Sterilisation – Dampsterilisatorer – Store sterilisatorer

Sterilization – Steam sterilizers – Large sterilizers

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EUROPEAN STANDARD EN 285:2015+A1

NORME EUROPÉENNE

EUROPÄISCHE NORM October 2021

ICS 11.080.10 Supersedes EN 285:2015

English Version

Sterilization - Steam sterilizers - Large sterilizers

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

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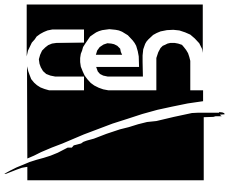

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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Indholdsfortegnelse

Europæisk forord

Dette dokument (EN 285:2015+A1:2021) er udarbejdet af teknisk komite CEN/TC 102 "Sterilizers for medical purposes", hvis sekretariat varetages af DIN.

Dette dokument erstatter ⟨A1⟩ EN 285:2015 ⟨A1⟩.

Denne Europæiske Standard skal senest december 2021 have status som national standard enten ved udgivelse af en identisk tekst eller ved formel godkendelse, og modstridende nationale standarder skal være trukket tilbage senest juni 2022.

Dette dokument er udarbejdet af CEN i henhold til standardiseringsanmodning fra Europa-Kommissionen og EFTA, og det understøtter væsentlige krav i et eller flere EU-forordninger.

Sammenhængen med EU-direktiver er angivet i det informative anneks ZA, der er en integreret del af dette dokument.

Dette dokument indeholder tillæg 1, der blev godkendt af CEN 23. maj 2021.

Begyndelsen og slutningen af tekst, der er indført i eller ændret ved tillæg, er fremhævet i teksten med symbolerne ⟨A1⟩ ⟨A1⟩.

Følgende ændringer er foretaget i forhold til EN 285:2015:

- de normative referencer er opdateret og rettet i den normative tekst
- note til term er tilføjet i 3.17 og 3.27
- 6.2 er vedtaget
- 6.4.4.2 er tilføjet
- note er tilføjet i 8.1.3 og 15.1
- sammenhængen mellem anneks ZA og de generelle krav til sikkerhed og ydeevne i forordning (EU) 2017/745 herunder tabel ZA.1, ZA.2 og ZA.3 er tilføjet.

Tilbagemeldinger og spørgsmål vedrørende dette dokument bør rettes til brugernes nationale standardiseringsorganisation. En fuldstændig liste over disse organisationer findes på CEN's hjemmeside.

Der gøres opmærksom på, at indhold i denne standard kan være underlagt patentrettigheder. CEN [og/eller CENELEC] kan ikke drages til ansvar for at identificere sådanne patentrettigheder.

I henhold til CEN/CENELEC's interne regler er de nationale standardiseringsorganisationer i følgende lande forpligtet til at implementere denne Europæiske Standard: Belgien, Bulgarien, Cypern, Danmark, Estland, Finland, Frankrig, Grækenland, Irland, Island, Italien, Kroatien, Letland, Litauen, Luxembourg, Malta, Nederlandene, Norge, Polen, Portugal, Republikken Nordmakedonien, Rumænien, Schweiz, Slovakiet, Slovenien, Spanien, Storbritannien, Sverige, Tjekkiet, Tyrkiet, Tyskland, Ungarn og Østrig.

Indledning

Dette dokument specificerer testprocedurer og godkendelseskriterier for at bekræfte, om sterilisatoren er sikker og kan frembringe en driftscyklus til sterilisering af de typer medicinsk udstyr og lastkonfigurationer, der anvendes til medicinsk brug. Det kan også anvendes i andre produktionssektorer og industrier. Derudover kan nationale bestemmelser nødvendiggøre overvejelser om den påvirkning, som sterilisatoren kan have på miljøet.

