SLOVENSKI STANDARD
oSIST prEN 868-8:2017

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Embalaža za končno sterilizirane medicinske pripomočke - 8. del: Ponovno uporabljivi vsebniki za parne sterilizatorje po EN 285 - Zahteve in preskusne metode

Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 8: Wiederverwendbare Sterilisierbehälter für Dampf-Sterilisatoren nach EN 285 - Anforderungen und Prüfverfahren

Matériaux et systèmes d'emballage pour les dispositifs médicaux stérilisés au stade terminal - Partie 8 : Conteneurs réutilisables de stérilisation pour stérilisateurs à la vapeur d'eau conformes à l'EN 285 - Exigences et méthodes d'essai

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EUROPEAN STANDARD

NORME EUROPÉENNE

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English Version

Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods

Matériaux d'emballage pour les dispositifs médicaux - Partie 8 : Conteneurs réutilisables de stérilisation pour stérilisateurs à la vapeur d'eau conformes à l'EN 285 - Exigences et méthodes d'essai

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 8: Wiederverwendbare Sterilisierbehälter für Dampf-Sterilisatoren nach EN 285 - Anforderungen und Prüfverfahren

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 102.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (prEN 868-8:2017) has been prepared by Technical Committee CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 886-8:2009.

Annex A provides details of significant technical changes between this European Standard and the previous edition.

EN 868 consists of the following parts, under the general title *Packaging for terminally sterilized medical devices*:

— *Part 2: Sterilization wrap — Requirements and test methods;*

— *Part 3: Paper for use in the manufacture of paper bags (specified in* EN 868-4*) and in the manufacture of pouches and reels (specified in* EN 868-5*) — Requirements and test methods;*

— *Part 4: Paper bags — Requirements and test methods;*

— *Part 5: Sealable pouches and reels of porous materials and plastic film construction — Requirements and test methods;*

— *Part 6: Paper for low temperature sterilization processes — Requirements and test methods;*

— *Part 7: Adhesive coated paper for low temperature sterilization processes — Requirements and test methods;*

— *Part 8: Re-usable sterilization containers for steam sterilizers conforming to* EN 285 *— Requirements and test methods;*

— *Part 9: Uncoated nonwoven materials of polyolefines — Requirements and test methods;*

— *Part 10: Adhesive coated nonwoven materials of polyolefines — Requirements and test methods.*

In addition, ISO/TC 198 “Sterilization of health care products” in collaboration with CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices” has prepared the EN ISO 11607- series “Packaging for terminally sterilized medical devices”. The EN ISO 11607 series specifies general requirements for materials, sterile barrier systems and packaging systems (Part 1) and validation requirements for forming, sealing and assembly processes (Part 2).

Introduction

The EN ISO 11607 series consists of two parts under the general title “Packaging for terminally sterilized medical devices”. Part 1 of this series specifies general requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use. Part 2 of this series specifies validation requirements for forming, sealing and assembly processes.

General requirements for all types of sterile barrier systems are provided by EN ISO 11607-1.

The EN 868 series can be used to demonstrate compliance with one or more of the requirements specified in EN ISO 11607-1.

CEN/TC 102/WG 4 also appreciates the initiatives of CEN with regard to the minimization of adverse environmental impacts by standards. It was agreed that this subject should be given priority during the next edition of the EN ISO 11607 series that is the basic reference for all parts of the EN 868 series.

1 Scope

This part of EN 868 provides test methods and values for re-usable containers used as sterile barrier systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use. These containers are intended to be used in steam sterilizers conforming to EN 285.

NOTE 1 The need for a packaging material inside the container is determined by the manufacturers and users.

Other than the general requirements as specified in EN ISO 11607-1 and EN ISO 11607-2 this part of EN 868 specifies materials, test methods and values that are specific to the products covered by this European Standard.

NOTE 2 When it is intended to use the containers in a steam sterilizer not conforming to EN 285 the sterilization performance of the container in the specific sterilization cycle to be used is validated by the user. Other attributes of the container are also reviewed for compatibility with the sterilizer cycle, e.g. operating temperature.

