

EUROPEAN STANDARD

**EN 868-2**

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2017

ICS 11.080.30

Supersedes EN 868-2:2009

English Version

## Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods

Emballages des dispositifs médicaux stérilisés au stade  
terminal - Partie 2: Enveloppe de stérilisation -  
Exigences et méthodes d'essai

Verpackungsmaterialien für in der Endverpackung zu  
sterilisierende Medizinprodukte - Teil 2:  
Sterilisierverpackung - Anforderungen und  
Prüfverfahren

This European Standard was approved by CEN on 4 December 2016.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

<b>Contents</b>	<b>Page</b>
<b>European foreword</b> .....	<b>4</b>
<b>Introduction</b> .....	<b>5</b>
<b>1 Scope</b> .....	<b>6</b>
<b>2 Normative references</b> .....	<b>6</b>
<b>3 Terms and definitions</b> .....	<b>7</b>
<b>4 Requirements</b> .....	<b>7</b>
<b>5 Information to be supplied by the manufacturer</b> .....	<b>11</b>
<b>Annex A (informative) Details of significant technical changes between this European Standard and the previous edition</b> .....	<b>12</b>
<b>Annex B (informative) Method for the determination of drape</b> .....	<b>13</b>
<b>B.1 Apparatus</b> .....	<b>13</b>
<b>B.1.1 Softness tester</b> .....	<b>13</b>
<b>B.1.2 Rule</b> .....	<b>13</b>
<b>B.2 Procedure</b> .....	<b>13</b>
<b>B.3 Test report</b> .....	<b>13</b>
<b>Annex C (normative) Method for the determination of water repellency</b> .....	<b>14</b>
<b>C.1 Apparatus</b> .....	<b>14</b>
<b>C.2 Reagent</b> .....	<b>14</b>
<b>C.3 Procedure</b> .....	<b>14</b>
<b>C.4 Repeatability and reproducibility</b> .....	<b>14</b>
<b>C.5 Test report</b> .....	<b>15</b>
<b>Annex D (normative) Method for the determination of pore size</b> .....	<b>16</b>
<b>D.1 Principle</b> .....	<b>16</b>
<b>D.2 Test liquid</b> .....	<b>16</b>
<b>D.3 Apparatus</b> .....	<b>16</b>
<b>D.4 Preparation of test specimens</b> .....	<b>18</b>
<b>D.5 Procedure</b> .....	<b>18</b>
<b>D.6 Result</b> .....	<b>19</b>
<b>D.6.1 Calculation and expression of results</b> .....	<b>19</b>
<b>D.6.2 Derivation of formula for calculation of equivalent pore radius</b> .....	<b>19</b>
<b>D.7 Repeatability and reproducibility</b> .....	<b>20</b>
<b>D.8 Test report</b> .....	<b>20</b>

<b>Annex E (informative) Repeatability and reproducibility of test methods .....</b>	<b>21</b>
<b>Bibliography .....</b>	<b>23</b>

## European foreword

This document (EN 868-2:2017) 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 868-2:2009.

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.

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 materials for 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.

While materials specified in 4.2.2.1 to 4.2.2.3 of this part of EN 868 are intended for single use, the materials specified in 4.2.2.4 are intended for reuse.

## 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 20187, *Paper, board and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples (ISO 187)*

EN 20811, *Textiles — Determination of resistance to water penetration — Hydrostatic pressure test (ISO 811)*

EN 29073-3, *Textiles — Test methods for nonwovens — Part 3: Determination of tensile strength and elongation (ISO 9073-3)*

EN ISO 535, *Paper and board — Determination of water absorptiveness — Cobb method (ISO 535)*

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

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 1974, *Paper — Determination of tearing resistance — Elmendorf method (ISO 1974)*

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

EN ISO 9237, *Textiles — Determination of permeability of fabrics to air (ISO 9237)*