Ved en dampsteriliseringsproces anvendes vand i væske- og dampformig tilstand, der som damp skal penetrere ind i lasten og kondensere på udstyrets overflader. Fordelingen af fugt og temperatur gennem hele steriliseringslasten og selve steriliseringsprocessen kan ikke måles direkte for hver rutinemæssig steriliseringsproces. Dette gøres ved at sammenligne måleresultater med cyklusparametre, der tidligere er vist ved validering, for at skabe en effektiv steriliseringsproces for det eksponerede medicinske udstyr.

En betjeningsvejledning, der følger med sterilisatoren, skal indeholde fyldestgørende oplysninger om sterilisatoren, programmerede driftscyklusser og sikker drift. Krav til validering og rutinekontrol af sterilisering behandles ikke, da de er specificeret i EN ISO 17665-1.

Medicinsk udstyr, der anvendes i sundhedssektoren, kan have forskellige egenskaber, som fx materialer, masse, form, volumen og emballage. Hver steriliseringslast kan omfatte et variabelt antal pakker, der hver indeholder forskellige typer variabelt fordelt medicinsk udstyr.

Reproducerbarheden af steriliseringsprocessen kan påvirkes af denne variabilitet og også af andre ændringer, som kan omfatte

– afvigelse af de definerede cyklusparametre

– tilbageholdelse af luft i lasten, luftlækage og ikke-kondenserbare gasser i dampen

– ophobning af ikke-kondenserbare gasser og/eller dampkondensat

– overophedning af dampen

– valg af uhensigtsmæssig driftscyklus og

– lastens orientering.

Tilstanden "steril" er specificeret i EN 556-1. Til dampsterilisering i sundhedssektoren kræver eller anbefaler Den Europæiske Farmakopé kombinationer af minimumprocesparametre for at opnå en væsentlig inddækning. Denne Europæiske Standard identificerer kombinationer af steriliseringstemperaturer og holdetider med tolerancer anbefalet af "Working Party on Pressure-steam Sterilisers"[1)]. Anvendelse af disse værdier er berettiget, når der også tages hensyn til steriliseringslasters variable laster i sundhedssektoren.

Procesvariabler og procesparametre som defineret i EN ISO 17665-1 karakteriserer steriliseringsprocessens mikrobicidale effektivitet. Cyklusparametre er forbundet med styringen af driftscyklussen og har betydning for opnåelse af procesparametre, ensartet damppenetration, evakuering af luft, tørring og forringelse af medicinsk udstyr og dets emballage.

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, Wymakere CAP, Kelmaker JC): Sterilization by Steam Under Increased Pressure, The Lancet (1959), p. 425-435.

Denne Europæiske Standard specificerer eksempler på testlaster og teststykker, hvis formål er at udgøre en specifik udfordring for driftscyklussen. Resultaterne fra hver test bidrager samlet til at antage, at sterilisatoren og driftscyklusserne er egnet til medicinsk brug. En testlast repræsenterer ikke nødvendigvis en konfiguration af medicinsk udstyr. Egnetheden af en driftscyklus til et bestemt produkt vil kræve validering (se EN ISO 17665-1). Ved at specificere numeriske betingelser for bestået og ikke-bestået anvendes testene til at bekræfte, at cyklusparametrene for driftscyklussen er opnået og opretholdt.

Grænseværdier for forsyningernes egenskaber og renhed vedrører egenskaberne ved det medicinske udstyr, hvorfor denne Europæiske Standard ikke indeholder specifikke krav til ydelser. Standarden indeholder imidlertid vejledning og information om anbefalede egenskaber, grænseværdier og testmetoder.

Kondensat fra steriliseringskammeret vil indeholde urenheder fra lasten og er derfor ikke repræsentativt for kvaliteten af den tilførte damp. Anbefalede grænser for renheden af fødevand og kondensat adskiller sig fra kravene i Den Europæiske Farmakopé for renset vand. Denne forskel skal kompensere for øget korrosion af steriliseringskammeret og instrumenter som følge af en højere kondensattemperatur. Niveauet af bakterielle endotoksiner indeholdt i dampen vil afhænge af kvaliteten af fødevandet og dampgenereringsudstyret[2)].

