BRITISH STANDARD

BS EN 868-9:2009

Packaging for terminally sterilized medical devices

Part 9: Uncoated nonwoven materials of polyolefines — Requirements and test methods

ICS 11.080.30; 55.040

BSI
British Standards

National foreword

This British Standard is the UK implementation of EN 868-9:2009. It supersedes BS EN 868-9:2000 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee LBI/35, Sterilizers, autoclaves and disinfectors.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Packaging for terminally sterilized medical devices - Part 9: Uncoated nonwoven materials of polyolefines - Requirements and test methods

Matériaux d'emballage pour les dispositifs médicaux stérilisés au stade terminal - Partie 9: Non tissés à base de polyoléfines, non enduits, pour la fabrication de sachets, gaines et opercules thermoscellables - Exigences et méthodes d'essai

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 9: Unbeschichtete Faservliesmaterialien aus Polyolefinen - Anforderungen und Prüfverfahren

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Contents

Page

Foreword

This document (EN 868-9:2009) 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of an identical text or by endorsement, at the latest by November 2009, and conflicting national standards shall be withdrawn at the latest by November 2009.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 868-9:2000.

Annex A provides details of significant technical changes between this European Standard and the previous edition.

EN 868 consists of the following parts, under the general title *Packaging for terminally sterilized medical devices*:

Part 2: Sterilization wrap — Requirements and test methods;

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;

Part 4: Paper bags — Requirements and test methods;

Part 5: Sealable pouches and reels of porous materials and plastic film construction — Requirements and test methods;

Part 6: Paper for low temperature sterilization processes — Requirements and test methods;

Part 7: Adhesive coated paper for low temperature sterilization processes — Requirements and test methods;

Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 — Requirements and test methods;

Part 9: Uncoated nonwoven materials of polyolefines — Requirements and test methods;

Part 10: Adhesive coated nonwoven materials of polyolefines — Requirements and test methods.

In addition, ISO/TC 198 "Sterilization of health care products" in collaboration with CEN/TC 102 "Sterilizers for medical purposes" has prepared the EN ISO 11607 series "Packaging for terminally sterilized medical devices". The EN ISO 11607 series specifies general requirements for materials, sterile barrier systems and packaging systems (Part 1) and validation requirements for forming, sealing and assembly processes (Part 2).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

The EN ISO 11607 series consists of two parts under the general title "Packaging for terminally sterilized medical devices". Part 1 of this series specifies general requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use. Part 2 of this series specifies validation requirements for forming, sealing and assembly processes.

Every sterile barrier system shall fulfil the requirements of EN ISO 11607-1.

The EN 868 series can be used to demonstrate compliance with one or more of the requirements specified in EN ISO 11607-1.

During the revision of EN 868 parts 2 to 10 CEN/TC 102/WG 4 recognized Resolution CEN/BT 21/2003 relating to the implementation of the uncertainty of measurement concept in standards. Following this Resolution and the corresponding guidance, CEN/TC 102/WG 4 has initiated a review of the test methods needed to show compliance with the requirements specified in EN 868 parts 2 to 10 with the intention that the information required by CEN/BT 21/2003 be available for inclusion in EN 868 parts 2 to 10 during one of their next revisions.

CEN/TC 102/WG 4 also appreciates the initiatives of CEN with regard to the minimization of adverse environmental impacts by standards. It was agreed that this subject should be given priority during the next edition of the EN ISO 11607 series that is the basic reference for all parts of the EN 868 series.

1 Scope

This part of EN 868 provides test methods and values for uncoated nonwoven materials of polyolefines used for sterile barrier systems and/or packaging systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use.

NOTE 1 The need for a protective packaging may be determined by the manufacturer and the user.

This part of EN 868 only introduces performance requirements and test methods that are specific to the products covered by this part of EN 868 but does not add or modify the general requirements specified in EN ISO 11607-1.

As such, the particular requirements in 4.2 to 4.3 can be used to demonstrate compliance with one or more but not all of the requirements of EN ISO 11607-1.

NOTE 2 When additional materials are used inside the sterile barrier system in order to ease the organization, drying or aseptic presentation (e.g. inner wrap, container filter, indicators, packing lists, mats, instrument organizer sets, tray liners or an additional envelope around the medical device) then other requirements, including the determination of the acceptability of these materials during validation activities, may apply.