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 13937-1, *Textiles — Tear properties of fabrics — Part 1: Determination of tear force using ballistic pendulum method (Elmendorf) (ISO 13937-1)*

EN ISO 13938-1, *Textiles — Bursting properties of fabrics — Part 1: Hydraulic method for determination of bursting strength and bursting distension (ISO 13938-1)*

ISO 2470-2, *Paper, board and pulps — Measurement of diffuse blue reflectance factor — Part 2: Outdoor daylight conditions (D65 brightness)*

ISO 3689, *Paper and board — Determination of bursting strength after immersion in water*

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 6588-2:2012, *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 material, preformed sterile barrier system or sterile barrier system, the requirements of EN ISO 11607-1 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 4.2 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 868-2 does not automatically mean compliance to EN ISO 11607-1.

A confirmation of compliance to EN 868-2 shall contain a statement whether EN ISO 11607-1 is 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 Performance requirements and test methods**

NOTE See Annex E for repeatability and reproducibility of the test methods: pore diameters, sulphate content, chloride content and water repellency. 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.

## 4.2.1 General

**4.2.1.1** 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 6588-2.

**4.2.1.2** The average mass of 1 m<sup>2</sup> of the conditioned wrap when tested in accordance with EN ISO 536 shall be within  $\pm 5\%$  of the nominal value stated by the manufacturer.

**4.2.1.3** The pH of an aqueous extract of the wraps shall be not less than 5 or greater than 8 when tested in accordance with ISO 6588-2, hot extraction method.

**4.2.1.4** The chloride content of the wrap, calculated as sodium chloride, shall not exceed 0,05 % when tested in accordance with ISO 9197 using a hot extract prepared in accordance with ISO 6588-2:2012, 7.2 except that 2 ml of potassium chloride solution is not added.

**4.2.1.5** The sulphate content of the wrap, calculated as sodium sulphate, shall not exceed 0,25 % when tested in accordance with ISO 9198, using a hot extract prepared in accordance with ISO 6588-2:2012, 7.2 except that 2 ml of potassium chloride solution is not added.

**4.2.1.6** When tested in accordance with ISO 2470-2 the material shall not exhibit an increase in D65 brightness, due to the optical brightener agents, of more than 1 %; calculated as the ratio of the D65 brightness measured with the 420 nm UV-cut-off filter in place to the D65 brightness measured without 420 nm UV-cut-off filter.

**4.2.1.7** When exposed at 25 cm from a UV light source, the material shall not have per 0,01 m<sup>2</sup> more than five fluorescent spots, each having an axis greater than 1 mm.

NOTE The UV light to be used is the one described as per Annex C.

**4.2.1.8** The manufacturer shall provide drapeability results and associated test method on request.

NOTE For test method, see e.g. EN ISO 9073-9 and Annex B.

## 4.2.2 Specific requirements

### 4.2.2.1 Wrap made of plain paper

**4.2.2.1.1** 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 ISO 1974.

**4.2.2.1.2** The air permeance of the conditioned wrap shall be not less than 1,7  $\mu\text{m}/\text{Pa} \cdot \text{s}$  at an air pressure of 1,47 kPa when tested in accordance with ISO 5636-3.

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

**4.2.2.1.4** 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.

**4.2.2.1.5** 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 C.

**4.2.2.1.6** When tested in accordance with Annex D, the average of the pore diameters of the ten test pieces shall be lower than or equal to 35  $\mu\text{m}$ . No value shall be greater than 50  $\mu\text{m}$ .

**4.2.2.1.7** 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.

**4.2.2.1.8** 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.

**4.2.2.1.9** The surface absorbency of each side of the paper shall be not more than 20 g/m<sup>2</sup> when tested in accordance with EN ISO 535 using a 60 s exposure time (Cobb test).

#### **4.2.2.2 Wrap made of creped paper**

**4.2.2.2.1** The wrap shall be creped to give increased flexibility.

**4.2.2.2.2** 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.

**4.2.2.2.3** 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 C.

**4.2.2.2.4** When tested in accordance with Annex D, the average of the pore diameters of the ten test pieces shall be lower than or equal to 35 µm. No value shall be greater than 50 µm.