For at minimere menneskelige fejl under rutinemæssig brug specificerer denne Europæiske Standard automatisk styring af driftscyklussen og et fejldetekteringssystem, der er konstrueret til automatisk at detektere ændringer af både forsyninger og driftscyklus, som kan påvirke sikringen af sterilitet. En luftdetektor er valgfrit udstyr, som ved indstilling og test i henhold til denne Europæiske Standard rutinemæssigt vil udfordre driftscyklussen og registrere, om udstyret er bestået/ikke-bestået. Andre metoder til rutinemæssig vurdering af specifikke ydeevneaspekter kan anvendes, som fx kemiske eller biologiske indikatorer, forudsat at deres ydeevne bestemmes og verificeres ved hjælp af validerede testprocedurer.

Software kan kun anvendes i kombination med hardware. Testene beskrevet i denne standard kan anvendes til verifikation og endelig validering af styresystemets repeterbarhed, pålidelighed og ydeevne. Kravene i denne Europæiske Standard har til formål at forhindre, at produkter betragtes som "sterile", hver gang der opstår en enkeltfejltilstand i styre- og målesystemet. Derudover specificerer denne Europæiske Standard, at der skal ske en elektronisk/permanent registrering af driftscyklussen.

Denne Europæiske Standard henviser til afsnit i den generelle sikkerhedsstandard EN 61010-1 og den specifikke sikkerhedsstandard for sterilisatorer EN 61010-2-040 og tilbyder som alternativ EN ISO 12100 og andre harmoniserede sikkerhedsstandarder, der er anført i Den Europæiske Unions Tidende under direktivet om medicinsk udstyr eller maskindirektivet. Oplysninger om sammenhængen mellem denne Europæiske Standard og de væsentlige krav i direktivet om medicinsk udstyr og maskindirektivet findes i tabel ZA.1 og ZA.2.

Det europæiske direktiv om trykbærende udstyr gælder for sterilisatorer, og dette behandles med henvisning til harmoniserede standarder for trykbærende udstyr. Uden for EU kan andre specifikationer for trykbærende udstyr gælde.

Denne Europæiske Standard indeholder ingen specifikke krav til sterilisering af væsker eller testmetoder til vurdering af varmeoverførslen til en væske. Sterilisering af en væske eller sterilisering af indeholdte produkter kræver særlige midler til overvågning af temperaturprofilen i væsken eller ved henvisning til en såkaldt 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.

Ydeevnekravene specificeret i dette dokument er ikke beregnet til, at processen effektivt kan inaktivere de tilgrundliggende stoffer i spongiforme encefalopatier, som fx scrapie, bovin spongiform encefalopati (BSE) (kogalskab) og Creutzfeldt-Jakobs sygdom (CJD). Nogle nationale forskrifter kræver dog anvendelse af modificerede dampprocesser som en del af et generelt dekontamineringsprogram for prionsygdomme.

1 Anvendelsesområde

Dette dokument fastlægger krav til og relevante tests for store dampsterilisatorer, der primært anvendes i sundhedssektoren til sterilisering af medicinsk udstyr og tilbehør hertil indeholdt i et eller flere steriliseringsmoduler. Testlasterne beskrevet i dette dokument udvælges således, at de er repræsentative for størstedelen af lasterne (dvs. emballerede varer bestående af metal, gummi og porøse materialer) til vurdering af almindelige dampsterilisatorer til medicinsk udstyr. Specifikke laster (fx tunge metalgenstande eller lange og/eller smalle lumen) vil imidlertid kræve, at der anvendes andre testlaster.

Dette dokument gælder for dampsterilisatorer, der er konstrueret til at rumme mindst ét steriliseringsmodul eller har et kammervolumen på mindst 60 l.

Store dampsterilisatorer kan også anvendes ved den kommercielle produktion af medicinsk udstyr.

Dette dokument fastlægger ikke krav til store dampsterilisatorer beregnet til at anvende, indeholde eller blive udsat for brændbare stoffer eller stoffer, som kan forårsage forbrænding. Dette dokument specificerer ikke krav til udstyr, der er beregnet til at bearbejde biologisk affald eller humant væv.

