal objects or long and/or narrow lumen) will require the use of other test loads.

This European Standard applies to steam sterilizers designed to accommodate at least one sterilization module or having a chamber volume of at least 60 l.

Large steam sterilizers can also be used during the commercial production of medical devices.

This European Standard does not specify requirements for large steam sterilizers intended to use, contain or be exposed to flammable substances or substances which could cause combustion. This European Standard does not specify requirements for equipment intended to process biological waste or human tissues.

This European Standard does not describe a quality management system for the control of all stages of the manufacture of the sterilizer.

NOTE 1 Attention is drawn to the standards for quality management systems e.g. EN ISO 13485.

NOTE 2 Environmental aspects are addressed in Annex A.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 764-7:2002, *Pressure equipment - Part 7: Safety systems for unfired pressure equipment*

EN 867-5:2001, *Non-biological systems for use in sterilizers - Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S*

EN 1041:2008+A1:2013, *Information supplied by the manufacturer of medical devices*

EN 13445-1:2014, *Unfired pressure vessels - Part 1: General*

EN 13445-2:2014, *Unfired pressure vessels - Part 2: Materials*

EN 13445-3:2014[3)], *Unfired pressure vessels - Part 3: Design*

EN 13445-4:2014, *Unfired pressure vessels - Part 4: Fabrication*

EN 13445-5:2014, *Unfired pressure vessels - Part 5: Inspection and testing*

EN 13445-8:2014, *Unfired pressure vessels - Part 8: Additional requirements for pressure vessels of aluminium and aluminium alloys*

EN 14222:2003, *Stainless steel shell boilers*

3) This document is impacted by the stand-alone amendment EN 13445-3:2014/A1:2015.