INTERNATIONAL STANDARD

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AMENDMENT 1
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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

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Foreword

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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).

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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