ICS 11.080.30

ČSN
EN ISO 11607-1
OPRAVA 1
85 5280

Duben 2018

ČESKÁ TECHNICKÁ NORMA

Obaly pro závěrečně sterilizované zdravotnické prostředky – Část 1: Požadavky na materiály, systémy sterilní bariéry a systémy balení

Upozornění

ČSN EN ISO 11607-1 (85 5280) Obaly pro závěrečně sterilizované zdravotnické prostředky – Část 1: Požadavky na materiály, systémy sterilní bariéry a systémy balení z března 2018 se na základě Correction Notice vydaného CEN dne 2017-11-22 opravuje takto:

Nahrazuje se titulní strana evropské normy a evropská předmluva a doplňuje se změna ISO 11607-1:2006/Amd.1:2014.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11607-1

July 2017

ICS 11.080.30

Supersedes EN ISO 11607-1:2009

English Version

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)

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage (ISO 11607-1:2006, y compris Amd 1:2014)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 1: Anforderungen an Materialien, Sterilbarrieresysteme und Verpackungssysteme (ISO 11607-1:2006, einschließlich Amd 1:2014)

This European Standard was approved by CEN on 18 July 2017.

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

Ref. No. EN ISO 11607-1:2017 E

European foreword

The text of ISO 11607-1:2006, including Amd 1:2014 has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11607-1:2017 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 January 2018, and conflicting national standards shall be withdrawn at the latest by January 2018.

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 standard replaces EN ISO 11607-1:2009.

This document has been prepared under a standardization request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, Annex ZB, and Annex ZC, which are an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard 'within the meaning of Annex ZA', the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	**Equivalent dated standard**	
	EN	**ISO or IEC**
ISO 5636-5		ISO 5636-5:2013

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, 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.

Endorsement notice

The text of ISO 11607-1:2006, including Amd 1:2014 has been approved by CEN as EN ISO 11607-1:2017 without any modification.

INTERNATIONAL STANDARD

ISO 11607-1

First edition
2006-04-15

AMENDMENT 1
2014-07-15

Packaging for terminally sterilized medical devices —

Part 1: Requirements for materials, sterile barrier systems and packaging systems

AMENDMENT 1

Emballages des dispositifs médicaux stérilisés au stade terminal —

Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage

AMENDEMENT 1

Reference number
ISO 11607-1:2006/Amd.1:2014(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 198, *Sterilization of health care products*.

ISO 11607 consists of the following parts, under the general title Packaging for terminally sterilized medical devices:

— *Part 1: Requirements for materials, sterile barrier systems and packaging systems*

— *Part 2: Validation requirements for forming, sealing and assembly processes*

Packaging for terminally sterilized medical devices —

Part 1: Requirements for materials, sterile barrier systems and packaging systems

AMENDMENT 1

Page v, Introduction, 2nd paragraph, 3rd sentence

Replace 'This part of ISO 11607 is harmonized with EN 868-1' with 'This part of ISO 11607 replaces EN 868-1'.

Page 1, Clause 1, Scope

Add the following new paragraph at the end:

> 'This part of ISO 11607 does not apply to packaging materials and/or systems used to contain a contaminated medical device during transportation of the item to the site of reprocessing or disposal.'

Page 1, Clause 2, Normative references

Delete the date of publication of ISO 5636-5.

Page 2, definition 3.4

Replace the definition of 3.4 with the following definition, and delete the note:

> 'characteristics of the closure which ensure that it prevents the ingress of microorganisms, demonstrated under test conditions which consider sterilization process, handling, distribution, transport and storage'

Page 2, definition 3.8

Replace the definition of 3.8 with the following definition:

> 'property of the sterile barrier system which ensures that it prevents the ingress of microorganisms, demonstrated under test conditions which consider sterilization process, handling, distribution, transport and storage'

Page 3, definition 3.12

Replace '[ISO 9000:2000]' with '[ISO 9000:2005]'.

Page 4, definition 3.19

Replace the definition of 3.19 with the following definition, and delete the note:

> 'characteristic of the seal which ensures that it prevents the ingress of microorganisms, demonstrated under test conditions which consider sterilization process, handling, distribution, transport and storage'

Page 6, 4.2.2

Replace 'It is not necessary' with 'It shall not be necessary'.

