BS EN 868-4:2017

BSI Standards Publication

Packaging for terminally sterilized medical devices -

Part 4: Paper bags — Requirements and test methods

National foreword

This British Standard is the UK implementation of EN 868-4:2017. It supersedes BS EN 868-4:2009 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

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 4: Paper bags - Requirements and test methods

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 4: Sacs en papier - Exigences et méthodes d'essai

Verpackungsmaterialien für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 4: Papierbeutel - Anforderungen und Prüfverfahren

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European foreword

This document (EN 868-4:2017) has been prepared by Technical Committee CEN/TC 102 "Sterilizers and associated equipment for processing of medical devices", 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of an identical text or by endorsement, at the latest by August 2017, and conflicting national standards shall be withdrawn at the latest by August 2017.

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

This document supersedes EN 868-4:2009.

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 and associated equipment for processing of medical devices" has prepared the series EN ISO 11607 "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 organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey 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.

General requirements for all types of sterile barrier systems are provided by EN ISO 11607-1 and EN ISO 11607-2.

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

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 European Standard specifies test methods and values for paper bags manufactured from paper specified in EN 868-3, used as sterile barrier systems and/or packaging systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use.

Other than the general requirements as specified in EN ISO 11607-1 and EN ISO 11607-2 this part of EN 868 specifies materials, test methods and values that are specific to the products covered by this European Standard.

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

2 Normative references

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

EN 868-3, *Packaging for terminally sterilized medical devices - 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 ISO 1924-2, *Paper and board - Determination of tensile properties - Part 2: Constant rate of elongation method (20 mm/min) (ISO 1924-2)*

EN ISO 11140-1, *Sterilization of health care products - Chemical indicators - Part 1: General requirements (ISO 11140-1)*

EN ISO 11607-1:2009+A1:2014, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006+AMD1:2014)*

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

ISO 6588-2:2012, *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*

ISO 9197, *Paper, board and pulps — Determination of water-soluble chlorides*

ISO 9198, *Paper, board and pulp — Determination of water-soluble sulfates*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 11607-1:2009+A1:2014 apply.

4 Requirements

4.1 General

For any preformed sterile barrier system or sterile barrier system, the requirements of EN ISO 11607-1 and EN ISO 11607-2 shall apply.

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 4.5 can be used to demonstrate compliance with one or more but not all of the requirements of EN ISO 11607-1.

NOTE 1 Compliance to EN 868–4 does not automatically mean compliance to EN ISO 11607-1.

A confirmation of compliance to EN 868-4 shall contain a statement whether EN ISO 11607-1 and EN ISO 11607-2 are covered.

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, can apply.

4.2 Construction and design

4.2.1 General

4.2.1.1 The bags shall be manufactured from single web paper specified in EN 868-3.

4.2.1.2 The following terms shall be used to describe the design of the bag:

a) back – the surface of the bag with a longitudinal seam;

b) front – the surface of the bag with no longitudinal seam;

c) unlipped – where the length of both the front and back surfaces are the same and the front surface has a thumb cut (9 ± 3) mm deep and not less than 15 mm wide;

d) lipped – where the length of the back surface is greater than the length of the front surface by not less than 10 mm and not more than 25 mm;

e) gusseted – where the construction of the bag includes side panels;

f) ungusseted – where the longitudinal edges of the front and back surfaces are contiguous;

g) seal top – where there is a continuous strip of seal adhesive on the inner surface of the front, back and gussets (if gusseted) of the top of the bag;

h) plain top – where there is no seal adhesive.

4.2.1.3 The adhesive(s) used in the construction of the bag shall be water resistant and non-corrosive, subsequently referred to as “construction adhesive(s)”.

4.2.2 Bottom seal formation

The bottom seal shall be formed by using one of the following methods:

a) the bottom shall be double folded with each fold bonded with “construction adhesive”, or

b) the bottom shall be sealed across the entire width with a “construction adhesive” or with a seal not less than 6,5 mm in depth, or

c) the bottom shall be sealed across the entire width as described in b) and then folded once, or more, each fold being bonded with (a) construction adhesive(s) or with a heat seal.

