BS EN 868-5:2018

BSI Standards Publication

Packaging for terminally sterilized medical devices

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

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National foreword

This British Standard is the UK implementation of EN 868-5:2018. It supersedes BS EN 868-5:2009, which is withdrawn.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.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 5: Sachets et gaines scellables constitués d'une face matière poreuse et d'une face film plastique - Exigences et méthodes d'essai

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 5: Siegelfähige Klarsichtbeutel und -schläuche aus porösen Materialien und Kunststoff-Verbundfolie - Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 20 August 2018.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN 868-5:2018) 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of an identical text or by endorsement, at the latest by June 2019, and conflicting national standards shall be withdrawn at the latest by June 2019.

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 868-5:2009.

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 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 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 document specifies test methods and values for sealable pouches and reels manufactured from porous materials complying with either EN 868 part 2, 3, 6, 7, 9 or 10 and plastic film complying with Clause 4. These sealable pouches and reels are 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 document.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 868-2:2017, *Packaging for terminally sterilized medical devices — Part 2: Sterilization wrap — Requirements and test methods*

EN 868-3:2017, *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 868-6:2017, *Packaging for terminally sterilized medical devices — Part 6: Paper for low temperature sterilization processes — Requirements and test methods*

EN 868-7:2017, *Packaging for terminally sterilized medical devices — Part 7: Adhesive coated paper for low temperature sterilization processes — Requirements and test methods*

EN 868-9:2018, *Packaging for terminally sterilized medical devices — Part 9: Uncoated nonwoven materials of polyolefines — Requirements and test methods*

EN 868-10:2018, *Packaging for terminally sterilized medical devices — Part 10: Adhesive coated nonwoven materials of polyolefines — Requirements and test methods*

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

EN ISO 11607-1:2017, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006, including Amd 1:2014)*

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

ASTM D882:2012, *Test Methods for Tensile Properties of the Thin Plastic Sheeting*

ASTM F88/F88M:2015, *Standard Test Method for Seal Strength of Flexible Barrier Materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 11607-1:2017 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

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 4.5 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 868-5 does not automatically mean compliance to EN ISO 11607-1.

A confirmation of compliance to EN 868-5 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, 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 Materials

4.2.1 Porous material

The porous material shall comply with the requirements of Clause 4 of either EN 868-2:2017, EN 868-3:2017, EN 868-6:2017, EN 868-7:2017, EN 868-9:2018 or EN 868-10:2018.

If the intended method of sterilization is irradiation only, the requirements for wet strength properties and permeability to air for porous materials are not applicable.

4.2.2 Plastic film

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

4.2.2.2 The plastic film shall be free from pinholes when tested in accordance with Annex C.

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

NOTE Slight continuous surface irregularities arising from the extrusion of the plastic film is not regarded as a defect.

4.2.2.4 The plastic film shall be sealable to the porous material under the conditions specified.

4.2.2.5 The breaking factor of the plastics film, machine direction and cross direction, shall be not less than 20 N per 15 mm width when tested in accordance with ASTM D882:2012 (Method A).

4.3 Construction and design

4.3.1 Reel material shall be constructed from one web of porous material and one web of plastic film, sealed together along parallel sides.

Pouches shall be constructed from one web of porous material and one web of plastic film by sealing three sides and may include an area to effect closure of the pouch.

4.3.2 The overall width of the seal(s) shall be not less than 6 mm. For ribbed seals, the sum of the widths of the ribs shall be not less than 6 mm.

4.3.3 The distance between the end of a pouch and the nearest edge of the width wise seal shall be sufficient to enable the two webs to be separated and peeled apart.

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

4.3.4 One of the materials of a pouch shall be:

a) 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 seal; or

b) lipped such that the length of one web is greater than the length of the other web by not less than 1,0 mm.

NOTE The requirements of 4.3.4 do not apply to a reel that is sealed at the third side.

4.3.5 The pouch and/or reel shall be closed according to the manufacturer's instructions.

NOTE 1 For validation requirements for forming, sealing and assembly processes, see EN ISO 11607-2.