NOTE 3 When additional materials are used inside the sterile barrier system in order to ease the organization, drying or aseptic presentation (e.g. inner wrap, indicators, packing lists, mats, instrument organizer sets, tray liners or an additional envelope around the medical device) then other requirements, including the determination of the acceptability of these materials during validation activities, can apply.

Secretary remark (to be deleted by formal vote stage): CEN/TC 102/WG 4 proposes to change the Scope of the work item in order to align the scope with the recently published new editions of EN 868-2*, –3, 4- –6 and –7. Please consider that a positive ballot on* prEN 858-8 *during enquiry includes the approval of the revised scope.*

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 285:2015, *Sterilization - Steam sterilizers - Large sterilizers*

EN 10088-1, *Stainless steels - Part 1: List of stainless steels*

EN ISO 4017:2014, *Fasteners - Hexagon head screws - Product grades A and B (ISO 4017:2014)*

EN ISO 11607-1:2009, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)*

ISO 4582, *Plastics — Determination of changes in colour and variations in properties after exposure to daylight under glass, natural weathering or laboratory light sources*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 11607-1:2009 and EN 285:2015 apply.

4 Requirements

4.1 General

For any preformed sterile barrier system or sterile barrier system, the requirements of EN ISO 11607-1 apply.

This part of EN 868 only introduces performance requirements and test methods that are specific to the products covered by this part of EN 868 but does not add or modify the general requirements specified in EN ISO 11607-1.

As such, the particular requirements in 4.2, 4.3 and 4.4 can be used to demonstrate compliance with one or more but not all of the requirements of EN ISO 11607-1.

NOTE 1 Compliance to EN 868–8 does not automatically mean compliance to EN ISO 11607-1.

A confirmation of compliance to EN 868-8 shall contain a statement whether EN ISO 11607-1 is covered.

NOTE 2 When additional materials are used inside the sterile barrier system in order to ease the organization, drying or aseptic presentation (e.g. inner wrap, container filter, indicators, packing lists, mats, instrument organizer sets, tray liners or an additional envelope around the medical device) then other requirements, including the determination of the acceptability of these materials during validation activities, can apply.

4.2 Requirements for construction and design

4.2.1 Shape and dimension

4.2.1.1 The container shall be in the general form of a parallelepipedal box.

NOTE Slight curvature or camber of the flat surfaces can be acceptable. Rounding of the corners is desirable.

4.2.1.2 The container including all connected parts, e.g. carrying devices shall fit within one sterilization module (see EN 285).

NOTE 1 If the container does not fit within one sterilization module, but complies with all other requirements of this part of the standard, the manufacturer can claim compliance with EN ISO 11607-1, but not with EN 868–8.

NOTE 2 For guidance on dimensions see informative Annex B.

4.2.1.3 For ease of cleaning all internal corners shall be radiused.

4.2.2 Lids and lid-latching devices

4.2.2.1 Access to the interior of the container shall be provided by a lid.

4.2.2.2 The lid shall be secured to the base during use by locking devices. The closure shall comply with the requirements in EN ISO 11607-1:2009, 5.1.10 c).

4.2.3 Tamper evident closure system

4.2.3.1 A tamper evident closure system complying with EN ISO 11607-1:2009, 5.1.10 a) shall be available.

4.2.3.2 If the 'tamper evident' closure system is not a single-use disposable item, i.e. does not irrevocably break when opened, then a special tool, key, code or treatment shall be required to re-set the closure system.

4.2.4 Gasket

4.2.4.1 The interface between the lid and base shall be provided with a closure gasket. The closure formed by the gasket with the lid latched in position shall provide microbial barrier properties as specified in EN ISO 11607-1:2009, 5.2 and 5.1.10 c).

4.2.4.2 The gasket shall be accessible for cleaning. Frequency and method of maintenance shall be specified by the manufacturer (see Clause 5).