4.2.3 Back seam construction

4.2.3.1 The longitudinal seam shall be made at the back of the bag with a continuous double line of “construction adhesive(s)”.

4.2.3.2 A coloured adhesive shall be used to enable a simple visual check on the continuity of both glue lines.

4.2.3.3 The dye shall not impair the adhesive.

4.3 Process indicator

If one or more Type I indicator(s) (process indicator(s)) are printed on the pouches and tubes, the indicator’s performance shall comply with the requirements of EN ISO 11140-1. Each individual indicator shall be not less than 100 mm^2 in area. Indicators shall not be affected by the sealing procedure.

4.4 Seal strip

4.4.1 For bags with a seal closure the seal adhesive shall be applied as a continuous strip to the inner surface of the front, back and (if gusseted) the gussets of the bag.

4.4.2 The width of the seal strip shall be (25 ± 3) mm for bags with a width not exceeding 200 mm and (40 ± 3) mm for bags with a width exceeding 200 mm.

4.4.3 The top edge of the seal strip shall be positioned not less than 2 mm and not more than 10 mm from the lower lip or bottom of the thumb cut.

4.5 Performance requirements and test methods

NOTE See Annex D for repeatability and reproducibility of the test methods: sulphate content and chloride content. For information on statement of precision and/or bias, repeatability and reproducibility of other test methods, see EN ISO 11607-1:2009+A1:2014, Table B.1.

4.5.1 The pH of the aqueous extract of the paper and adhesive sandwich shall be within the range 4,5 to 8,0 when tested in accordance with Annex B.

4.5.2 The chloride content of the aqueous extract of the paper and adhesive sandwich, calculated as sodium chloride, shall not exceed 0,05 % when tested in accordance with Annex B.

4.5.3 The sulphate content of the aqueous extract of the paper and adhesive sandwich, calculated as sodium sulphate, shall not exceed 0,25 % when tested in accordance with Annex B.

4.5.4 The tensile strength of the back seam joint of each bag seal shall be not less than 2,20 kN/m per unit width, when tested in accordance with Annex C.

4.6 Marking

4.6.1 Bags

The bag shall be clearly marked with:

a) "Do not use if the sterile barrier system is damaged" or other equivalent phrase;

b) a process indicator(s) if applicable;

c) the name or trade name of the manufacturer;

d) lot number[1];

e) nominal dimensions and/or identification code;

f) intended for single use only.

4.6.2 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 a size code, for the bag;

b) quantity;

c) the name or trade name and address of the manufacturer or his authorized representative;

d) date of manufacture in accordance with ISO 8601;

e) lot number[1];

f) the recommended storage conditions;

g) intended for single use only.

NOTE 1 Regulatory requirements apply to marking and can change in the future, e.g. Unique Device Identification (UDI).

NOTE 2 Symbols for marking can be used see EN ISO 15223-1.

5 Information to be supplied by the manufacturer

The manufacturer shall supply instructions for recommended sealing and/or closure conditions and for the monitoring of critical parameters of seal and/or closure integrity. Such instructions shall contain the date of issue or the revision.

NOTE 1 For validation of closure and sealing conditions, see EN ISO 11607-2.

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

NOTE 2 For heat seals these parameters include the range of temperature, pressure and time.

NOTE 3 For requirements on information to be provided by the manufacturer national or regional legislation can apply, see in particular Directive 93/42/EEC, Annex I, Section 13 [5].

Annex A
(informative)

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

Changes between this European Standard and EN 868-4:2009 are the following:

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

   1) including EN ISO 11607-2 as a normative reference;

   2) elucidating the requirements given by EN ISO 11607-1 and EN ISO 11607-2 as general requirements for this standard;

   3) formulating the significance and limits of the requirements of this standard with respect to the requirements given by EN ISO 11607-1;

   4) linking the test methods with regard to information on statement of precision and bias, repeatability and reproducibility to EN ISO 11607-1:2009+A1:2014, Table B.1;

   5) amendment of test method for determination of tensile strength as given by Annex C;

b) providing of informative data for repeatability and reproducibility of the following test methods as per Annex D:

   1) chloride content;

   2) sulphate content;

c) updating of the bibliography.