**4.2.2.2.5** 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.

**4.2.2.2.6** 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.

#### **4.2.2.3 Wrap made of nonwoven material**

NOTE For the purpose of this specification, a nonwoven for sterile barrier systems can be described as a bonded web made of textile and/or non-textile fibres.

**4.2.2.3.1** The internal tearing resistance of the conditioned nonwoven wrap shall be not less than 750 mN in the machine direction and 1 000 mN in the cross direction when tested in accordance with EN ISO 1974.

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

**4.2.2.3.3** 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.

**4.2.2.3.4** 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.

**4.2.2.3.5** The resistance to water penetration of the nonwoven wrap shall be determined using the hydrostatic head test based on EN 20811. Test results shall be documented.

**4.2.2.3.6** 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.

**4.2.2.3.7** 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.

#### **4.2.2.4 Wrap made of woven textile material**

**4.2.2.4.1** When the woven textile material is to be used to manufacture packaging intended to be irradiation sterilized only, it is not necessary for it to be permeable to air, so 4.2.2.4.6 need not to apply.

**4.2.2.4.2** Requirements for the processing of reusable fabrics as given in EN ISO 11607-1:2009, 5.1.11 and 5.1.12 apply and shall include the means to quantify and control the number of processing cycles.

**4.2.2.4.3** The tensile strength, dry and wet, of the wrap shall be not less than 300 N in the warp and weft directions when tested in accordance with strip method of EN 29073-3.

**4.2.2.4.4** The tear strength, dry and wet, of the wrap shall be not less than 6 N in the warp and weft directions when tested in accordance with EN ISO 13937-1. The samples for the "wet" test shall be prepared according to EN 29073-3.

**4.2.2.4.5** The bursting strength "dry" and "wet" of the wraps shall not be less than 100 kPa when tested in accordance with EN ISO 13938-1. The preparation of samples for wet state testing shall be performed according to EN 29073-3.

**4.2.2.4.6** The air permeability of the wrap shall be not more than 20 mm/s when tested in accordance with EN ISO 9237.

**4.2.2.4.7** The resistance to water penetration of the woven textile material shall be determined using the hydrostatic head test based on EN 20811. Test conditions and test results shall be documented.

### **4.3 Marking**

#### **4.3.1 Transport packaging**

The transport packaging shall be legibly and durably marked with the following information:

- a) reference, stock or catalogue number;
- b) quantity;
- c) name/company and address of the manufacturer; address shall include: street/road, number/house/floor, postal code, city, state/region and country;
- d) name and address of authorized representative within the European Community in the case where the manufacturer does not have a registered place of business in the community; address shall include: street/road, number/house/floor, postal code city, state/region and country;
- e) date of manufacture in accordance with ISO 8601;
- f) lot number<sup>1)</sup>;
- g) nominal sheet size or nominal width of rolls in millimetres and length in metres;
- h) the recommended storage conditions;

---

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

- i) whether sterilization wrap is 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.

#### **4.3.2 Inner package**

The inner package with sheets or inner label with reels shall be legibly and durably marked with the information a), b), e), f) and g) according to 4.3.1.

### **5 Information to be supplied by the manufacturer**

The following information should be supplied in addition to EN ISO 11607-1:2009, Clause 7:

- a) recommendations for particular applications of sterilization wrap (e.g. sterile barrier system, transport packaging, packaging system);
- b) the nature and extent of any identified risks associated with the use of the packaging material and/or system;
- c) any information pertinent to the packaged medical device as may be required (see EN 1041).

NOTE 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 [10].