NOTE 2 The closure and or sealing system can give the possibility to indicate whether or not the seal has been opened.

4.4 Process indicator

If one or more Type I indicator(s) [process indicator(s)] are printed on the pouches and reels, 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.

4.5 Performance requirements and test methods

4.5.1 When tested in accordance with the method described in Annex D, the strength of the seal shall be not less than required for the intended purpose, both before and after being subjected to the sterilization process.

NOTE 1 The specification for seal strength before and after exposure to sterilization processes can differ.

For use for sterilization in healthcare facilities, the minimum value for seal strength shall be 1,5 N per 15 mm for steam sterilization and 1,2 N per 15 mm for other sterilization processes.

NOTE 2 Requirements for seal strength set forth in this Standard are valid for pouches and reels delivered as preformed sterile barrier systems to healthcare facilities and for healthcare facilities to create a sterile barrier system. For applications in industry, different values can be established based on the specific applications and on the validation requirements of EN ISO 11607.

NOTE 3 Healthcare facilities are locations where patients are medically treated and/or medical devices are terminally sterilized (e.g. hospital, dentist office, practitioner).

4.5.2 The seal shall be continuous and cover the specified width. There shall be no disruption of the surface of the porous material adjacent to the seal area upon opening. Compliance shall be tested in accordance with Annex E.

4.5.3 If applicable, for porous materials, the direction of the peel marked on the product shall correspond to that direction which ensures least fibre disturbance. Compliance shall be tested in accordance with Annex F.

4.6 Marking

4.6.1 Pouches and reels

4.6.1.1 Pouches and reel material shall be clearly marked with information required by EN ISO 11607-1. Additionally, the following information shall be provided unless agreed otherwise between the supplier and the customer:

a) the words "*Do not use if the sterile barrier system is damaged*", or symbol (see EN ISO 15223-1:2016, Table 1, symbol 5.2.8);

b) lot number[1)];

c) the manufacturers name or trade name;

d) process indicator(s), if applicable;

e) the direction of peel which will ensure the least fibre tear for reels;

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 lot number, process indicator, peel direction, and nominal dimensions or identification code [see 4.6.1.1 b), d), e) and f)], the print repeat interval on reel material shall be not greater than 155 mm. For other information mentioned in 4.6.1.1 a) and c), the print repeat interval shall be not greater than 310 mm.

4.6.1.4 Preformed sterile barrier systems placed on the market for delivery to healthcare facilities shall not be supplied individually labelled with a CE logo and/or with the symbol "sterile".

NOTE 1 This is to avoid confusion in terms of legal responsibility with the CE mark for the final product.

NOTE 2 For CE marking of transport and/or storage packaging, see 4.6.2 h).

4.6.2 Transport and/or storage packaging

Each unit of the transport and/or storage packaging 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 or authorized representative's name or trade name, and address;

d) date of manufacture in accordance with ISO 8601;

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

e) lot number;

f) any specific storage conditions, if applicable

g) compatible sterilization process(es);

h) CE mark.

5 Information to be supplied by the manufacturer

The manufacturer shall supply instructions for sealing, including recommended process parameters.

NOTE 1 For validation of sealing processes, see EN ISO 11607-2.

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

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 [10], and Regulation 2017/745, Annex I, Chapter III [11].

Annex A
(informative)

Details of significant technical changes between this document and the previous edition

Changes between this document and EN 868-5:2009 are the following:

a) normative references have been updated;

b) references to ASTM standards have been added;

c) changes in order to align this document with the EN ISO 11607- series, in particular by

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

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

d) various performance and marking requirements have been made clearer;

e) the test methods for the determination of the strength of the seal for pouches and reel material according to Annex D have been amended;

f) the test method for the determination of peel characteristics of paper/plastic laminate products according to Annex E has been amended;

g) updating of the bibliography.

NOTE This list is not exhaustive.