NOTE This list is not exhaustive.

Annex B
(normative)

Method for the determination of pH value, chloride and sulphate in paper bags

B.1 Preparation of test pieces

From the bag(s) cut a number of specimens so that in each case the back seam joint and a 10 mm width of paper on either side of the joint is included. Take a sufficient number of the specimens to weigh 10 g and cut these into small squares approximately 10 mm x 10 mm.

B.2 pH value

Prepare an aqueous extract and determine the pH value of the extract by the method described in ISO 6588-2.

B.3 Chloride

Prepare an aqueous extract in accordance with ISO 6588-2:2012, 7.2 except that 2 ml of potassium chloride solution is not added and determine the chloride content in accordance with ISO 9197.

B.4 Sulphate

Prepare an aqueous extract in accordance with ISO 6588-2:2012, 7.2 except that 2 ml of potassium chloride solution is not added and determine the sulphate content by the method described in ISO 9198.

B.5 Test report

The test report shall include the following information:

a) the pH to the nearest 0,1 pH unit;

b) the percentage of sodium chloride in the extract rounded to two significant figures;

c) the percentage of sodium sulphate in the extract rounded to two significant figures;

d) on request the identification of the product under test, the identification of the test-house and the date;

e) the normative reference of the test method.

Annex C
(normative)

Method for the determination of the tensile strength of the back seam joint in paper bags (see 4.5.4)

C.1 Preparation of the test pieces

Cut 5 strips, each 15 mm wide, from the bag(s) at right angles to the joint such that a 15 mm length of joint is in the centre of each strip.

C.2 Procedure

Using the test samples carry out the test in accordance with the method given in EN ISO 1924-2.

If during the test the paper fails before the specified value is achieved the test is invalidated as the seam has not been tested. The reason for the paper failure shall be investigated.

C.3 Test report

The test report shall include the following information:

a) the tensile strength (in kN/m per unit width) for each of the five samples rounded to two significant figures;

b) the identification of the product under test, the identification of the test-house and the date;

c) the normative reference of the test method.

Annex D
(informative)

Repeatability and Reproducibility of test methods

The precision of the following test methods have been assessed by a Round Robin Test protocol in 2010 and 2011, conducting a precision experiment as described in ISO 5725-2:

— chloride content;

— sufate content.

Table D.1 summarizes core conditions on interlaboratory testing. Table D.2 summarizes the significance of results.

Table D.1 — Test matrix

	Number of Laboratories	**Number of test runs**	**Replication**	**Number of sample materials**	**Type of materials**
Chloride content	3	7	2	4	Plain paper
Sulfate content	3	7	2	4	Plain paper

Table D.2 — Precision of test methods - Significance of results

			Repeatability s_r [a]		**Reproducibility s_R [a]**	
Test	**Units**	EN 868-4 **specification**	**Relative to mean results**	**Expressed as % specification limit**	**Relative to mean result**	**Expressed as % specification value**
Chloride content	%	Not > 0,05	0,002	4,0	0,186*m* +0,00	26,6
Sulfate content	%	Not > 0,25	0,01	4,0	0,183*m* + 0,01	23,2
[a] s = standard deviation						

NOTE Table D.2 has been adopted from the publication accordingly. Detailed information concerning the assessment, i.e. objective, methods, results, analysis and discussion, conclusions and recommendations, are published (see [4]).

Bibliography

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

[2] EN ISO 15223-1, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1)*

[3] ISO 5725-2, *Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method*

[4] BERRY C.W., HARDING L. Validation of Test Methods for Characterizing and Specifying Materials Used in the Construction of Sterilization Packaging. *Packag. Technol. Sci.* 2012

[5] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

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