The materials specified in this part of EN 868 are intended for single use only.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 20811, *Textiles — Determination of resistance to water penetration — Hydrostatic pressure test*

EN 21974, *Paper — Determination of tearing resistance (Elmendorf method) (ISO 1974:1990)*

EN ISO 536, *Paper and board — Determination of grammage (ISO 536:1995)*

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

EN ISO 2758, *Paper — Determination of bursting strength (ISO 2758:2001)*

EN ISO 11607-1:2006, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)*

ISO 5636-3, *Paper and board — Determination of air permeance (medium range) — Part 3: Bendtsen method*

ISO 6588-2, *Paper, board and pulps — Determination of pH of aqueous extracts — Part 2: Hot extraction*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ASTM D 2724:1987, *Test Methods for Bonded, Fused and Laminated Apparal Fabrics*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 11607-1:2006 apply.

4 Requirements

4.1 General

The requirements of EN ISO 11607-1 apply.

NOTE EN ISO 11607-1:2006, 5.1.4 refers to conditions during production and handling with respect to their impact on the product (e.g. electrostatic conductivity, bioburden if applicable).

4.2 Materials

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.

4.3 Performance requirements and test methods

4.3.1 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 6588-2 modified to test temperature of (60 ± 5) °C.

4.3.2 The average mass of 1 m² of the conditioned material when tested in accordance with EN ISO 536 shall be within ± 7 % of the nominal value stated by the manufacturer.

4.3.3 The tensile strength of the conditioned material shall be not less than 4,8 kN/m in the machine direction and not less than 5,0 kN/m in the cross direction when tested in accordance with EN ISO 1924-2.

4.3.4 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.

4.3.5 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.

4.3.6 The bursting strength of the conditioned material shall be not less than 575 kPa when tested in accordance with EN ISO 2758.

4.3.7 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 to apply to materials solely for use in irradiation sterilization packaging.

4.3.8 The resistance to water penetration of the conditioned material shall be determined using the hydrostatic head test based on EN 20811. This test method is currently under revision and considering other test conditions (use of support screen with an open area greater than 50 % in order to avoid early fabric rupture). Minimum requirements will be set as soon as the revised test method is available. Manufacturers may report test results.

4.4 Marking of the protective packaging

The protective 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 trade name, and address;

d) date of manufacture in accordance with ISO 8601;

e) lot number[1];

f) nominal mass in grams per square metre;

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

h) the recommended storage conditions.

5 Information to be supplied by the manufacturer

For requirements on information to be provided by the manufacturer national or regional legislation may apply, see in particular Directive 93/42/EEC, Annex I, Section 13.

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

Annex A
(informative)

Details of significant technical changes between this European Standard and the previous edition

Changes between this European Standard and EN 868-9:2000 are the following:

a) changes in order to align this European Standard with the EN ISO 11607 series, in particular by

   1) amending the main element of the title, the scope and the terminology;

   2) using EN ISO 11607-1 as normative reference regarding the general requirements for materials, sterile barrier systems and packaging systems;

   3) deleting requirements that are covered by EN ISO 11607 (such as requirements on raw materials, conditioning, quality of the material with regard to tears, creases, localised thickening, leaching of toxic substances);

b) in addition to a) first dash, the scope has been modified to

   1) explain that other requirements might be of relevance for additional materials being used inside a sterile barrier system;

   2) clarify that the materials covered by this European Standard are intended for single use only;

c) an explanatory note has been inserted to refer the user of this European Standard to the general requirements on conditions during production and handling with respect to their impact on the product in EN ISO 11607;

d) requirements on tensile strength in machine direction and on bursting strength have been amended;

e) requirement on the tolerance of the thickness of the material has been deleted;

f) the requirement on resistance to water penetration has been formulated by taking into consideration that the applicable test method in EN 20811 is currently under revision and that a value on resistance to water penetration can only be set on the basis of data received with this revised test method;

g) requirements on marking have been amended;

h) requirements on information to be provided by the manufacturer have been added;

i) informative annex on dimensions and tolerances has been deleted;

j) text has been revised editorially (e.g. by updating normative and informative references).

NOTE This list is not exhaustive.

Bibliography

[1] EN 1041, *Information supplied by the manufacturer of medical devices*

[2] EN ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing (ISO 10993-1:2003)*

[3] EN ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006)*

[4] 93/42/EEC, COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

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