Annex B
(normative)

Method for the determination of resistance to the intended sterilization process

B.1 Preparation of test specimens

Take 10 of the items under test (pouches or lengths of reel material) and half fill with absorbent cotton gauze (see European Pharmacopeia [9]) without compression.

B.2 Procedure

Seal the test specimens in accordance with the manufacturer's recommendations.

Place the test specimens in a sterilizer. The operating cycle shall be adjusted to the limits defined by the manufacturer of the packaging material. Services supplied to the sterilizer (steam, air, water, etc.) shall be at the limits specified by the manufacturer of the sterilizer. Carry out the operating cycle. Remove the specimens and examine visually.

NOTE For European standards on sterilizers, see EN 285, EN 13060, EN 1422 and EN 14180; for general requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices general, see EN ISO 14937.

B.3 Test report

The test report shall include the following information:

a) the number of plastics interply bonds which separate or become cloudy;

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

c) the normative reference of the test method.

Annex C
(normative)

Method for the determination of pinholes in plastic laminate

NOTE Other test methods can be used if it can be demonstrated that they have the same sensitivity as the following reference test method.

C.1 Apparatus and reagents

C.1.1 A weighted sponge made from a block of cellulose sponge of nominal dimensions 110 mm x 75 mm x 32 mm bonded with a waterproof adhesive to a steel plate 110 mm x 75 mm x 12 mm such that the total mass is (800 ± 50) g.

C.1.2 A shallow tray not less than 15 mm deep and of minimum dimensions 130 mm x 95 mm.

C.1.3 Absorption paper white, medium or medium/fast absorption filter, or chromatography paper.

C.1.4 A flat glass surface.

C.1.5 Dye solution, 1 g/100 ml aqueous amaranth red containing 0,005 % cetrimide[2)] (a mixture of dodecyl-, tetradecyl-, hexadecyl- and trimethylammonium bromide) as a wetting agent.

C.2 Preparation of test pieces

Take 5 conditioned pouches or lengths of reel material not less than 250 mm long and remove the plastics layer identifying the outer surface.

Test pieces shall be conditioned following the test sample conditioning requirements of EN ISO 11607-1:2017, Clause 4.

C.3 Procedure

Place a piece of absorption paper of similar size to the test specimen on the flat glass surface, and place the inner surface of the film to be tested in contact with the absorption paper.

For gusseted pouches or reel material, the test should be carried out on a single web of plastic film which includes an area that had been folded.

Pour the dye into the shallow tray and put the sponge in the tray for 1 min. Remove the sponge draining surplus liquid off on the edge of the tray.

Place the sponge on the test specimen ensuring that the edge of the sponge is not within 15 mm of the edge of the test specimen and allow to stand for 2 min.

Remove the sponge and examine the absorption paper for staining due to penetration of the dye. Repeat the procedure for the remaining test specimens.

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2) Cetrimide should be handled and disposed of by taking into consideration regional or national regulation.

C.4 Test report

The test report shall include the following information:

a) the number of specimens where staining of the absorption paper occurs;

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

c) the normative reference of the test method.

Annex D
(normative)

Method for the determination of the strength of the seal for pouches and reel material

D.1 Principle

The seal strength of the pouch and reels before and after sterilization is determined by cutting at least one strip at 90° through each of the seals and pulling apart on a tensile testing machine meeting the requirements of ASTM F88/F88M.

NOTE For example, for preformed sterile barrier systems of type "chevron pouch" this would be four samples.

D.2 Test method

For test method, see ASTM F88/F88M.

D.3 Preparation of test specimen — Instructions for sampling

Prepare strips from non-sterilized as well as from sterilized pouches or reels. Each strip shall be 15 mm wide following sampling instructions of ASTM F88/F88M. If only one sample is taken from a seal, then this shall be from approximately the mid-point.

NOTE Consider additional samples when the length of a seal exceeds 500 mm.

To determine the seal strength after sterilization, expose the pouches or reel material to the intended sterilization cycle using a sterilizer designed, constructed and operated in accordance with the requirements of relevant International or European Standards.

