

Packaging materials for terminally sterilized medical devices

Part 4: Paper bags — Requirements and test methods

ICS 11.080.30; 55.040; 55.080

National foreword

This British Standard is the UK implementation of EN 868-4:2009. It supersedes BS EN 868-4:1999 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee LBI/35, Sterilizers, autoclaves and disinfectors.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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English Version

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

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

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

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

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Foreword

This document (EN 868-4:2009) 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of an identical text or by endorsement, at the latest by November 2009, and conflicting national standards shall be withdrawn at the latest by November 2009.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 868-4:1999.

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 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).

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