Page 6, 4.2.3

Replace 'Health care facilities may use' with 'Health care facilities shall consider using'.

Page 10, 5.3.2, Note

Replace the first sentence of the note with the following:

'For example, see ISO 17665-1, ISO 11135, ISO 11137 (all parts), ISO 14937; EN 285, EN 1422, or EN 14180.'

Page 11, 6.1.5, Note

Update the date of publication of the reference; read: 'ANSI/AAMI ST65:2008'.

Page 12, 6.3.2, last sentence

Make a note from the last sentence and update the date of publication of the reference; read:

'NOTE For a review of this topic, refer to ANSI/AAMI ST65:2008 and Hansen et al. 1995[36].'

Page 13, 7.1

Add the following new dash before the first dash:

'— the name or trade name and address of the manufacturer or his authorized representative;'

Add, as a new 8th dash, the following:

'— whether the materials and/or preformed sterile barrier systems are intended for single use or reuse;'

Add the following new last dash:

'— if instructions for use are supplied, they shall contain the date of issue or the latest revision.'

Page 13, 7.2

Replace 'for preformed sterile barrier systems' with: 'with the material, preformed sterile barrier system or sterile barrier system'.

Page 17, B.1, 1st paragraph

Replace the second sentence with the following:

'When using test methods and procedures listed in Table B.1 it is important to note the date of issue of these documents.'

Page 17, B.1, 2nd paragraph

Replace the first sentence with the following:

'The criteria for inclusion of test methods and procedures given in Table B.1 are that they must be nominated for inclusion and commercially available from a standards development organization, trade association or national standards body.'

Page 17 and the following, B.2

Replace the list of test methods given in B.2 with the following new Table B.1:

Table B.1 — Test methods and their status

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
Accelerated aging	ASTM F1980	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	NA[a]	NA	YES
	EN 868–8	Packaging for terminally sterilized medical devices – Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 – Requirements and test methods	NA	NA	YES
Air permeance	ISO/TS 5636-2	Paper and board — Determination of air permeance (medium range) — Part 2: Schopper method	NO	NO	NA
	ISO 5636-3	Paper and board — Determination of air permeance (medium range) — Part 3: Bendtsen method	NO	NO	NA
	ISO 5636-5	Paper and board — Determination of air permeance and air resistance (medium range) — Part 5: Gurley method	NO	NO	NA
	ASTM D737	Standard test method for air permeability of textile fabrics	YES	—	NA
	TAPPI T460	Air Resistance of Paper (Gurley Method)	YES	—	NA
	TAPPI T536	Resistance of paper to passage of air (high-pressure Gurley method)	YES	—	NA
Alcohol repellency	AATCC-193	Aqueous Liquid Repellency: Water/ Alcohol Solution Resistance Test	NO	NO	NA
Basis weight	ISO 536	Paper and board — Determination of grammage	NO	NO	NA
	ASTM D4321	Standard test method for package yield of plastic film	YES	—	NA
	ASTM D3776–6M	Standard test methods for mass per unit area (weight) of fabric	YES	—	NA
	TAPPI T410	Grammage of Paper and Paperboard (Weight per Unit Area)	YES	—	NA
Biocompatibility	ISO 10993-1	Biological evaluation of medical devices — Part 1: Evaluation and testing	NA	NA	YES
	ASTM F2475	Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials	NA	NA	YES
Burst	ISO 2758	Paper — Determination of bursting strength	YES	—	NA
	TAPPI T403	Bursting Strength of Paper	YES	—	NA
	ASTM F1140	Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages	YES	—	NA
	ASTM F2054	Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates	YES	—	NA