## **Annex A** (informative)

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

Changes between this European Standard and EN 868-2:2009 are the following:

- a) changes in order to align this European Standard with the EN ISO 11607 series, in particular by:
  - 1) adopting terms and definitions of EN ISO 11607 series without additional elements, i.e. deleting “sterile field” and “surgical drape” which are covered by the EN 13795 series;
  - 2) elucidating the requirements given by EN ISO 11607-1 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;
- b) the test method on fluorescence is in accordance with ISO 2470-2. The test method according Annex B has been deleted;
- c) updating of the following test methods by a statement of repeatability and reproducibility:
  - 1) method for the determination of water repellency as per Annex C;
  - 2) method for the determination of pore size as per Annex D;
- d) providing of informative data for repeatability and reproducibility of the following test methods as per Annex E:
  - 1) method for the determination of water repellency as per Annex C;
  - 2) method for the determination of pore size as per Annex D;
  - 3) chloride content;
  - 4) sulphate content;
- e) updating of the bibliography.

NOTE This list is not exhaustive.

## **Annex B** (informative)

### **Method for the determination of drape**

#### **B.1 Apparatus**

##### **B.1.1 Softness tester**

Softness tester comprising a clamp formed by a pair of flat jaws or rollers, designed to grip the end of a 25 mm wide strip of paper along a horizontal axis at right angles to its length, and mounted on a spindle to enable the clamped end of the strip to be rotated about the spindle axis.

The edges of the clamping surfaces shall be coincident and means provided for indicating when the clamp has rotated through 90° from any initial position.

##### **B.1.2 Rule**

Rule, graduated in millimetres.

#### **B.2 Procedure**

Condition the specimen at  $(23 \pm 1)$  °C and  $(50 \pm 2)$  % relative humidity for not less than 24 h. Cut 10 test pieces, each 25 mm in width and 200 mm in length, five with the length in the machine direction of the sample and five with the length in the cross direction.

Level the machine so that the axis of the clamping edges is horizontal and place the end of the test piece between them. Arrange the protruding length such that on rotating the spindle clockwise at a speed of 1 r/min (15 s for a 90° turn) with the strip to the left, the strip falls through the vertical to the right and on rotating the spindle counter clockwise, the strip does not fall back to the left when turned through 90° from that point.

Reduce the protruding length until a rotation of  $(90 \pm 2)$ ° clockwise and counter clockwise causes the end of the strip to fall from one side to the other.

Measure the effective protruding length (critical length) from the line where the edges of the jaws or rollers grip the test piece to the end of the strip.

#### **B.3 Test report**

The test report shall include the following information:

- a) the mean critical length (in mm) for both machine and cross directions of the paper;
- b) on request, 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 C** (normative)

### **Method for the determination of water repellency**

#### **C.1 Apparatus**

**C.1.1 An ultraviolet light source and light meter** with a range of wavelength of 315 nm to 390 nm.

**C.1.2 Flat dish**, approximately 200 mm x 150 mm x 15 mm.

**C.1.3 Desiccator.**

**C.1.4 Stopwatch.**

**C.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.

#### **C.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.

#### **C.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  $(300 \pm 20) \mu\text{W}/\text{cm}^2$ . 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  $(23 \pm 1) \text{ }^\circ\text{C}$ .

#### **C.4 Repeatability and reproducibility**

See Annex E for repeatability and reproducibility of the test method.

## **C.5 Test report**

The test report shall include the following information:

- a) the mean penetration time in seconds for each side of the paper;
- b) on request, 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 (normative)

### Method for the determination of pore size

#### D.1 Principle

The pressure required to force air bubbles through the interstices of a material, wetted by a liquid and having a film of the same liquid applied to its upper surface, is observed. This pressure, together with the known surface tension of the liquid, is used to estimate the size of the interstices in the material.

#### D.2 Test liquid

The test liquid used should allow the paper to be wetted completely, have low solvent power for proofing materials, cause no swelling of the fibres, have constancy of surface tension, non-toxicity, low flammability, freedom from foaming, and moderate cost.

NOTE Ethanol R has been found to be suitable.

