SLOVENSKI STANDARD
oSIST prEN 868-4:2015

01-oktober-2015

Embalaža za končno sterilizirane medicinske pripomočke - 4. del: Papirnate vrečke - Zahteve in preskusne metode

Packaging for terminally sterilized medical devices - Part 4: Paper bags - Requirements and test methods

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 4: Papierbeutel - Anforderungen und Prüfverfahren

Matériaux et systèmes d'emballage pour les dispositifs médicaux stérilisés au stade terminal - Partie 4 : Sacs en papier - Exigences et méthodes d'essai

Ta slovenski standard je istoveten z: **prEN 868-4**

ICS:

11.080.30	Sterilizirana embalaža	Sterilized packaging

oSIST prEN 868-4:2015 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 868-4

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ICS 11.080.30

Will supersede EN 868-4:2009

English Version

Packaging for terminally sterilized medical devices - Part 4: Paper bags - Requirements and test methods

Matériaux et systèmes d'emballage pour les dispositifs médicaux stérilisés au stade terminal - Partie 4 : Sacs en papier - Exigences et méthodes d'essai

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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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Foreword

This document (prEN 868-4:2015) has been prepared by Technical Committee CEN/TC 102 “Sterilizers for medical purposes”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 868-4:2009.

Annex A provides details of significant technical changes between this draft 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 for medical purposes 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.

Every sterile barrier system needs to fulfil the requirements of 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.