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
Chlorides	ISO 9197	Paper, board and pulps — Determination of water-soluble chlorides	—	YES	NA
	TAPPI T 256	Water-soluble chlorides in pulp and paper	—	YES	NA
	EN 868–4	Packaging for terminally sterilized medical devices — Part 4: Paper bags — Requirements and test methods (Annex B: Method for the determination of pH value, chloride and sulfate in paper bags)	NO	NO[b]	NA
Cleanliness	TAPPI T 437	Dirt in paper and paperboard	YES	—	NA
	TAPPI T 564	Transparent chart for the estimation of defect size	NO	NO	NA
Coat weight	ASTM F2217	Standard practice for coating /adhesive weight determination	NA	NA	YES
Conditioning	ISO 187	Paper, board and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples	NA	NA	YES
	ASTM D4332	Standard practice conditioning containers, packages or packaging components for testing	NA	NA	YES
	ISO 2233	Complete, filled transport packages and unit loads — Conditioning for testing	NA	NA	YES
Dimensions	ASTM F2203	Standard test method for linear measurement using precision steel rule	YES	—	NA
Drapability	ISO 9073-9	Textiles — Test methods for nonwovens — Part 9: Determination of drape coefficient	NO	NO	NA
	ISO 2493-1	Paper and board — Determination of bending resistance — Part 1: Constant rate of deflection	YES	—	NA
	ISO 2493-2	Paper and board — Determination of bending resistance — Part 2: Taber-type tester	YES	—	NA
	DIN 53121	Testing of paper and board — Determination of the bending stiffness by the beam method	NO	NO	NA
	TAPPI T489	Bending Resistance (Stiffness) of Paper and Paperboard (Taber-Type Stiffness Tester in Basic Configuration)	YES	—	NA
	TAPPI T566	Bending resistance (stiffness) of Paper (Taber-type Tester in 0 to 10 Taber stiffness unit configuration)	YES	—	NA
Flexural durability	ASTM F392	Standard test method for flex durability of flexible barrier materials	YES	—	NA

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
Microbial barrier	ASTM F1608	Standard test method for microbial ranking of porous packaging materials (Exposure chamber method)	YES	—	NA
	ASTM F2638	Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier	YES	—	NA
	DIN 58953–6	Sterilization — Sterile supply — Sterilization paper for bags and tube packings — test; subclause 2.14: Testing for germ proofness in moisture and Clause 15: Testing for germ proofness with passage of air	YES[f, g]	NA[f]	NA
	BS 6256	Specification for paper for steam sterilization paper bags, pouches and reels for medical use Appendix C: Methods for determination of methylene blue particulate penetration	NO	NO	NA
	ASTM F2101	Test method for evaluating the bacterial filtration efficiency (BFE) of medical face masks materials, using a biological aerosol of staphylococcus aureus	—	YES	NA
	SS 876 0019	Health care textiles — Bacterial penetration — Wet	NO	NO	NA
Oxygen permeance	ASTM D3985	Standard Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheeting Using a Coulometric Sensor	YES	—	NA
	ASTM F1307	Standard Test Method for Oxygen Transmission Rate Through Dry Packages Using a Coulometric Sensor	YES	—	NA
	ASTM F1927	Standard Test Method for Determination of Oxygen Gas Transmission Rate, Permeability and Permeance at Controlled Relative Humidity Through Barrier Materials Using a Coulometric Detector	YES	—	NA
	ASTM F2622	Standard Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheeting Using Various Sensors	YES	—	NA
Peel-open characteristic	EN 868–5	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods (Annex C: Determination of peel characteristics of paper/plastic laminate products)	NO	NO	NA

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
Performance testing	ASTM D4169	Practice for performance testing of shipping containers and systems	NA	NA	YES
	ISTA 1,2 and 3 Series	International Safe Transit Association Preshipment Test Procedures	NA	NA	YES
	ISTA 4AB	Packaged – product for shipment in known distribution channels	NA	NA	YES
	ISTA 7D	Thermal controlled transport packaging for parcel delivery system shipment	NA	NA	YES
	ISO 4180	Packaging — Complete, filled transport packages — General rules for the compilation of performance test schedules	NA	NA	YES
	EN 868–8	Packaging for terminally sterilized medical devices – Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 – Requirements and test methods	NO	NO	NA
	ASTM F2825	Standard Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery	NA	NA	YES
	ASTM D7386	Standard Practice for Performance Testing of Packages for Single Parcel Delivery Systems	NA	NA	YES
pH	ISO 6588-1	Paper, board and pulps — Determination of pH of aqueous extracts — Part 1: Cold extraction	YES	—	NA
	ISO 6588-2	Paper, board and pulps — Determination of pH of aqueous extracts — Part 2: Hot extraction	YES	—	NA
	TAPPI T509	Hydrogen ion concentration (pH) of paper extracts (cold extraction method)	YES	—	NA
	TAPPI T435	Hydrogen ion concentration (pH) of paper extracts (hot extraction method)	YES	—	NA
Pore size	EN 868–2	Packaging for terminally sterilized medical devices – Part 2: Sterilization wrap – Requirements and test methods (Annex C: Method for the determination of pore size[c])	NO	NO[b]	NA
Printing and coating	ASTM F2250	Standard Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials	NA	NA	YES
	ASTM F2252	Standard Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials Using Tape	NA	NA	YES

