

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

Part 1. General requirements and test methods

The European Standard EN 868-1 : 1997 has the status of a
British Standard

ICS 11.080; 55.040

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National foreword

This British Standard is the English language version of EN 868-1 : 1997.

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 committee 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.

Attention is also drawn to current British Standards BS 6254 : 1989, BS 6255 : 1989, BS 6256 : 1989, BS 6257 : 1997 and BS 6871 : 1989. Further Parts of EN 868 corresponding to these standards are in preparation. On publication of the corresponding Parts of BS EN 868, the current British Standards will be withdrawn.

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

The subsequent Parts of EN 868 deal with a number of specific and commonly used materials. These materials are not a comprehensive list of those which may be used to achieve compliance with the requirements of Part 1.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 16, 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 1: General requirements and test methods

Matériaux et systèmes d'emballages pour les
dispositifs médicaux devant être stérilisés —
Partie 1: Exigences générales et méthodes d'essai

Verpackungsmaterialien und -systeme für zu
sterilisierende Medizinprodukte —
Teil 1: Allgemeine Anforderungen und Prüfverfahren

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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.

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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

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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 August 1997, and conflicting national standards shall be withdrawn at the latest by August 1997.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this standard.

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

This standard is the first of a series of draft European Standards concerned with packaging materials and systems for medical devices which are to be sterilized. These other draft European Standards currently are:

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

prEN 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 Part 4 of this standard) and in the manufacture of pouches and reels (specified in Part 5 of this standard) — Requirements and test methods*

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

prEN 868-5 *Packaging materials and systems for medical devices which are to be sterilized — Part 5: Heat sealable pouches and reel material manufactured from paper and plastic — Requirements and test methods*

prEN 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*

prEN 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*

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

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Introduction

This standard 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. Subsequent standards in this series (prEN 868-2 et sequence) specify particular requirements for a range of commonly used packaging materials and systems. It is intended that compliance with one of the subsequent particular standards can be used to demonstrate conformance with one or more of the requirements of this Part (general requirements) as specified in the particular standard.

The adequacy of a packaging system depends additionally on the manner in which each unit is closed or sealed. Attention is drawn to the need to validate and monitor the packaging process (see also European Standards on quality systems and ISO 11607).

1 Scope

1.1 This European Standard specifies the requirements and test methods for packaging materials and systems:

- which are used for packaging of medical devices which are to be terminally sterilized; and
- which are intended to maintain sterility of the device.

NOTE 1. This standard has been developed as a means to show compliance with relevant European Directives. If health care facilities e.g. hospitals do not place medical devices on the market, they are not covered by these Directives. Nevertheless, such health care facilities can fulfil the same requirements as manufacturers but can use alternative means to demonstrate conformity to this standard.

NOTE 2. Compliance with other Parts of prEN 868 series can be used to demonstrate compliance with one or more of the requirements of this standard.

1.2 This standard does not apply to packaging materials and systems used for packaging aseptically manufactured products.

1.3 This European Standard does not describe a quality assurance system for control of all stages of manufacture.

NOTE. Attention is drawn to the standards for quality systems (see e.g. EN ISO 9001, EN ISO 9002, EN 46001 or EN 46002) which control all stages of manufacture including the sterilization process. It is not a requirement of this standard to have a complete quality system during manufacture but certain elements of such a system can be applied.

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 550 *Sterilization of medical devices — Validation and routine control of ethylene oxide sterilization*
- EN 552 *Sterilization of medical devices — Validation and routine control of sterilization by irradiation*
- EN 554 *Sterilization of medical devices — Validation and routine control of sterilization by moist heat*
- 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)*

3 Definitions

For the purposes of this European Standard, the following definitions apply.

3.1 bioburden

Population of viable micro-organisms on an item.

3.2 closure

Means used to close a package where no seal is formed; e.g. by repeated folding to construct a tortuous path.

3.3 closure integrity

Characteristics of the closure which ensures that it presents a microbial barrier.

3.4 final pack

Pack in which a medical device is sterilized.

NOTE. In addition to the primary pack a secondary and/or transport pack can be included.

3.5 microbial barrier

Ability to prevent the ingress of micro-organisms.

3.6 packaging material

Any material used in the fabrication or sealing of a packaging system or primary pack.