SLOVENSKI STANDARD
SIST EN 868-5:2000

01-julij-2000

Embalažni materiali in sistemi za medicinske pripomočke, ki jih je treba sterilizirati - 5. del: Papirnate vrečke in neskončni zvitki papirja v kombinaciji s prosojnimi polimernimi folijami, izdelani s toplotnim varjenjem - Zahteve in preskusne metode

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

Verpackungsmaterialien und -systeme für zu sterilisierende Medizinprodukte - Teil 5: Heiß- und selbstsiegelfähige Klarsichtbeutel und -schläuche aus Papier und Kunststoff-Verbundfolie - Anforderungen und Prüfverfahren

Matériaux et systemes d'emballages pour les dispositifs médicaux devant etre stérilisés - Partie 5: Sachets et gaines thermoscellables et auto-scellables en papier et en film plastique - Exigences et méthodes d'essai

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11.080.30	Sterilizirana embalaža	Sterilized packaging

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EUROPEAN STANDARD

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EN 868-5

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English version

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

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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

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 European 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 heat and self-sealable pouches and reels manufactured from paper complying with EN 868-3 and plastic film complying with clause 4 of this Draft European 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.

Heat and self-sealable pouches and reels specified in this standard are suitable for use as packaging of medical devices which are to be terminally sterilized.

The use of heat and self-sealable pouches and reels as primary package enables ease of aseptic presentation where it is important for the user to be able to see the contents of the pack before it is opened.

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)

ASTM D 882 : 1995
Test Methods for Tensile Properties of Thin Plastic Sheeting

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 Paper

The paper shall comply with the requirements of EN 868-3.

4.2.2 Plastic film

4.2.2.1 The plastic film shall be a composite of two or more layers. When tested in accordance with Annex A the plastics interply bond shall not separate nor become cloudy.

4.2.2.2 No substance known to be toxic shall leach out of the plastics film or adhesive area in sufficient quantity to cause a health hazard.

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

4.2.2.3 The plastics film shall be free from pinholes when tested in accordance with Annex B.

4.2.2.4 When examined by unaided normal or corrected vision in transmitted light (daylight or good artificial light) the plastics film shall be free from foreign matter and/or other imperfections which would adversely affect compliance with the requirements of 4.5.

> NOTE: Slight continuous surface irregularities arising from the extrusion of the film should not be regarded as a defect.

4.2.2.5 The plastics film shall be heat sealable to the paper under the conditions specified by the manufacturer (see 4.7).

4.2.2.6 The breaking factor of the plastics film shall be not less than 20 N per 15 mm width when tested in accordance with ASTM D 882 : 1995 (Method A).

4.3 Construction and design

4.3.1 Reel material shall be constructed from one layer of paper and one layer of plastics composite film, heat sealed together along parallel sides.

Pouches shall be constructed from one layer of paper and one layer of plastics composite film by heat sealing three sides and may include a self adhesive area to effect closure of the filled pouch.

4.3.2 The overall width of the heat seal(s) shall be not less than 6 mm when determined in accordance with Annex C.

4.3.3 The distance between the end of a pouch and the nearer edge of the widthwise heat seal shall be sufficient to enable the two webs to be separated and peeled apart.

> NOTE: The side seals can extend beyond the widthwise seal to the end of the pouch provided that this does not impair peelability.

4.3.4 One web of the material of a pouch shall either:

a) be provided with a thumb notch not more than 12 mm deep at either the top or bottom of the pouch or at both ends. The bottom of the notch shall be at least 1 mm from the heat seal; or

b) be lipped such that the length of one web is greater than the length of the other web by not less than 10 mm and not more than 25 mm when the pouch is to be closed by heat sealing.

Where the pouch is to be closed by means of a self adhesive area, it shall be positioned on the paper lip and shall have a minimum width of 19 mm and be covered by a release material. Provision shall be made to ensure that when closure is effected, channelling through or around the adhesive area is prevented. The closure system shall give clear indication whether or not the pouch has been opened.

4.4 Process indicator

If a process indicator is printed on the pouches and tubes, 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.

4.5 Performance requirements and test methods

4.5.1 When tested in accordance with the method described in Annex D (dry samples) the strength of the heat seal joint shall be not less than 1,5 N per 15 mm width, both before and after being subjected to the sterilization process.

4.5.2 When tested in accordance with Annex D (wet samples) the wet strength of the heat seal joint shall be not less than 1,2 N per 15 mm width, both before and after being subjected to the steam and/or ethylene oxide sterilization process.

4.5.3 When tested in accordance with Annex C the seal shall cover the full width and the total length of the individual heat seal lines and there shall be no splitting of the paper more than 10 mm from the heat seal lines.

4.5.4 When tested in accordance with Annex A the sealed pouch or tube shall not burst.

4.5.5 When tested in accordance with Annex E the direction of the peel marked on the product shall correspond to that direction which ensures least fibre disturbance.

4.6 Marking

4.6.1 Marking of pouches and reels

4.6.1.1 Pouches and reel material shall be clearly marked with the following information unless agreed otherwise between the supplier and the customer:

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

b) lot number[1]);

c) the manufacturers name or trade mark;

d) a process indicator(s) if applicable;

e) the direction of peel which will ensure the least fibre disturbance;

f) nominal dimensions and/or identification code.

4.6.1.2 The product shall not be printed on any surface which is designed to come into direct contact with the items to be packaged.

4.6.1.3 For reels and/or pouches intended for general use an area of not less than 50 % of the total face area shall be left free from print.

4.6.1.4 The print repeat interval on reel material shall be not greater than 155 mm.

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/and an identification code, for the pouch or reel and reference to this Standard;

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) the recommended storage conditions.

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

4.7 Information

For heat and self-sealable pouches and reels the manufacturer shall supply the purchaser with the following information on request:

a) Heat sealable

– 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.

b) Self-sealable

– specified instructions on the closure system.