SLOVENSKI STANDARD
SIST EN 868-9:2001

01-april-2001

Embalažni materiali in sistemi za medicinske pripomočke, ki jih je treba sterilizirati - 9. del: Površinsko neobdelani "nonwovenmateriali iz poliolefinov za vrečke, neskončne zvitke in ščitnike, izdelane s toplotnim varjenjem - Zahteve in preskusne metode

Packaging materials and systems for medical devices which are to be sterilized - Part 9: Uncoated nonwoven materials of polyolefines for use in the manufacture of heat sealable pouches, reels and lids - Requirements and test methods

Verpackungsmaterialien und -systeme für zu sterilisierende Medizinprodukte - Teil 9: Unbeschichtete Vliesstoffe aus Polyolefinen für die Herstellung von heißsiegelfähigen Klarsichtbeuteln, -schläuchen und -deckeln - Anforderungen und Püfverfahren

Matériaux et systemes d'emballages pour les dispositifs médicaux devant etre stérilisés - Partie 9: Non tissés a base de polyoléfines, non enduits, pour la fabrication de sachets, gaines et opercules thermoscellables - Exigences et méthodes d'essai

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Packaging materials and systems for medical devices which are to be sterilized – Part 9: Uncoated nonwoven materials of polyolefines for use in the manufacture of heat sealable pouches, reels and lids – Requirements and test methods

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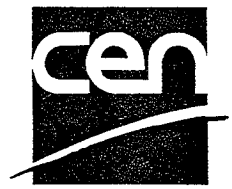
This European Standard was approved by CEN on 9 December 1999.

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.



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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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 2000, and conflicting national standards shall be withdrawn at the latest by August 2000.

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.

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.

EN 868-9 Packaging materials and systems for medical devices which are to be sterilized – Part 9: Uncoated nonwoven materials of polyolefines for use in the manufacture of heat sealable pouches, reels and lids – Requirements and test methods.

EN 868-10 Packaging materials and systems for medical devices which are to be sterilized – Part 10: Adhesive coated nonwoven materials of polyolefines for use in the manufacture of heat sealable pouches, reels and lids – Requirements and test methods.

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 EN 868 provides examples of particular requirements for uncoated nonwoven materials of polyolefines 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.

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.

The material specified in this part of the series EN 868 is intended for use in part or complete manufacture of heat sealable pouches, form and fill packs and lidding materials for packs.

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 20534
Paper and board – Determination of thickness and apparent bulk density or apparent sheet density (ISO 534:1988).

EN 21974
Paper – Determination of tearing resistance (Elmendorf method) (ISO 1974:1990).

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

EN ISO 536
Paper and board – Determination of grammage (ISO 536:1995).

EN 20811
Textiles – Determination of resistance to water penetration – Hydrostatic pressure test.

ISO 2758
Paper – Determination of bursting strength.

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.

ASTM D 2724:1987
Test Methods for Bonded, Fused and Laminated Apparel Fabrics.

3 Terms and definitions

For the purposes of this standard, the terms and definitions given in 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

4.2.1 Raw materials used for the manufacture of packaging materials may be virgin or reclaimed materials, provided that 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.

4.2.2 The uncoated material shall be translucent or opaque and made of continuous filaments of polyolefines of a high level of purity and shall not release any substances in such quantities as could constitute a health risk.

NOTE: Attention is drawn to EN ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing (ISO 10993-1:1997).

4.3 Conditioning

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

4.4 Performance requirements and test methods

4.4.1 No colour shall leach out of the material. Compliance shall be tested by visual examination of a hot extract prepared in accordance with the method given in ISO 6588 modified to test temperature of (60 ± 5) °C.

4.4.2 Whether printed or not, no substance known to be toxic shall leach out of the material, in sufficient quantity to cause a health risk. Until relevant European or International Standards are published, National regulations may apply.

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

4.4.4 The average mass of 1 m^2 of the conditioned material when tested in accordance with EN ISO 536 shall be within ±7 % of the nominal value stated by the manufacturer.

4.4.5 The tensile strength of the conditioned material shall be not less than 5,0 kN/m in the machine direction and 5,0 kN/m in the cross direction when tested in accordance with EN ISO 1924-2.

4.4.6 The internal tearing resistance of the conditioned material shall be not less than 1 000 mN in both machine and cross directions when tested in accordance with EN 21974.

4.4.7 The delamination factor of the conditioned material shall be not less than 1 N/25,4 mm when tested in accordance with ASTM D 2724:1987.

4.4.8 The bursting strength of the conditioned material shall be not less than 700 kPa when tested in accordance with ISO 2758.

4.4.9 The air permeance of the conditioned material shall be not less than 1 μm/Pa·s at an air pressure of 1,47 kPa when tested in accordance with ISO 5636-3.

NOTE: This requirement need not apply to materials solely for use in irradiation sterilization packaging.

4.4.10 The thickness of the conditioned material shall be within ±50 % of the nominal value stated by the manufacturer. Compliance shall be tested in accordance with EN 20534.

4.4.11 The hydrostatic head of the conditioned material shall be not less than 1 000 mm when tested in accordance with EN 20811.

4.5 Marking of the transport packaging

The transport packaging shall be legibly and durably marked with the following information:
a) reference, stock or catalogue number;
b) quantity;
c) the manufacturer's or supplier's name or trademark;
d) lot number [1];
e) nominal mass in grams per square metre;
f) nominal sheet size in millimetres or nominal width of rolls in millimetres and length in metres;
g) recommended storage conditions.

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

Annex A (informative)

Dimensions, weights and tolerances

A.1 For dimensional tolerances for edges of sheets and width of rolls of a nominal size stated by the manufacturer the following tolerances should apply:

– Nominal size up to 1 000 mm: ±5 mm.

– Nominal size > 1 000 mm: ±10 mm.

– Roll length: ±2,5 %.

A.2 Weight tolerances should be stated.