

Packaging for terminally sterilized medical devices -
Part 10: Adhesive coated nonwoven materials of
polyolefines - Requirements and test methods

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 868-10:2018 sisaldab Euroopa standardi EN 868-10:2018 ingliskeelset teksti.	This Estonian standard EVS-EN 868-10:2018 consists of the English text of the European standard EN 868-10:2018.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 19.12.2018.	Date of Availability of the European standard is 19.12.2018.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

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English Version

Packaging for terminally sterilized medical devices - Part
10: Adhesive coated nonwoven materials of polyolefines -
Requirements and test methods

Matériaux et systèmes d'emballage pour les dispositifs
médicaux stérilisés au stade terminal - Partie 10 :
Matériaux non tissés à base de polyoléfines enduits
d'adhésif - Exigences et méthodes d'essai

Verpackungen für in der Endverpackung zu
sterilisierende Medizinprodukte - Teil 10:
Klebmittelbeschichtete Faservliesmaterialien aus
Polyolefinen - Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 19 October 2018.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.



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COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (EN 868-10:2018) 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 868-10:2009.

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.

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 document specifies test methods and values for sealable adhesive coated nonwoven materials of polyolefines, manufactured from nonwovens complying with EN 868-9 used for sterile barrier systems and/or packaging systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use.

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.

The materials specified in this part of EN 868 are intended for single use only.

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

ISO 811, *Textiles — Determination of resistance to water penetration — Hydrostatic pressure test*

EN ISO 1924-2, *Paper and board — Determination of tensile properties — Part 2: Constant rate of elongation method (20 mm/min) (ISO 1924-2)*

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

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

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

ISO 6588-2, *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*

ASTM D2724, *Standard Test Methods for Bonded, Fused, and Laminated Apparel Fabrics*

ASTM F88/F88M:2015, *Standard Test Method for Seal Strength of Flexible Barrier Materials*