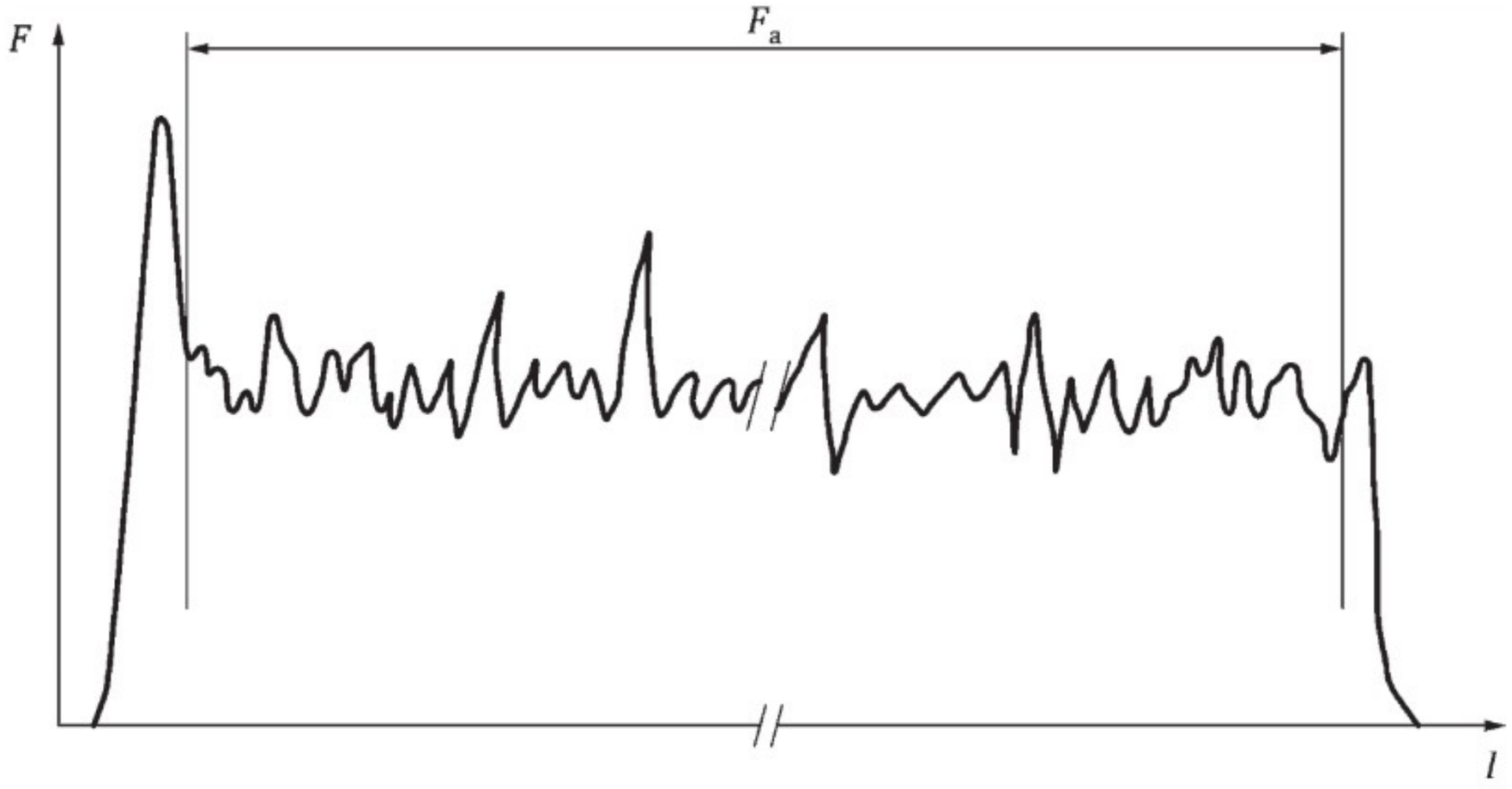
D.4 Procedure

Follow the procedure as described in ASTM F88/F88M using a separation rate of 200 mm/min and record the average force over the middle of the measured seal profile curve by discarding 10 % on each side of the measuring curve (see Figure D.1). Results shall be reported in units of N/15 mm.

