Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 868-2:2009 sisaldab Euroopa standardi EN 868-2:2009 ingliskeelset teksti.	This Estonian standard EVS-EN 868-2:2009 consists of the English text of the European standard EN 868-2:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.07.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.07.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 20.05.2009.	Date of Availability of the European standard text 20.05.2009.
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EUROPEAN STANDARD

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EN 868-2

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English Version

Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods

Matériaux d'emballage pour les dispositifs médicaux stérilisés au stade terminal - Partie 2: Enveloppe de stérilisation - Exigences et méthodes d'essai

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 2: Sterilisierverpackung - Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 23 April 2009.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists 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 Management Centre has the same status as the official versions.

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Foreword

This document (EN 868-2:2009) has been prepared by Technical Committee CEN/TC 102 “Sterilizers for medical purposes”, 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 November 2009, and conflicting national standards shall be withdrawn at the latest by November 2009.

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.

This document supersedes EN 868-2:1999.

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 for medical purposes" has prepared the series EN ISO 11607 "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 organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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 shall 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.

During the revision of EN 868 parts 2 to 10, CEN/TC 102/WG 4 recognized Resolution CEN/BT 21/2003 relating to the implementation of the uncertainty of measurement concept in standards. Following this Resolution and the corresponding guidance, CEN/TC 102/WG 4 has initiated a review of the test methods needed to show compliance with the requirements specified in EN 868 parts 2 to 10 with the intention that the information required by CEN/BT 21/2003 be available for inclusion in EN 868 parts 2 to 10 during one of their next revisions.

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 materials for sterile barrier systems and/or packaging systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use.

NOTE 1 The need for a protective packaging may be determined by the manufacturer and the user.

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 can be used to demonstrate compliance with one or more but not all of the requirements of EN ISO 11607-1.

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, may apply.

The materials specified in 4.2.2.1 to 4.2.2.3 of this part of EN 868 are intended for single use, the materials specified in 4.2.2.4 are intended for reuse.

NOTE 3 If the intended purpose according to the manufacturer of the material for sterile barrier system specifies the use as sterile field, then the additional requirements of the EN 13795 series apply.

2 Normative references

The following referenced documents are indispensable for the application 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 20187, *Paper, board and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples (ISO 187:1990)*

EN 20535, *Paper and board — Determination of water absorptiveness — Cobb method (ISO 535:1991)*

EN 20811, *Textiles — Determination of resistance to water penetration — Hydrostatic pressure test*

EN 21974, *Paper — Determination of tearing resistance (Elmendorf method) (ISO 1974:1990)*

EN 29073-3, *Textiles — Test methods for nonwovens — Part 3: Determination of tensile strength and elongation*

EN ISO 536, *Paper and board — Determination of grammage (ISO 536:1995)*

EN ISO 1924-2, *Paper and board — Determination of tensile properties — Part 2: Constant rate of elongation method (ISO 1924-2:1994)*

EN ISO 2758, *Paper — Determination of bursting strength (ISO 2758:2001)*

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

EN ISO 13937-1, *Textiles — Tear properties of fabrics — Part 1: Determination of tear force using ballistic pendulum method (Elmendorf) (ISO 13937-1:2000)*

EN ISO 13938-1, *Textiles — Bursting properties of fabrics — Part 1: Hydraulic method for determination of bursting strength and bursting distension (ISO 13938-1:1999)*

ISO 3689, *Paper and board — Determination of bursting strength after immersion in water*

ISO 3781, *Paper and board — Determination of tensile strength after immersion in water*

ISO 5636-3, *Paper and board — Determination of air permeance (medium range) — Part 3: Bendtsen method*

ISO 6588-2:2005, *Paper, board and pulps — Determination of pH of aqueous extracts — Part 2: Hot extraction*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 9197, *Paper, board and pulps — Determination of water-soluble chlorides*

ISO 9198, *Paper, board and pulp — Determination of water-soluble sulfates*

ISO 9237, *Textiles — Determination of the permeability of fabrics to air*