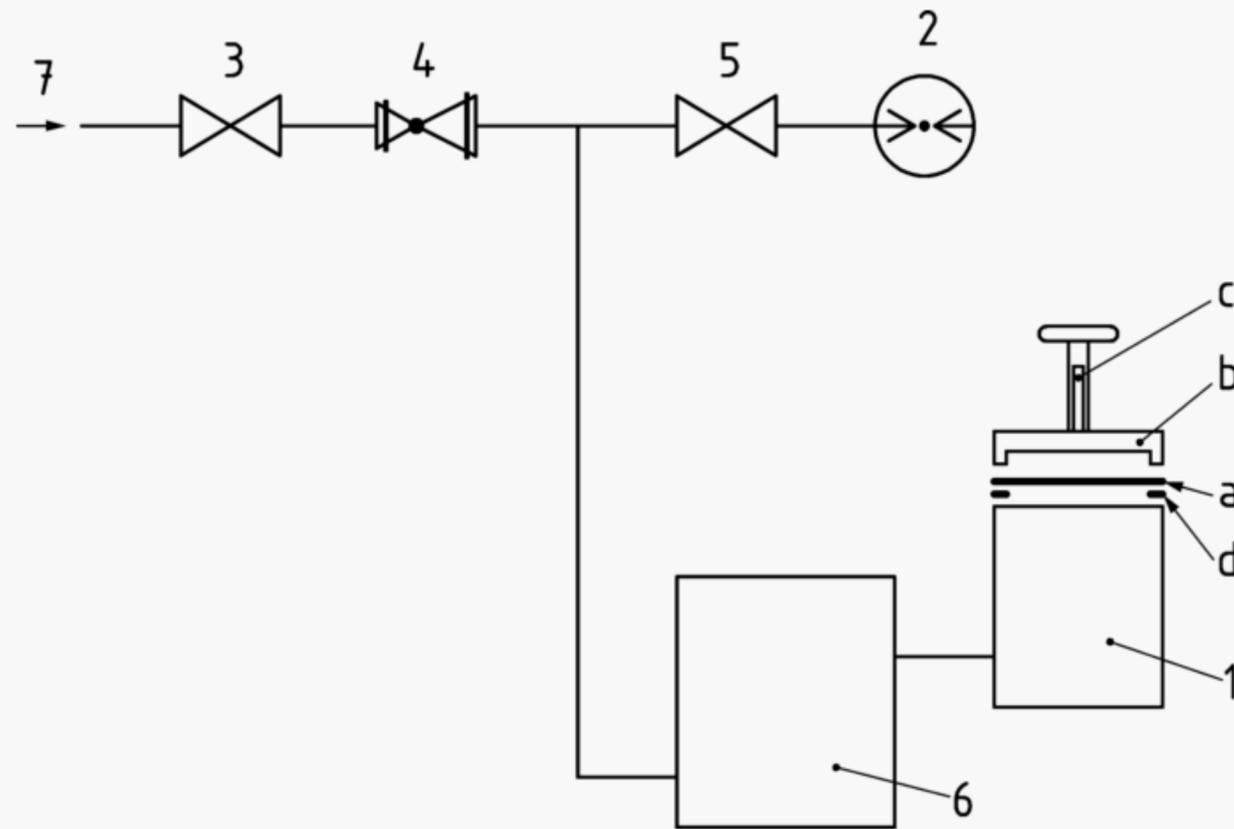
#### D.3 Apparatus

**D.3.1** The apparatus is shown diagrammatically in Figure D.1. The principal parts are as follows:

- a) the testing head "1": a cylindrical vessel of an appropriate material (e.g. brass) over which the specimen "a" can be clamped by a clamping ring "b" and screw "c". It is fitted with a synthetic rubber gasket "d" of 50 mm internal diameter to make a seal against the specimen;
- b) pressure measuring device;
- c) a stop-valve which serves to direct air to the testing head;
- d) a variable flow valve set to give the required rate of rise of pressure in "1";
- e) a stop-valve which directs air to the pressure measuring device;
- f) air reservoir of about 2,5 l capacity connected to "1"; this ensures that the rate of flow of air necessary to maintain the required rise of pressure is so large that the loss of air through the material when bubbling begins will not reduce the rate of rise of pressure;
- g) the air supply.

