

PAKENDATULT STERILISEERITUD MEDITSIINISEADME  
PAKENDAMINE. OSA 4: PABERKOTID. NÕUDED JA  
KATSEMEETODID

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

|                                                                                                                     |                                                                                                                                    |
|---------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| See Eesti standard EVS-EN 868-4:2017 sisaldab Euroopa standardi EN 868-4:2017 ingliskeelset teksti.                 | This Estonian standard EVS-EN 868-4:2017 consists of the English text of the European standard EN 868-4:2017.                      |
| 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 08.02.2017. | Date of Availability of the European standard is 08.02.2017.                                                                       |
| Standard on kättesaadav Eesti Standardikeskusest.                                                                   | The standard is available from the Estonian Centre for Standardisation.                                                            |

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile [standardiosakond@evs.ee](mailto:standardiosakond@evs.ee).

ICS 11.080.30

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:  
Koduleht [www.evs.ee](http://www.evs.ee); telefon 605 5050; e-post [info@evs.ee](mailto:info@evs.ee)

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Homepage [www.evs.ee](http://www.evs.ee); phone +372 605 5050; e-mail [info@evs.ee](mailto:info@evs.ee)

English Version

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

Emballages des dispositifs médicaux stérilisés au stade  
terminal - Partie 4: Sacs en papier - Exigences et  
méthodes d'essai

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

This European Standard was approved by CEN on 4 December 2016.

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.



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

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

| <b>Contents</b>                                                                                                                        | <b>Page</b> |
|----------------------------------------------------------------------------------------------------------------------------------------|-------------|
| <b>European foreword</b> .....                                                                                                         | <b>3</b>    |
| <b>Introduction</b> .....                                                                                                              | <b>4</b>    |
| <b>1 Scope</b> .....                                                                                                                   | <b>5</b>    |
| <b>2 Normative references</b> .....                                                                                                    | <b>5</b>    |
| <b>3 Terms and definitions</b> .....                                                                                                   | <b>5</b>    |
| <b>4 Requirements</b> .....                                                                                                            | <b>6</b>    |
| <b>5 Information to be supplied by the manufacturer</b> .....                                                                          | <b>8</b>    |
| <b>Annex A (informative) Details of significant technical changes between this European Standard and the previous edition</b> .....    | <b>10</b>   |
| <b>Annex B (normative) Method for the determination of pH value, chloride and sulphate in paper bags</b> .....                         | <b>11</b>   |
| <b>B.1 Preparation of test pieces</b> .....                                                                                            | <b>11</b>   |
| <b>B.2 pH value</b> .....                                                                                                              | <b>11</b>   |
| <b>B.3 Chloride</b> .....                                                                                                              | <b>11</b>   |
| <b>B.4 Sulphate</b> .....                                                                                                              | <b>11</b>   |
| <b>B.5 Test report</b> .....                                                                                                           | <b>11</b>   |
| <b>Annex C (normative) Method for the determination of the tensile strength of the back seam joint in paper bags (see 4.5.4)</b> ..... | <b>12</b>   |
| <b>C.1 Preparation of the test pieces</b> .....                                                                                        | <b>12</b>   |
| <b>C.2 Procedure</b> .....                                                                                                             | <b>12</b>   |
| <b>C.3 Test report</b> .....                                                                                                           | <b>12</b>   |
| <b>Annex D (informative) Repeatability and Reproducibility of test methods</b> .....                                                   | <b>13</b>   |
| <b>Bibliography</b> .....                                                                                                              | <b>14</b>   |

## European foreword

This document (EN 868-4:2017) 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 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 August 2017, and conflicting national standards shall be withdrawn at the latest by August 2017.

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 868-4:2009.

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 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 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 and EN ISO 11607-2.

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 European Standard specifies test methods and values for paper bags manufactured from paper specified in EN 868-3, used as 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 European Standard.

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

## 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 868-3, *Packaging for terminally sterilized medical devices - 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*

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 11140-1, *Sterilization of health care products - Chemical indicators - Part 1: General requirements (ISO 11140-1)*

EN ISO 11607-1:2009+A1:2014, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006+AMD1:2014)*

EN ISO 11607-2, *Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2)*

ISO 6588-2:2012, *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*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 11607-1:2009+A1:2014 apply.