In case of a ribbed seal the non-sealed areas including 10 % on each side shall not be considered in the calculation of this average force (see Figure D.2).

In order to produce comparable data, it is recommended to use technique B of ASTM F88/F88M:2015 (supported tail of the specimen).

NOTE Gripping instead of guiding the tail end during manual support can negatively influence the results.



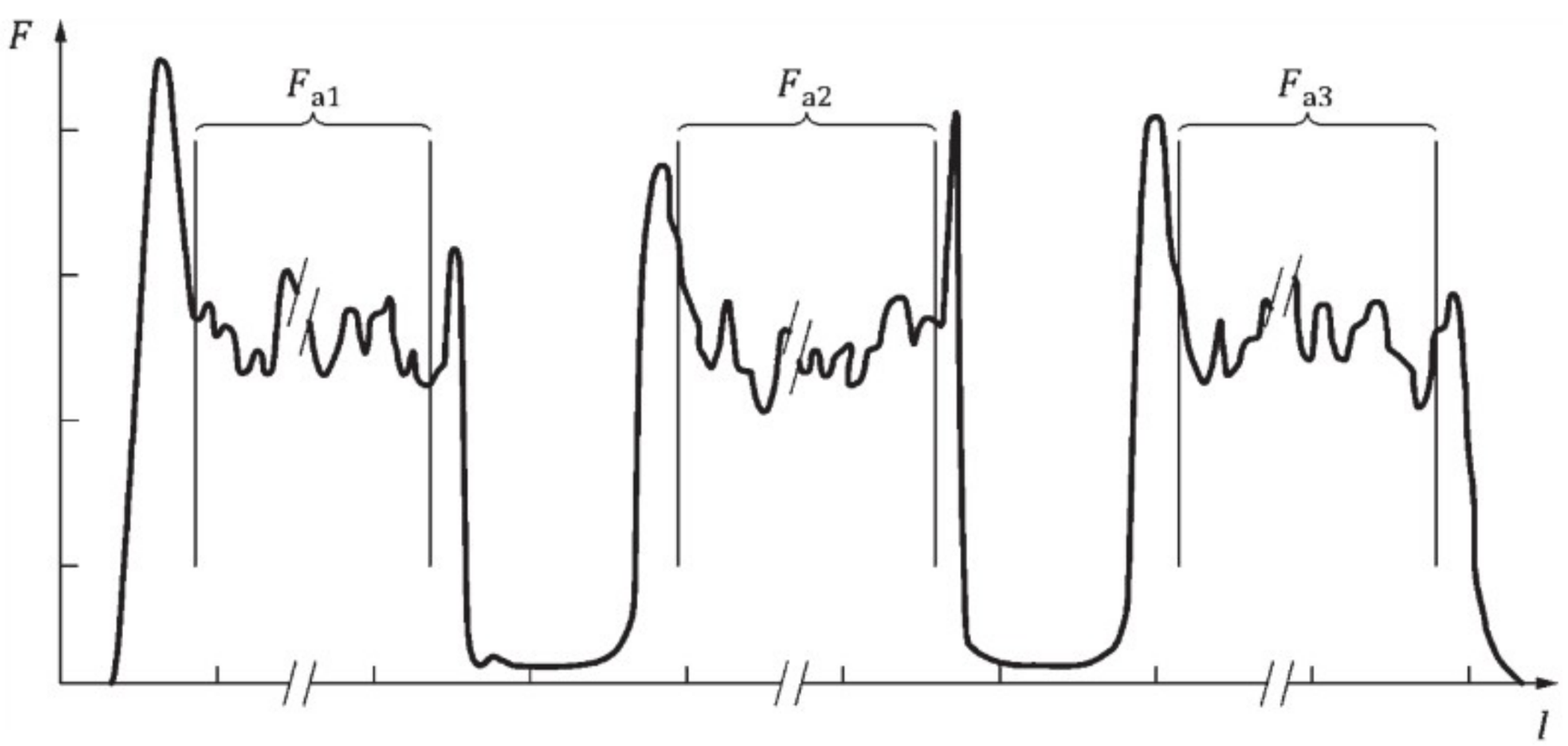
Key

F force in Newton (N)

l length in Millimetre (mm)