**D.3.2** Using the apparatus shown in Figure D.1 the test is conducted as follows:

Turn on the air supply. Open valve "3" to direct air to the test head via reservoir "6", and adjust valve "4" to give the required rate of pressure rise. Leave stop-valve "5" open during testing. When the first bubble appears in the test material, "5" is closed to allow the pressure reached to be read from the measuring device "2".



**Key**

- |      |                           |   |               |
|------|---------------------------|---|---------------|
| 1    | testing head              | a | specimen      |
| 2    | pressure measuring device | b | clamping ring |
| 3, 5 | stop valve                | c | screw         |
| 4    | variable blow valve set   | d | rubber gasket |
| 6    | air reservoir             |   |               |
| 7    | air supply                |   |               |

**Figure D.1 — Diagrammatic representation of the apparatus for the determination of the pore size**

**D.3.3** Apparatus for measurement of the equivalent pore size, having the following characteristics:

- a) Means shall be provided for clamping the specimen of material in such a manner that:
- 1) it is horizontal;
  - 2) a circular area of the material 50 mm in diameter will be subjected to steadily increasing air pressure on the lower face;
  - 3) no leakage of the test liquid occurs during the test period;
  - 4) the specimen does not slip in the clamps.

NOTE 1 The clamps need to be faced with resilient material which is resistant to the test liquid. With some forms of apparatus, it has been found that the correct conditions of clamping can be attained if the clamps are faced with a suitable grade of synthetic rubber.

- b) The rate of increase in air pressure shall be 2 kPa/min to 2,5 kPa/min (200 mm head of water per minute to 250 mm head of water per minute).<sup>2)</sup>

---

2) 1 mm head of water = 9,80655 Pa.

- c) A pressure measuring device connected to the test head shall be calibrated in kilopascals (or millimetres head of water).
- d) The pressure measuring device shall have a suitable range.

NOTE 2 A pressure measuring device which provides for pressure up to 6 kPa (600 mm head of water) is suitable for most materials. A pressure measuring device providing pressures of up to 10 kPa (1 m head of water) is used for measurements on close materials, e.g. ventiles, clean room overalls, theatre clothing and drapes.

#### **D.4 Preparation of test specimens**

After receipt, handle the material as little as possible and do not sharply fold, iron or treat in any way other than by conditioning. Cut specimens from the material in shape convenient for handling and clamping. Take the test specimens from different places in the material, avoiding any creases, so that they represent the material as fully as possible.

NOTE For most types of apparatus, it is convenient to cut specimens from the material in the form of 75 mm x 75 mm squares.

Unless otherwise stipulated, test 10 specimens from any sample of material submitted.

#### **D.5 Procedure**

**D.5.1** Conduct the test in the standard atmosphere for testing specified in EN 20187.

**D.5.2** Determine the surface tension of the test liquid by any convenient method to the nearest 0,5 mN/m.

NOTE Within the range of the standard atmosphere, the surface tension of Ethanol R usually lies between 22 mN/m and 24 mN/m, with a temperature coefficient of - 0,005 mN/(m · K). The Wilhelmy stalagmometer, single and double capillary methods have all been found satisfactory for measuring surface tension.

**D.5.3** Soak the conditioned specimen under about 15 mm (depth) of the test liquid in a glass dish. After soaking for a minimum period of 3 min remove the specimen with forceps and clamp it on the testing head. Pour a few millilitres of the test liquid onto the surface of the material; pour just sufficient to cover the material completely after it has bulged slightly under the pressure exerted on the underside during the test. Record the temperature of the test liquid at this stage.