Dette dokument beskriver ikke et kvalitetsledelsessystem til styring af alle trin i fremstillingen af sterilisatoren.

NOTE 1 Opmærksomheden henledes på standarderne for kvalitetsledelsessystemer, fx EN ISO 13485.

NOTE 2 Miljøforhold er behandlet i anneks A.

2 Normative referencer

I dette dokument bliver der henvist normativt til hele eller dele af følgende dokumenter, som dermed er nødvendige for dette dokuments anvendelse. For daterede referencer gælder kun den anførte udgave. For udaterede referencer gælder den nyeste udgave af det pågældende dokument (inklusive evt. tillæg).

〚A1〛 EN 764-7:2002,[3)] *Pressure equipment – Part 7: Safety systems for unfired pressure equipment* 〚A1〛

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*

〚A1〛 EN 13445-1:2014,[4)] *Unfired pressure vessels – Part 1: General* 〚A1〛

〚A1〛 EN 13445-2:2014,[4)] *Unfired pressure vessels – Part 2: Materials* 〚A1〛

〚A1〛 EN 13445-3:2014,[4)] *Unfired pressure vessels – Part 3: Design* 〚A1〛

〚A1〛 EN 13445-4:2014[4)], *Unfired pressure vessels – Part 4: Fabrication* 〚A1〛

〚A1〛 EN 13445-5:2014,[4)] *Unfired pressure vessels – Part 5: Inspection and testing* 〚A1〛

〚A1〛 EN 13445-8:2014,[4)] *Unfired pressure vessels – Part 8: Additional requirements for pressure vessels of aluminium and aluminium alloys* 〚A1〛

EN 14222:2003, *Stainless steel shell boilers*

3) Som påvirket af EN 764-7:2002/AC:2006.
4) Inklusiv alle tillæg og påvirket af Issue 5.

EN 22768-1:1993, *General tolerances – Part 1: Tolerances for linear and angular dimensions without individual tolerance indications (ISO 2768-1:1989)*

〉A1〈 EN 60204-1:2018, *Safety of machinery – Electrical equipment of machines – Part 1: General requirements (IEC 60204-1:2005, modified)* 〉A1〈

EN 60584-1:2013, *Thermocouples – Part 1: EMF specifications and tolerances (IEC 60584-1:2013)*

EN 60751:2008, *Industrial platinum resistance thermometers and platinum temperature sensors (IEC 60751:2008)*

EN 60770-1:2011, *Transmitters for use in industrial-process control systems – Part 1: Methods for performance evaluation (IEC 60770-1:2011)*

〉A1〈 EN 61010-1:2010,[5] *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements (IEC 61010-1:2010)* 〉A1〈

〉A1〈 EN 61010-2-040:2015, *Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2015)* 〉A1〈

EN 61326-1:2013, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements (IEC 61326-1:2012)*

EN ISO 228-1:2003, *Pipe threads where pressure-tight joints are not made on the threads – Part 1: Dimensions, tolerances and designation (ISO 228-1:2000)*

EN ISO 3746:2010, *Acoustics – Determination of sound power levels and sound energy levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746:2010)*

EN ISO 11140-3:2009, *Sterilization of health care products – Chemical indicators – Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test (ISO 11140-3:2007, including Cor 1:2007)*

EN ISO 12100:2010, *Safety of machinery – General principles for design – Risk assessment and risk reduction (ISO 12100:2010)*

〉A1〈 EN ISO 13408-2:2018, *Aseptic processing of health care products – Part 2: Filtration (ISO 13408-2:2018)* 〉A1〈

[5] Dette dokument påvirkes af tillæg EN 61010–1:2010/A1:2019 og rettelsesblad EN 61010–1:2010/A1:2019/AC:2019–04.

