SLOVENSKI STANDARD
SIST EN 868-2:2000

01-julij-2000

Embalažni materiali in sistemi za medicinske pripomočke, ki jih je treba sterilizirati - 2. del. Sterilizacijski embalažni materiali za zavijanje - Zahteve in preskusne metode

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

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

Matériaux et systemes d'emballages pour les dispositifs médicaux devant etre stérilisés - Partie 2: Enveloppes de stérilisation - Exigences et méthodes d'essai

Ta slovenski standard je istoveten z: **EN 868-2:1999**

ICS:

11.080.30	Sterilizirana embalaža	Sterilized packaging

SIST EN 868-2:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 868-2

June 1999

ICS 11.080.30; 55.040

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

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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.

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

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of an identical text or by endorsement, at the latest by December 1999, and conflicting national standards shall be withdrawn at the latest by December 1999.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 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.

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 localised thickening sufficient to impair its functioning.

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

4.4.1.3

NOTE: The paper can be printed.

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

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

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

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

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

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

4.4.1.8 When tested in accordance with 2.5 of DIN 58953-6 : 1987 the wrap 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 m^2.

4.4.1.9 For materials where the intended use, as specified by the manufacturer, includes its use as a sterile field where contact with low surface tension liquids can occur, the repellency to low surface tension liquids shall be not less than 7 when tested in accordance with Annex A. This requirement need not be addressed if the use of the material is restricted to packaging purposes only.

4.4.1.10 The surface resistivity of the conditioned sterilization wrap shall be less than $1 \times 10^{13}\ \Omega$ when tested in accordance with BS 6524 : 1984.

4.4.2 Specific requirements

4.4.2.1 Plain paper

4.4.2.1.1 The internal tearing resistance of the conditioned wrap shall be not less than 500 mN in both machine and cross direction when tested in accordance with EN 21974.

4.4.2.1.2 The air permeance of the conditioned wrap shall be not less than 1,7 µm/Pa · s at an air pressure of 1,47 kPa when tested in accordance with ISO 5636-3.

4.4.2.1.3 The bursting strength of the conditioned wrap shall be not less than 110 kPa when tested in accordance with ISO 2758.

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

4.4.2.1.5 The water repellency of the wrap shall be such that the penetration time is not less than 30 s when tested in accordance with Annex B.

4.4.2.1.6 The maximum equivalent pore size diameter shall not exceed 50 µm when tested in accordance with Annex C.

4.4.2.1.7 The drape of the wrap shall be not more than 160 mm in the machine direction and 125 mm in the cross direction when tested in accordance with Annex D.

4.4.2.1.8 The tensile strength of the conditioned wrap shall be not less than 1,33 kN/m in machine direction and not less than 0,67 kN/m in cross direction when tested in accordance with EN ISO 1924-2.

4.4.2.1.9 The wet tensile strength of the wrap shall be not less than 0,33 kN/m in machine direction and not less than 0,27 kN/m in cross direction when tested in accordance with ISO 3781.

4.4.2.1.10 The surface absorbency of each side of the paper shall be not more than 20 g/m^2 when tested in accordance with EN 20535 using a 60 s exposure time (Cobb test).

4.4.2.2 Creped Paper

4.4.2.2.1 The wrap shall be creped to give increased flexibility.

4.4.2.2.2 The elongation at break of the conditioned wrap shall be not less than 10 % in the machine direction and not less than 2 % in the cross direction when tested by measurement of the elongation in conjunction with the test for tensile strength in accordance with EN ISO 1924-2.

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

4.4.2.2.4 The maximum equivalent pore size diameter shall not exceed 50 µm when tested in accordance with Annex C.

4.4.2.2.5 The drape of the wrap shall be not more than 125 mm in the machine direction and 160 mm in the cross direction when tested in accordance with Annex D.

4.4.2.2.6 The tensile strength of the conditioned wrap shall be not less than 1,33 kN/m in machine direction and not less than 0,67 kN/m in cross direction when tested in accordance with EN ISO 1924-2.

