

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

Part 2: Sterilization wrap — Requirements and test methods

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National foreword

This British Standard is the English language version of EN 868-2:1999. It supersedes BS 6254:1989 and BS 6255:1989, which are withdrawn.

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.

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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 11 and a back cover.

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English version

Packaging materials and systems for medical devices which are to be sterilized — Part 2: Sterilization wrap — Requirements and test methods

Matériaux et systèmes d'emballages pour les dispositifs médicaux devant être stérilisés —
Partie 2: Enveloppes de stérilisation — Exigences et méthodes d'essai

Verpackungsmaterialien und -systeme für zu sterilisierende Medizinprodukte —
Teil 2: Sterilisierverpackung — Anforderungen und Prüfverfahren

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

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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.

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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 of European Standards 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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Introduction

Part 1 of this series of European Standards specifies general requirements and test methods for all packaging materials and systems intended for use as packaging for medical devices which are to be terminally sterilized in their packaging.

1 Scope

This part of the series of EN 868 provides examples of particular requirements and test methods for sterilization wrap suitable for use as packaging of medical devices which are to be terminally sterilized. It introduces no additional requirements to the general requirements of Part 1 but provides guidance based upon various elements of former, relevant national standards.

As such, the particular requirements in 4.2 to 4.5 can be used to demonstrate compliance with one or more but not all of the requirements of Part 1.

NOTE If the intended use as specified by the manufacturer includes the possibility of the material being used for other applications (e.g. sterile field, container filter or as an inner wrap for containers), then additional and/or other requirements can apply.

2 Normative references

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references, the latest edition of the publication referred to applies.

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

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

EN 28601, *Data elements and interchange formats — Information interchange — Representation of dates and times* (ISO 8601:1988 and technical corrigendum 1:1991).

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

ISO 536, *Paper and board — Determination of grammage*.

ISO 2758, *Paper — Determination of bursting strength*.

ISO 3689, *Paper and board — Determination of bursting strength after immersion in water* (Revision of ISO 3689:1976).

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, *Paper, board and pulps — Determination of pH of aqueous extracts*.

ISO 9073-9, *Textiles — Test methods for nonwovens — Part 9: Determination of drape coefficient*.

ISO 9197-1, *Paper, board and pulps — Determination of water-soluble chlorides — Part 1: General method*.

ISO 9198, *Paper, board and pulps — Determination of water-soluble sulfates — Titrimetric method*.

DIN 58953-6:1987, *Sterilization — Sterile supply — Sterilization paper for bags and tube packaging — Test*.

BS 6524:1984, *Method for determination of the surface resistivity of a textile fabric*.

3 Definitions

For the purposes of this European Standard, the definitions of EN 868-1 apply.

4 Requirements

4.1 General

The requirements of EN 868-1 apply.

NOTE The following particular requirements and test methods can be used to demonstrate compliance with one or more, but not all, of the requirements of EN 868-1.

4.2 Materials

Raw materials used for the manufacture of packaging materials may be virgin or reclaimed materials, provided the source, history and traceability of all raw materials, especially recycled materials, are known and controlled to ensure that the finished product will consistently meet the requirements of this standard.

NOTE With current commercial technologies it is unlikely that reclaimed material other than manufacturing waste will be sufficiently controlled to allow its safe use for medical device packaging.

4.3 Conditioning

Where reference is made in the following performance requirements to “conditioned” wrap or to the need for conditioning prior to carrying out a test the wrap shall be conditioned in accordance with the method given in EN 20187.

4.4 Performance requirements and test methods

4.4.1 General

4.4.1.1 When examined by unaided normal or corrected vision in transmitted light (daylight or good artificial light) the wrap shall be free from tears, creases or localized thickening sufficient to impair its functioning.