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
Puncture	ASTM D1709	Standard test method for impact resistance of plastic film by free-falling dart method	YES	—	NA
	ASTM F1306	Standard test method for slow rate penetration resistance of flexible barrier films and laminates	YES	—	NA
	ASTM D3420	Standard test method for pendulum impact resistance of plastic film	YES[d]	—	NA
Seal strength	ASTM F88/F88M	Standard test method for seal strength of flexible Barrier materials	YES	—	NA
	EN 868–5	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods	NO	NO	NA
Specification development	ASTM F2559 /2559F	Standard Guide for Writing a Specification for Sterilizable Peel Pouches	NA	NA	YES
	ASTM F99	Standard Guide for Writing a Specification for Flexible Barrier Rollstock Materials	NA	NA	YES
	ASTM F17	Standard Terminology Relating to Flexible Barrier Packaging	NA	NA	YES
	ASTM F2097	Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products	NA	NA	YES
Static electricity	BS 6524	Method for determination of the surface resistivity of a textile fabric	NO	NO	NA
	ASTM D257	Standard Test Methods for DC Resistance or Conductance of Insulating Materials	—	YES	NA

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
Sterile barrier system Integrity	ASTM F2228	Standard test method for non-destructive detection of leaks in medical packaging which incorporates porous barrier material by CO_2 tracer gas method	YES	—	NA
	ASTM F1929	Standard test method for detecting seal leaks in porous medical packaging by dye penetration	YES	—	NA
	ASTM F2227	Standard test method for non-destructive detection of leaks in non-sealed and empty medical packaging trays by CO_2 tracer gas method	YES	—	NA
	ASTM F2391	Standard Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas	YES	—	NA
	ASTM F2096	Standard test method for detecting gross leaks in packaging by internal pressurization (Bubble test)	YES	—	NA
	ASTM F1886/ F1886M	Standard test method for determining integrity of seals for medical packaging by visual inspection	YES	—	NA
	ASTM F2338	Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay	YES	—	NA
	ASTM D3078	Standard test method for determination of leaks in flexible packaging by bubble emission	YES	—	NA
	ASTM F2095	Standard Test Methods for Pressure Decay Leak Test for Flexible Packages With and Without Restraining Plates	YES	—	NA
Sulfates	ISO 9198	Paper, board and pulps — Determination of water-soluble sulfates	—	YES	NA
	TAPPI T255	Water-soluble sulfates in pulp and paper, Test Method	—	YES	NA
	EN 868–4	Packaging for terminally sterilized medical devices — Part 4: Paper bags - Requirements and test methods (Annex B: Method for the determination of pH value, chloride and sulfate in paper bags)	NO	NO[b]	NA
Tear resistance	ASTM D1922	Standard test method for propagation tear resistance of plastic film and thin sheeting by pendulum method	YES	—	NA
	ASTM D1938	Standard test method for tear-propagation resistance (trouser tear) of plastic film and thin sheeting by a single tear-method	YES	—	NA
	ISO 1974	Paper — Determination of tearing resistance (Elmendorf method)	NO	NO	NA