4.4.2.2.7 The wet tensile strength of the wrap shall be not less than 0,33 kN/m in machine direction and not less than 0,27 kN/m in cross direction when tested in accordance with ISO 3781.

4.4.2.3 Nonwoven wrapping material

NOTE: For the purpose of this specification, a nonwoven for sterilization wrapping can be described as a bonded web made of textile and/or non-textile fibres with exclusion of mineral fibres.

4.4.2.3.1 The internal tearing resistance of the conditioned nonwoven wrap shall be not less than 750 mN in the machine direction and 1000 mN in the cross direction when tested in accordance with EN 21974.

4.4.2.3.2 The bursting strength of the conditioned nonwoven wrap shall be not less than 130 kPa when tested in accordance with ISO 2758.

4.4.2.3.3 The wet bursting strength of the nonwoven wrap shall be not less than 90 kPa when tested in accordance with ISO 3689 using an immersion time of 10 min.

4.4.2.3.4 The elongation at break of the conditioned nonwoven wrap shall be not less than 5 % in the machine direction and not less than 7 % in the cross direction when tested in accordance with EN ISO 1924-2.

4.4.2.3.5 In the absence of historical evidence with water repellency in accordance with 4.4.2.1.5 and 4.4.2.2.3, the nonwoven wrap shall be tested for saline repellency. The saline repellency of the nonwoven wrap shall be not less than 75 min when tested in accordance with Annex E.

4.4.2.3.6 The air permeance of the conditioned nonwoven wrap shall be not less than 10 l/min/100 cm² when tested in accordance with Annex F.

4.4.2.3.7 The drapeability of the conditioned nonwoven wrap shall be not greater than 85 % when tested in accordance with ISO 9073-9.

4.4.2.3.8 The tensile strength of the conditioned nonwoven wrap shall be not less than 1,00 kN/m in machine direction and not less than 0,65 kN/m in cross direction when tested in accordance with EN ISO 1924-2.

4.4.2.3.9 The wet tensile strength of the nonwoven wrap shall be not less than 0,75 kN/m in machine direction and not less than 0,50 kN/m in cross direction when tested in accordance with ISO 3781.

4.5 Marking

4.5.1 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 and nominal width of rolls in millimetres and length in metres;

g) the recommended storage conditions.

4.5.2 Inner package

The inner package with sheets or inner label with reels shall be legibly and durably marked with the information b), c), e) and f) according to 4.5.1.

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

Annex A (normative)

Method for the determination of repellency to low surface tension liquids

A.1 Principle

Drops of standard test liquid, consisting of a water-alcohol solution, are placed on the material surface and observed for penetration.

A.2 Apparatus

A.2.1 Water-alcohol solution with an alcohol repellency rating of 7 (70 % ethanol, 30 % distilled water).

A.2.2 Eye dropper, releasing drops of approximately 0,05 ml/s.

A.2.3 Transparent plastic plate, 250 mm x 1000 mm x 0,63 mm.

A.2.4 Three ring tripods.

A.2.5 Four mirrors.

A.2.6 High intensity light source to place between plate and mirror.

A.2.7 Timer.

A.3 Preparation of test specimens

Cut from the material to be tested, test specimens approximately 200 mm x 200 mm. Condition the specimens in a standard temperature atmosphere in accordance with EN 20187 for a minimum of 4 h.

A.4 Procedure

A.4.1 Place the plastic plate on the ring tripods and place the mirrors under it, positioning them to view the underside of the plate.

A.4.2 Place the four test specimens flat on the plate, and using the dropper, place 3 drops of test liquid at 3 separate sites on each specimen.

NOTE: The eye-dropper should be held close to the sample and the drops laid gently on the material.

A.4.3 Start the time after the last drop has been applied. After 5 min observe the underside of the test specimens using the mirrors and the light source. Record any penetration.

NOTE: Penetration is normally evidenced by the complete or partial darkening of the material immediately beneath the test liquid and is observed on the reverse side.

A.5 Test report

Report any penetration as an alcohol repellency rating of less than 7, and no penetration as an alcohol repellency rating of greater than 7.