4.2.5 Carrying devices

4.2.5.1 Each container shall be provided with a suitable carrying device.

NOTE Containers that are small enough to be grabbed, held and carried safely can be without a carrying device.

4.2.5.2 The carrying devices, the means of their attachment to the container, and the container itself shall be sufficiently robust to support the weight of the filled container without permanent deformation > 1 mm when tested in accordance with Annex C. If a permanent deformation is measured, performance characteristics of the container (in particular sterile barrier properties) shall be demonstrated to remain unchanged.

4.2.6 Stacking capability

4.2.6.1 The top and base of each container shall be sufficiently strong to allow stacking and shall be fitted with means to ensure that all containers of the same nominal size and of the same provenance shall stack securely.

After the test in accordance with Annex D, the container shall show no permanent deformation > 1 mm and shall have unchanged performance characteristics.

When tested in accordance with Annex E, the tested container shall remain stacked.

4.2.6.2 The containers shall be designed and constructed so that when stacked and loaded into the sterilizer in the manner specified by the manufacturer they will allow free passage of steam and/or air between containers.

Compliance shall be tested by the performance tests carried out as described in Annexes C to F.

4.2.7 Sterilant Port

4.2.7.1 Each container shall be provided with a sterilant port in one or more of its principle surfaces.

4.2.7.2 The sterilant port shall be designed to meet the following requirements:

It shall permit the attainment of the specified sterilization conditions.

Compliance shall be tested in accordance with Annex F.

It shall permit adequate drying when processed in a sterilizer conforming to EN 285.

Compliance shall be tested in accordance with Annex G.

It shall permit microbial barrier properties during removal, transport and subsequent storage as specified in EN ISO 11607-1:2009, 5.1.10 b).

Compliance shall be tested in accordance with applicable barrier tests (see EN ISO 11607-1:2009).

NOTE A condensate drain is considered to be a sterilant port.

4.2.8 Load

A full size container, i.e. of one sterilization module size, shall be designed and constructed to allow a total internal load of up to 10 kg to be sterilized in a sterilizer conforming to EN 285.

Fractional sizes shall accommodate proportionally smaller loads.

NOTE National or regional legislation on occupational health and work safety may require a limitation or restriction of the acceptable weight to carrying device.

4.3 Service life

The sterilization container and its components shall, when processed in accordance with the provided instructions for use, meet all requirements during its useful life as it is stated by the manufacturer.

NOTE 1 The manufacturer's instructions include also important information on service, cleaning procedures, the manner of inspection and acceptance criteria, maintenance and replacement of components (see e.g. EN ISO 11607-1:2009 and prEN ISO 17664:2016).

NOTE 2 500 cycles are considered a minimum as a useful life for containers and 100 cycles as a minimum for specific components like gaskets.

For demonstration of compliance, using accelerated aging protocols shall be regarded as sufficient challenge until data from real-time aging studies are available.

NOTE 3 For guidance on determination of useful life with respect to sterilization, see Annex H.

4.4 Material requirements

NOTE With regard to the verification of the material requirements no test is needed if historical evidence can be documented or if there are bibliographic references for materials which have been previously used satisfactorily.

4.4.1 The container and its components shall be able to withstand (both chemical and physical) steam sterilization in a sterilizer conforming to EN 285 without any adverse effects on the container or its components.

Compliance with EN ISO 11607-1:2009, 5.3 shall be tested:

a) in a container which has been subjected to the stated number of reprocessing cycles; and

b) on a container which has been subjected to 5 use-cycles, stored under ambient conditions with the lid closed for 6 months and then subjected to 5 further use-cycles.

4.4.2 The container and its reusable components shall be able to withstand proper cleaning procedures as indicated by the manufacturer without adverse effect to the container or its components.

Compliance with EN ISO 11607-1 shall be tested:

a) in a container which has been subjected to the stated number of cleaning procedures as indicated by the manufacturer; and

b) on a container which has been subjected to 5 use-cycles, stored under ambient conditions with the lid closed for 6 months and then subjected to 5 further use-cycles.