

Packaging materials and systems for medical devices which are to be sterilized —

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

The European Standard EN 868-3:1999 has the status of a British Standard

ICS 11.080.30; 55.040;

National foreword

This British Standard is the English language version of EN 868-3:1999. It supersedes most of the normative text of BS 6256:1989, which is subject to amendment to this effect. BS 6256:1989 is not yet withdrawn, because reference is made to it in annex D of EN 868-1:1997, with reference to the possibility of applying the methylene blue particulate penetration test (described in appendix C of BS 6256) as a means of assessing the microbial barrier properties of some types of sterilization packaging covered by EN 868.

The UK participation in its preparation was entrusted by Technical Committee LBI/35, Sterilizers, autoclaves and disinfectors, to Subcommittee LBI/35/9, Sterilization packaging materials, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

Sterilization packaging materials falling within the scope of EN 868-1 are considered to be medical devices under Directive 93/42/EEC and compliance with the requirements of EN 868-1 is a means of ensuring that particular essential requirements of the Directive are met (see annex ZA of EN 868-1). This part of EN 868 may be used to demonstrate compliance with some of the requirements of Part 1. However, compliance with this part of EN 868 alone may not necessarily be considered to ensure that the essential requirements of the Directive have been met.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 8, an inside back cover and a back cover.

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English version

Packaging materials and systems for medical devices which are to be sterilized — 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

Matériaux et systèmes d'emballages pour les dispositifs médicaux devant être stérilisés — Partie 3: Papier utilisé dans la fabrication de sacs en papier (spécifiés dans l'EN 868-4) et dans la fabrication de sachets et gaines (spécifiés dans l'EN 868-5) — Exigences et méthodes d'essai

Verpackungsmaterialien und -systeme für zu sterilisierende Medizinprodukte — Teil 3: Papier zur Herstellung von Papierbeuteln (festgelegt in EN 868-4) und zur Herstellung von Klarsichtbeuteln und -schläuchen (festgelegt in EN 868-5) — Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 13 May 1999.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

This European Standard 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 December 1999, and conflicting national standards shall be withdrawn at the latest by December 1999.

This standard is one of a series of European Standards concerned with packaging materials and systems for medical devices which are to be sterilized. This series consists of the following parts.

EN 868-1, *Packaging materials and systems for medical devices which are to be sterilized — Part 1: General requirements and test methods.*

EN 868-2, *Packaging materials and systems for medical devices which are to be sterilized — Part 2: Sterilization wrap — Requirements and test methods.*

EN 868-3, *Packaging materials and systems for medical devices which are to be sterilized — 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 868-4, *Packaging materials and systems for medical devices which are to be sterilized — Part 4: Paper bags — Requirements and test methods.*

EN 868-5, *Packaging materials and systems for medical devices which are to be sterilized — Part 5: Heat and self sealable pouches and reels of paper and plastic film construction — Requirements and test methods.*

EN 868-6, *Packaging materials and systems for medical devices which are to be sterilized — Part 6: Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation — Requirements and test methods.*

EN 868-7, *Packaging materials and systems for medical devices which are to be sterilized — Part 7: Adhesive coated paper for the manufacture of heat sealable packs for medical use for sterilization by ethylene oxide or irradiation — Requirements and test methods.*

EN 868-8, *Packaging materials and systems for medical devices which are to be sterilized — Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 — Requirements and test methods.*

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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