F_a average force

Figure D.1 — Example of seal profile of a flat seal



Key

F force in Newton (N)

l length in Millimetre (mm)

F_a average force: $F_a = (F_{a1} + F_{a2} + F_{a3})/3$

Figure D.2 — Example of seal profile of a three-ribbed seal

D.5 Test report

The test report shall include the following information:

a) the average recorded seal strength of each test piece in N per 15 mm width;

b) if the test has been performed with the tail supported or unsupported, and other specifications, if applicable;

c) the identification of the product under test, the identification of the test laboratory and the date;

d) the number of test samples and the identification of the side the sample(s) was/were taken from;

e) method and type of sterilization process and if samples have been processed or not;

f) the normative reference of the test method.

Annex E
(normative)

Method for the determination of peel characteristics of paper/ plastic laminate products

E.1 Apparatus

Ruler graduated in intervals of 0,5 mm.

E.2 Procedure

Slowly and carefully peel the seal apart by hand. Visually check that the seal extends along the total width and length of the intended seal area and that there is no splitting of the paper outside the seal area towards the inside of the pouch and/or reel, see Figure E.1.

Figure E.1 — Clean peel appearance with no splitting of paper direction inside

NOTE 1 When peeled apart, the seal area will generally show a matt appearance where the seal was effective but will retain its glossy appearance where the seal was not satisfactory.

Measure the width of the seal on the inner plastic surface at 6 points distributed around the pouch/reel seal area.

NOTE 2 For example, a chevron type seal area can be measured as follows: 2 points from one side seal, 2 points from the other side seal, one point from the left part of the chevron and one point from the right part of the chevron.

E.3 Test report

The test report shall include the following information:

a) the mean and minimum widths of seal and any instances of imperfection within the seal or of paper splitting more than nominal width of the seal;

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

c) the normative reference of the test method.

Annex F
(normative)

Method for the determination of fibre orientation

F.1 Apparatus

F.1.1 Pressure sensitive adhesive tape 25 mm nominal width. The adhesion of the tape when applied to, and then removed from paper as described below shall be sufficient to remove surface fibres.

F.1.2 Smooth faced roller of nominal width 200 mm and mass (10 ± 0,5) kg.

F.2 Procedure

By visual examination in incident light, determine the machine direction of the paper on which the heat seal is to be made. Cut two strips of the tape, each 125 mm nominal length and position them on the surface of the paper with their length parallel to the machine direction. Leaving a 10 mm portion unadhered at each end ensure that the rest of the tape is well adhered by rolling 5 times in each direction with the roller. Do not exert any pressure on the roller. Remove the strips by gripping the unadhered ends and pulling slowly and steadily at an angle of approximately 45°, peeling one strip in one direction, the other in the opposite direction. Examine the surface of the paper, and the tape, and visually estimate which pull direction caused the least disturbance of the paper surface.

F.3 Test report

The test report shall include the following information:

a) the peel direction which produces least disturbance of the paper surface;

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

c) the normative reference of the test method.

Bibliography

[1] EN 285, *Sterilization — Steam sterilizers — Large sterilizers*

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

[3] EN 13060, *Small steam sterilizers*

[4] EN 1422, *Sterilizers for medical purposes — Ethylene oxide sterilizers — Requirements and test methods*

[5] EN 14180, *Sterilizers for medical purposes — Low temperature steam and formaldehyde sterilizers — Requirements and testing*

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

[7] EN ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937)*

[8] EN ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)*

[9] European Pharmacopeia.

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

[11] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [3)]

3) Text with EEA relevance.

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