NOTE Very porous material, if relevant, can be more easily tested if the air pressure is allowed to increase on the underside of the specimen and bulge the specimen before the test liquid is poured on to cover the surface of the material completely.

**D.5.4** Under increasing air pressure, bubbles appear at different places over the upper surface; observe the specimen continuously whilst the pressure is increasing and record, to the nearest millimetre, the pressure at which the first bubble appears on the upper surface.

**D.5.5** Test further specimens until the requisite number of results is obtained.

## D.6 Result

### D.6.1 Calculation and expression of results

Calculate the equivalent pore radius  $r$  in micrometres for each specimen by means of the formula:

$$r = 2T \cdot 10^6 / \rho \cdot p \cdot g \quad (\text{D.1})$$

or simplified

$$r = 204 \cdot T / p \quad (\text{D.2})$$

where

$T$  is the surface tension of the test liquid at the temperature of the test, in mN/m;

$g$  is the acceleration due to gravity, in mm/s<sup>2</sup>;

$\rho$  is the density of water at the temperature of the test, in mg/mm<sup>3</sup>;

$p$  is the bubble pressure, in millimetres head of water.

Calculate the mean pore radius and express the result as pore diameter.

NOTE 1 The error introduced by taking  $\rho = 1 \text{ mg/mm}^3$  for the relative density of water at the temperature of the standard atmosphere for testing is small compared with the variability of the test results.

NOTE 2 Similarly, although  $g$  is known to vary about 0,5 % from place to place, the error introduced by assuming a constant value of 9 810 mm/s<sup>2</sup> is small compared with the variability of the test.

### D.6.2 Derivation of formula for calculation of equivalent pore radius

For a cylindrical tube, the pressure  $p$  in Pascals, necessary to force liquid through is given by the following formula:

$$p = \frac{2T \cos Q}{r} \quad (\text{D.3})$$

where

$T$  is the surface tension of liquid, in N/m;

$Q$  is the contact angle at liquid-solid-air interface, in degrees;

$r$  is the radius of tube, in metres.

This is the Laplace formula (see [8]).

The contact angle is very difficult to measure and therefore a liquid is chosen which completely wets the material, thus  $\cos Q = 1$  and the formula becomes:

$$p = \frac{2T}{r} \quad (\text{D.4})$$

This formula is the same as the simplified formula given in D.6.1.

The pressure is normally measured in millimetres head of water, because either a water manometer is used, or the pressure measuring device is calibrated in millimetres head of water.

Thus

$$p = p_b \cdot \rho \cdot g \quad (D.5)$$

where

$p_b$  is the head of water, in millimetres head of water;

$\rho$  is the density of water, in mg/mm<sup>3</sup>;

$g$  is the acceleration due to gravity, in mm/s<sup>2</sup>.

## D.7 Repeatability and reproducibility

See Annex E for repeatability and reproducibility of the test method.

## D.8 Test report

The test report shall include the following information:

- a) the equivalent pore diameter in micrometres for each specimen and the mean pore diameter in micrometres for the sample;
- b) details of any deviation from the specified procedure;
- c) on request, the identification of the product under test, the identification of the test-house and the date;
- d) the normative reference of the test method.

## Annex E (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:

- pore size;
- water repellency;
- chloride content;
- sulfate content.

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

**Table E.1 — Test matrix**

	<b>Number of Laboratories</b>	<b>Number of test runs</b>	<b>Replication</b>	<b>Number of sample materials</b>	<b>Type of materials</b>
<b>Pore size</b>	7	9	10	4	Plain paper, creped paper
<b>Water repellency</b>	3	16	10	3	Fine creped paper, Plain paper, creped paper
<b>Chloride content</b>	3	7	2	4	Plain paper
<b>Sulfate content</b>	3	7	2	4	Plain paper

