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Pakkematerialer til terminalsteriliseret medicinsk udstyr – Del 8: Genanvendelige sterilisationsbeholdere til dampsterilisatorer i ifølge EN 285 – Krav og prøvningsmetoder

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

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EUROPEAN STANDARD EN 868-8

NORME EUROPÉENNE

EUROPÄISCHE NORM December 2018

ICS 11.080.30 Supersedes EN 868-8:2009

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

Emballages des 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

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

This European Standard was approved by CEN on 20 August 2018.

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European foreword

This document (EN 868-8:2018) 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 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of an identical text or by endorsement, at the latest by June 2019, and conflicting national standards shall be withdrawn at the latest by June 2019.

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

This document supersedes 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).

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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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.

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Packaging for terminally sterilized medical devices –

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

1 Scope

This document specifies 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 document.

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 — The use of additional materials and/or accessories 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) is not covered in this part of EN 868. However, other requirements, including the determination of the acceptability of these materials and/or accessories during validation activities, can apply.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

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 11607-1:2017, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006, including Amd 1:2014)*

ISO 4582, *Plastics — Determination of changes in colour and variations in properties after exposure to glass-filtered solar radiation, natural weathering or laboratory radiation sources*