SLOVENSKI STANDARD
SIST EN 868-4:2000

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Embalažni materiali in sistemi za medicinske pripomočke, ki jih je treba sterilizirati - 4. del: Papirnate vrečke - Zahteve in preskusne metode

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

Verpackungsmaterialien und -systeme für zu sterilisierende Medizinprodukte - Teil 4: Papierbeutel - Anforderungen und Prüfverfahren

Matériaux et systemes d'emballages pour les dispositifs médicaux devant etre stérilisés - Partie 4: Sacs en papier - Exigences et méthodes d'essai

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EUROPEAN STANDARD

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English version

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

Matériaux et systèmes d'emballages pour les dispositifs médicaux devant être stérilisés - Partie 4: Sacs en papier - Exigences et méthodes d'essai

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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.

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

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Contents

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.

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 paper bags manufactured from paper specified in Part 3 of this standard.

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 4.7 can be used to demonstrate compliance with one or more but not all of the requirements of Part 1.

Paper bags specified in this part are suitable for use as packaging of medical devices which are to be terminally sterilized.

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 285
Sterilization – Steam sterilizers – Large sterilizers

EN 867-2
Non-biological systems for use in sterilizers – Part 2: Process indicators (Class A)

EN 868-1
Packaging materials and systems for medical devices which are to be sterilized – Part 1: General 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 1422
Sterilizers for medical purposes – Ethylene oxide sterilizers – Requirements and test methods

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 3781
Paper and board – Determination of tensile strength after immersion in water

ISO 6588
Paper, board and pulps – Determination of pH of aqueous extracts

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

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 Construction and design

4.2.1 General

4.2.1.1 The bags shall be manufactured from single web paper specified in EN 868-3.

4.2.1.2 The following terms shall be used to describe the design of the bag:

a) back – the surface of the bag with a longitudinal seam;

b) front – the surface of the bag with no longitudinal seam;

c) unlipped – where the length of both the front and back surfaces are the same and the front surface has a thumb cut (9 ± 3) mm deep and not less than 15 mm wide;

d) lipped – where the length of the back surface is greater than the length of the front surface by not less than 10 mm and not more than 25 mm;

e) gusseted – where the construction of the bag includes side panels;

f) ungusseted – where the longitudinal edges of the front and back surfaces are contiguous;

g) heat seal top – where there is a continuous strip of heat seal adhesive on the inner surface of the front, back and gussets (if gusseted) of the top of the bag;

h) plain top – where there is no heat seal adhesive.

4.2.1.3 The adhesive used in the construction of the bag shall be water resistant and non-corrosive, subsequently referred to as – "construction adhesive".

4.2.2 Bottom seal formation

The bottom seal shall be formed by using one of the following methods:

a) the bottom shall be double folded with each fold bonded with "construction adhesive", or

b) the bottom shall be sealed across the entire width with a "construction adhesive" or with a heat-seal not less than 6,5 mm in depth, or

c) the bottom shall be sealed across the entire width as described in b) and then folded once, or more, each fold being bonded with a construction adhesive or with a heat-seal.

4.2.3 Back seam construction

4.2.3.1 The longitudinal seam shall be made at the back of the bag with a double line of "construction adhesive".

4.2.3.2 A coloured adhesive shall be used to enable a simple visual check on the continuity of both glue lines.

4.2.3.3 The dye should not impair the adhesive.

4.3 Process indicator

4.3.1 If (a) process indicator(s) is(are) printed on the bag, the printing shall be in accordance with EN 867-2 and shall be not less than 100 mm² in area. If a single indicator is used, it shall be placed in such a way that it cannot be influenced by the sealing procedure. The performance requirements shall be in accordance with EN 867-2.

4.3.2 The colour change which should take place on exposure to the sterilization process shall be described in words adjacent to the imprint of process indicator.

4.4 Heat seal strip

4.4.1 For bags with a heat seal closure the heat seal adhesive shall be applied as a continuous strip to the inner surface of the front, back and (if gusseted) the gussets of the bag.

4.4.2 The width of the heat seal strip shall be (25 ± 3) mm for bags with a width not exceeding 200 mm and (40 ± 3) mm for bags with a width exceeding 200 mm.

4.4.3 The top edge of the heat-seal strip shall be positioned not less than 2 mm and not more than 10 mm from the lower lip or bottom of the thumb cut.

4.5 Performance requirements and test methods

4.5.1 NOTE: The paper can be printed.

Whether printed or not, no substance known to be toxic shall leach out of the bag in sufficient quantity to cause a health hazard.

Until relevant European or International Standards are published, National regulations can apply.

4.5.2 The pH of the aqueous extract of the paper and adhesive sandwich shall be within the range 4,5 to 8,0 when tested in accordance with Annex A.

4.5.3 The chloride content of the aqueous extract of the paper adhesive sandwich, calculated as sodium chloride, shall not exceed 0,05 % when tested in accordance with Annex A.

4.5.4 The sulphate content of the aqueous extract of the paper and adhesive sandwich, calculated as sodium sulphate, shall not exceed 0,25 % when tested in accordance with Annex A.

4.5.5 The tensile strength of the back seam joint shall be not less than 2,20 kN/m per unit width, when tested in accordance with Annex B.

4.5.6 The wet tensile strength of the back seam joint shall be not less than 0,45 kN/m per unit width when tested in accordance with Annex C.

4.5.7 Bags shall not burst when tested in accordance with Annex D.

4.6 Marking

4.6.1 Marking of bags

The bag shall be clearly marked with:

a) "Do not use if the pack is damaged" or other equivalent phrase;

b) a process indicator(s) if applicable.

c) the manufacturer's or supplier's name or trade mark;

d) lot number[1]);

e) nominal dimensions and/or identification code.

4.6.2 Marking of Transport Packaging

Each unit of transport package shall be legibly and durably marked with the following information:

a) description of contents including the size, or a size code, for the bag;

b) quantity;

c) the manufacturer's or supplier's name or trademark;

d) date of manufacture in accordance with EN 28601;

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[1]) A reference number in order to trace the manufacturing history of the product.

e) lot number[1]);

f) the recommended storage conditions.

4.7 Information

The manufacturer shall supply the purchaser with the following information on request:

For heat seal bags – the acceptable range of temperature, pressure and time settings to be used on heated jaw or rotary action heat sealers to obtain a satisfactory seal.

[1]) A reference number in order to trace the manufacturing history of the product.