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
Tensile properties	ISO 1924-2	Paper and board — Determination of tensile properties — Part 2: Constant rate of elongation method	YES	—	NA
	ISO 1924-3	Paper and board — Determination of tensile properties — Part 3: Constant rate of elongation method (100 mm/min)	YES	—	NA
	ASTM D882	Standard test method for tensile properties of thin plastic sheeting	YES	—	NA
	TAPPI T494	Tensile properties of paper and paperboard (using constant rate of elongation apparatus)	YES	—	NA
Thickness/ Density	ISO 534	Paper and board — Determination of thickness, density and specific volume	YES	—	NA
	ASTM F2251	Standard test method for thickness measurement of flexible packaging materials	YES	—	NA
	TAPPI T551	Thickness of Paper and Paperboard (Soft Platen Method)	YES	—	NA
	TAPPI T411	Thickness (caliper) of paper, paperboard and combined board	YES	—	NA
Vacuum leak	EN 868–8	Packaging for terminally sterilized medical devices – Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 – Requirements and test methods	NO	NO	NA
Visual inspection	EN 868–8	Packaging for terminally sterilized medical devices – Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 – Requirements and test methods	NO	NO	NA
Water resistance	ISO 811	Textile fabrics — Determination of resistance to water penetration — Hydrostatic pressure test	NO	NO	NA
	EDANA 170–1	Wet barrier — Mason Jar	NO	NO	NA
	EN 20535	Paper and board — Determination of water absorptiveness — Cobb method	NO	NO	NA
	AATCC-127	Water Resistance: Hydrostatic Pressure Test	NO	NO	NA
	TAPPI T441	Water Absorptiveness of Sized (Non-bibulous) Paper, Paperboard, and Corrugated Fiberboard (Cobb Test)	YES	—	NA
	EN 868–2	Packaging for terminally sterilized medical devices – Part 2: Sterilization wrap – Requirements and test methods (Annex C: Method for the water repellency [e])	NO	NO[b]	NA
Wet burst in wet condition	ISO 3689	Paper and board — Determination of bursting strength after immersion in water	NO	NO	NA

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
Wet tensile properties	ISO 3781	Paper and board — Determination of tensile strength after immersion in water	NO	NO	NA
	TAPPI T456	Tensile breaking strength of water-saturated paper and paperboard ("wet tensile strength")	YES	—	NA

[a] NA – not applicable

[b] For statement of precision and/or bias, see Berry, C. W. and Harding, L. (2012), Validation of Test Methods for Characterizing and Specifying Materials Used in the Construction of Sterilization Packaging. Packag. Technol. Sci.

[c] The test method for determination of the pore size can also be found in Annex D of EN 868–3:2009, EN 868–6:2009 and EN 868–7:2009.

[d] ASTM standard has only statement of precision.

[e] The test method for water repellency can also be found in Annex D of EN 868–3:2009, EN 868–6:2009 and EN 868–7:2009.

[f] Test is a pass/fail test, bias is obsolete.

[g] For statement for repeatability and reproducibility see D. Zahn, ISEGA Forschungs- und Untersuchungsgesellschaft mbH. Interlaboratory Test – "Microbial barrier testing of packaging materials for medical devices which are to be sterilized" according to DIN 58953-6:2010

Page 22 and the following, Bibliography

Delete reference [5]: ISO 5636-5:2003 as it is included in Clause 2

Add a new reference [5]: ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

Replace reference [6] with ISO 9001:2008, *Quality management systems — Requirements*

Replace reference [7] with ISO 10993-1:2009, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

Replace reference [8] with ISO 11135:—[1)], *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

Delete reference [15]: ISO 13683:1997.

Replace reference [17] with ISO 17665-1:2006, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*, and delete corresponding footnote 1.

Replace reference [18] with EN 285+A2:2009, *Steam sterilizers — Large sterilizers*

Delete the following references:

[19] EN 550:1994, [20] EN 552:1994,[21] EN 554:1994 and [22] EN 868-1:1997.

Update the date of publication of EN 868-3, EN 868-5, EN 868-6 and EN 868-7 by replacing '1999' with '2009' and update title, where applicable.

Replace reference [33] with EN 13795-1+A1:2009, *Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Part 1: General requirements for manufacturers, processors and products.*

1) To be published.

Replace reference [34] with EN 14180+A2:2009, *Sterilizers for medical purposes — Low temperature steam and formaldehyde sterilizers — Requirements and testing*

Replace reference [35] with AAMI/ANSI ST 65:2008, *Processing of reusable surgical textiles for use in health care facilities*

Add the following new reference at the end of Bibliography

Berry, C. W. and Harding, L. (2012), Validation of Test Methods for Characterizing and Specifying Materials Used in the Construction of Sterilization Packaging. Packag. Technol. Sci.

D. Zahn, ISEGA Forschungs- und Untersuchungsgesellschaft mbH. Interlaboratory Test – "Microbial barrier testing of packaging materials for medical devices which are to be sterilized" according to DIN 58953-6:2010. Available online from the Sterile Barrier Association (SBA) http://www.sterilebarrier.org/media/43501/Final-validation-report-germproofness-plus-author.pdf

Renumber the Bibliography.

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