SLOVENSKI STANDARD
SIST EN 868-6:2000

01-julij-2000

Embalažni materiali in sistemi za medicinske pripomočke, ki jih je treba sterilizirati - 6. del: Papir za izdelavo zavitkov za uporabo v medicini pri sterilizaciji z etilenoksidom ali obsevanjem - Zahteve in preskusne metode

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

Verpackungsmaterialien und -systeme für zu sterilisierende Medizinprodukte - Teil 6: Papier für die Herstellung von Verpackungen für medizinische Zwecke zur Sterilisation mit Ethylenoxid oder Strahlen - Anforderungen und Prüfverfahren

Matériaux et systemes d'emballages pour les dispositifs médicaux devant etre stérilisés - Partie 6: Papier pour la fabrication d'emballages a usage médical pour stérilisation par l'oxyde d'éthylene ou par irradiation - 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 6: Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation - Requirements and test methods

Matériaux et systèmes d'emballages pour les dispositifs médicaux devant être stérilisés - Partie 6: Papier pour la fabrication d'emballages à usage médical pour stérilisation par l'oxyde d'éthylène ou par irradiation - 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

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

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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 used in the manufacture of packs for medical use.

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.

The paper specified in this part of the series EN 868 is suitable for the manufacture of packages to be used in ethylene oxide or irradiation sterilization processes.

Paper specified in this Part of the series EN 868 is intended for use in part or complete manufacture of pouches and form and fill packs and lidding material 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 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 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

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

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 pulp shall be free from grit and untreated fragments of the original materials from which the pulp was prepared.

4.3 Conditioning

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

4.4 Performance requirements and test methods

NOTE: When the paper is to be used to manufacture packaging intended to be irradiation sterilized only, it is not necessary for it to have wet strength properties or any permeability to air, so 4.4.12, 4.4.13 and 4.4.16 need not apply.

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

4.4.2 No colour shall leach out of the paper. Compliance shall be tested by visual examination of a hot aqueous extract prepared in accordance with the method given in ISO 6588.

4.4.3 NOTE: The paper can be printed.

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

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

4.4.4 The average mass of 1 m² of the conditioned paper when tested in accordance with ISO 536 shall be within ± 5 % of the nominal value stated by the manufacturer.

4.4.5 The pH of an aqueous extract of the paper shall be not less than 5 nor greater than 8 when tested in accordance with ISO 6588, hot extraction method.

4.4.6 The chloride content of the paper, calculated as sodium chloride, shall not exceed 0,05 % when tested in accordance with ISO 9197-1, hot extraction method.

4.4.7 The sulphate content of the paper, calculated as sodium sulphate shall not exceed 0,25 % when tested in accordance with ISO 9198, hot extraction method.

4.4.8 When tested in accordance with 2.5 of DIN 58953-6 : 1987 the paper shall neither exhibit an increase in brightness due to the optical brightener of more than 1 % nor have more than five fluorescent spots, each having an axis greater than 1 mm per 0,01 m².

4.4.9 The internal tearing resistance of the conditioned paper shall be not less than 300 mN in both machine and cross direction when tested in accordance with EN 21974.

4.4.10 The air permeance of the conditioned paper shall be not less than 0,2 µm/Pa · s and not more than 6,0 µm/Pa · s when tested in accordance with ISO 5636-3.

4.4.11 The bursting strength of the conditioned paper shall be not less than 200 kPa when tested in accordance with ISO 2758.

4.4.12 The wet bursting strength of the paper shall be not less than 35 kPa when tested in accordance with ISO 3689 using an immersion time of 10 min.

4.4.13 The water repellency of the paper shall be such that the penetration time is not less than 20 s when tested in accordance with Annex A.

4.4.14 When tested in accordance with Annex B, the average of the pore diameters of the ten test pieces shall be lower or equal to 20 µm. No value shall be greater than 30 µm.

4.4.15 The tensile strength of the conditioned paper shall be not less than 4,0 kN/m in machine direction and not less than 2,0 kN/m in cross direction when tested in accordance with EN ISO 1924-2.

4.4.16 The wet tensile strength of the paper shall be not less than 0,80 kN/m in machine direction and not less than 0,40 kN/m in cross direction when tested in accordance with ISO 3781.

4.4.17 The surface absorbency of each side of the paper shall be not more than 20 g/m² when tested in accordance with EN 20535 using a 60 s exposure time (Cobb method).

4.4.18

NOTE: To facilitate printing, the Bendtsen roughness of one surface of the conditioned paper should be not greater than 500 ml/min when tested in accordance with ISO 8791-2.

4.5 Marking of 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) date of manufacture in accordance with EN 28601;

e) lot number[1]);

f) nominal sheet size in millimetres or nominal width of rolls in millimetres and length in metres;

g) the recommended storage conditions.

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

Annex A (normative)

Method for the determination of water repellency

A.1 Apparatus

A.1.1 An ultra-violet light source and light meter as described in DIN 58953-6 : 1987.

A.1.2 Flat dish, approximately 200 mm x 150 mm x 15 mm.

A.1.3 Desiccator.

A.1.4 Stopwatch.

A.1.5 Powder dispenser, with a sieve of nominal aperture size between 0,125 mm and 0,150 mm at one end and closed at the other.

A.2 Reagent

Dry indicator powder prepared as described below.

Grind 20 g of sucrose in a mortar and pass through a sieve of nominal aperture size 0,063 mm to 0,075 mm. Dry the sieved sucrose in a desiccator over silica gel or in an oven at 105 °C to 110 °C. Mix 10 g of the dry sucrose with 10 mg of sodium fluorescein and pass the mixture 5 times through a sieve of nominal aperture size 0,063 mm to 0,075 mm and finally transfer the dry indicator powder to the powder dispenser.

The dry indicator powder in the powder dispenser should be stored either in a desiccator or in an oven at 105 °C to 110 °C.

A.3 Procedure

Take 10 test pieces of conditioned paper, each of size 60 mm x 60 mm. Separate the samples into two groups of five, one group with the 'wire-side' uppermost and the other with the 'top-side' uppermost. For each sample make two folds, each 10 mm high at right angles along two edges. Fill the flat dish with purified water at the conditioning temperature to a depth of 10 mm. Switch on the UV lamp and allow it to develop full output and adjust the distance of the lamp so that the irradiance at the level of the water in the dish is (300 ± 20) μW/cm². Sprinkle the upper surface of a test piece thinly with indicator powder from the dispenser. Float the test piece on the water under the UV light source and note the time taken for a general fluorescence to appear. Repeat the procedure with the remaining nine test pieces.

The water repellency of the paper is considerably influenced by the temperature of the water which shall be maintained within the specified limits (23 ± 1) °C.

A.4 Test report

Report the mean penetration time in seconds for each side of the paper.