EUROPEAN STANDARD **EN 285:2015+A1**

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2021

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EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN 285:2015+A1:2021) has been prepared by Technical Committee CEN/TC 102 "Sterilizers for medical purposes", the secretariat of which is held by DIN.

This document supersedes A1 EN 285:2015 A1.

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 December 2021, and conflicting national standards shall be withdrawn at the latest by June 2022.

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

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

This document includes Amendment 1 approved by CEN on 23 May 2021.

The start and finish of text introduced or altered by amendment is indicated in the text by tags A1 A1.

The following amendments have been made in comparison EN 285:2015:

— normative references have been updated and corrected in the normative text;

— note to entry was added to 3.17 and 3.27;

— 6.2 was adopted;

— subclause 6.4.4.2 was added;

— note was added to 8.1.3 and 15.1;

— Annex ZA relationship with the General Safety and Performance Requirements of Regulation (EU) 2017/745 including Tables ZA.1, ZA.2 and ZA.3 was added.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

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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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This document 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 document 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 document 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 document 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 document 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 document does not specify requirements for equipment intended to process biological waste or human tissues.

This document 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.

〚A1〉 EN 764-7:2002,[3] *Pressure equipment - Part 7: Safety systems for unfired pressure equipment* 〈A1〛

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*

〚A1〉 EN 13445-1:2014,[4)] *Unfired pressure vessels - Part 1: General* 〈A1〛

〚A1〉 EN 13445-2:2014,[4)] *Unfired pressure vessels - Part 2: Materials* 〈A1〛

〚A1〉 EN 13445-3:2014,[4)] *Unfired pressure vessels - Part 3: Design* 〈A1〛

〚A1〉 EN 13445-4:2014[4)], *Unfired pressure vessels - Part 4: Fabrication* 〈A1〛

〚A1〉 EN 13445-5:2014,[4)] *Unfired pressure vessels - Part 5: Inspection and testing* 〈A1〛

〚A1〉 EN 13445-8:2014,[4)] *Unfired pressure vessels - Part 8: Additional requirements for pressure vessels of aluminium and aluminium alloys* 〈A1〛

EN 14222:2003, *Stainless steel shell boilers*

[3)] As impacted by corrigendum EN 764-7:2002/AC:2006.

[4)] Including all amendments and impacted by Issue 5.

EN 22768-1:1993, *General tolerances - Part 1: Tolerances for linear and angular dimensions without individual tolerance indications (ISO 2768-1:1989)*

〈A1〉 EN 60204-1:2018, *Safety of machinery - Electrical equipment of machines - Part 1: General requirements (IEC 60204-1:2005, modified)* 〈A1〉

EN 60584-1:2013, *Thermocouples - Part 1: EMF specifications and tolerances (IEC 60584-1:2013)*

EN 60751:2008, *Industrial platinum resistance thermometers and platinum temperature sensors (IEC 60751:2008)*

EN 60770-1:2011, *Transmitters for use in industrial-process control systems - Part 1: Methods for performance evaluation (IEC 60770-1:2011)*

〈A1〉 EN 61010-1:2010,[5] *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements (IEC 61010-1:2010)* 〈A1〉

〈A1〉 EN 61010-2-040:2015, *Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2015)* 〈A1〉

EN 61326-1:2013, *Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements (IEC 61326-1:2012)*

EN ISO 228-1:2003, *Pipe threads where pressure-tight joints are not made on the threads - Part 1: Dimensions, tolerances and designation (ISO 228-1:2000)*

EN ISO 3746:2010, *Acoustics - Determination of sound power levels and sound energy levels of noise sources using sound pressure - Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746:2010)*

EN ISO 11140-3:2009, *Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test (ISO 11140-3:2007, including Cor 1:2007)*

EN ISO 12100:2010, *Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)*

〈A1〉 EN ISO 13408-2:2018, *Aseptic processing of health care products - Part 2: Filtration (ISO 13408-2:2018)* 〈A1〉

[5] This document is impacted by the amendment EN 61010-1:2010/A1:2019 and corrigendum EN 61010-1:2010/A1:2019/AC:2019-04.