**Table E.2 — Precision of test methods - Significance of results**

Test	Units	EN 868-2 specification	Repeatability, $s_r^a$		Reproducibility, $s_R^a$	
			Relative to mean results	Expressed as % specification limit	Relative to mean result	Expressed as % specification value
<b>Pore size</b>	µm	< 50	0,069m + 0,98	8,9	0,084m + 2,91	14,2
<b>Water repellency</b>	s	Not < 20	0,032m + 0,84	7,4	0,120m - 0,01	11,9
<b>Chloride content</b>	%	Not > 0,05	0,002	4,0	0,186m + 0,00	26,6
<b>Sulfate content</b>	%	Not > 0,25	0,01	4,0	0,183m + 0,01	23,2

<sup>a</sup> s = standard deviation

NOTE Table E.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 [9]).

## Bibliography

- [1] EN 1041, *Information supplied by the manufacturer of medical devices*
- [2] EN 1149-1, *Protective clothing - Electrostatic properties - Part 1: Test method for measurement of surface resistivity*
- [3] EN 13795, *Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment — General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels*
- [4] EN ISO 9073-9, *Textiles - Test methods for nonwovens - Part 9: Determination of drapability including drape coefficient (ISO 9073-9)*
- [5] EN ISO 11607-2, *Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2)*
- [6] 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)*
- [7] 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*
- [8] ADAMSON. A. W., *Physical chemistry of surfaces*, New York, J. Wiley, 1976
- [9] 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
- [10] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices





# British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

## About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards-based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

## Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at [bsigroup.com/standards](http://bsigroup.com/standards) or contacting our Customer Services team or Knowledge Centre.

## Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at [bsigroup.com/shop](http://bsigroup.com/shop), where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

## Copyright in BSI publications

All the content in BSI publications, including British Standards, is the property of and copyrighted by BSI or some person or entity that owns copyright in the information used (such as the international standardization bodies) and has formally licensed such information to BSI for commercial publication and use.

Save for the provisions below, you may not transfer, share or disseminate any portion of the standard to any other person. You may not adapt, distribute, commercially exploit, or publicly display the standard or any portion thereof in any manner whatsoever without BSI's prior written consent.

## Storing and using standards

Standards purchased in soft copy format:

- A British Standard purchased in soft copy format is licensed to a sole named user for personal or internal company use only.
- The standard may be stored on more than 1 device provided that it is accessible by the sole named user only and that only 1 copy is accessed at any one time.
- A single paper copy may be printed for personal or internal company use only.

Standards purchased in hard copy format:

- A British Standard purchased in hard copy format is for personal or internal company use only.
- It may not be further reproduced – in any format – to create an additional copy. This includes scanning of the document.

If you need more than 1 copy of the document, or if you wish to share the document on an internal network, you can save money by choosing a subscription product (see 'Subscriptions').

## Reproducing extracts

For permission to reproduce content from BSI publications contact the BSI Copyright & Licensing team.

## Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to [bsigroup.com/subscriptions](http://bsigroup.com/subscriptions).

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

**PLUS** is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit [bsigroup.com/shop](http://bsigroup.com/shop).

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email [subscriptions@bsigroup.com](mailto:subscriptions@bsigroup.com).

## Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

## Useful Contacts

### Customer Services

**Tel:** +44 345 086 9001

**Email (orders):** [orders@bsigroup.com](mailto:orders@bsigroup.com)

**Email (enquiries):** [cservices@bsigroup.com](mailto:cservices@bsigroup.com)

### Subscriptions

**Tel:** +44 345 086 9001

**Email:** [subscriptions@bsigroup.com](mailto:subscriptions@bsigroup.com)

### Knowledge Centre

**Tel:** +44 20 8996 7004

**Email:** [knowledgecentre@bsigroup.com](mailto:knowledgecentre@bsigroup.com)

### Copyright & Licensing

**Tel:** +44 20 8996 7070

**Email:** [copyright@bsigroup.com](mailto:copyright@bsigroup.com)

### BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK