American National Standard

ANSI/AAMI/ISO 11607-1:2006/(R)2010

Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems

Association for the Advancement of Medical Instrumentation

The Objectives and Uses of AAMI Standards and Recommended Practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

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All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

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Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

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American National Standard

ANSI/AAMI/ISO 11607-1:2006/(R)2010
(Revision of ANSI/AAMI/ISO 11607:2000)

Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems

Approved 9 December 2005 by
Association for the Advancement of Medical Instrumentation

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Abstract: This standard specifies the 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.

Keywords: barrier systems, bioburden, closure, microbial, seal, validation

AAMI Standard

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Contents

Glossary of equivalent standards iv

Committee representation vi

Background of AAMI Adoption of ISO 11607-1:2006 ix

Foreword x

Introduction xi

1 Scope 1

2 Normative references 1

3 Terms and definitions 1

4 General requirements 6
4.1 General 6
4.2 Quality systems 6
4.3 Sampling 6
4.4 Test methods 6
4.5 Documentation 7

5 Materials and preformed sterile barrier systems 7
5.1 General requirements 7
5.2 Microbial barrier properties 10
5.3 Compatibility with the sterilization process 10
5.4 Compatibility with the labelling system 11
5.5 Storage and transport 11

6 Design and development requirements for packaging systems 11
6.1 General 11
6.2 Design 12
6.3 Packaging-system performance testing 13
6.4 Stability testing 13

7 Information to be provided 14

Annex A (informative) **Guidance on medical packaging** 15

Annex B (informative) **Standardized test methods and procedures that may be used to demonstrate compliance with the requirements of this part of ISO 11607** 18

Annex C (normative) **Test method for resistance of impermeable materials to the passage of air** 23

Bibliography 24

Glossary of equivalent standards

International standards adopted in the United States may include normative references to other international standards. For each international standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the international standard. (NOTE—Documents are sorted by international designation.)

Other normatively referenced international standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
IEC TR 62348:200x[1]	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO TS 10993-19:200x[1]	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO TS 10993-20:200x[1]	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical

International designation	U.S. designation	Equivalency
ISO 11137-1:200x[1]	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:200x[1]	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:200x[1]	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 200x[1]	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 200x[1]	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO 11138-4: 200x[1]	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 200x[1]	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-5:2000	ANSI/AAMI ST66:1999	Major technical variations
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000, A1:2002, and A2:2004	ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO TR 16142:2006	ANSI/AAMI/ISO TIR16142:2006	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:200x[1]	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:200x[1]	ANSI/AAMI/ISO 18472:2006	Identical
ISO TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical

[1]In production

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Packaging Working Group

The adoption of ISO 11607-1 as an American National Standard was initiated by the AAMI Packaging Working Group of the AAMI Sterilization Standards Committee. The AAMI Packaging Working Group also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Packaging Working Group (U.S. Sub-TAG for ISO/TC 198/WG 7) played an active part in developing the ISO standard.

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NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of AAMI adoption of ISO 11607-1:2006

As indicated in the foreword to the main body of this document (page x), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard.

ISO 11607-1 was developed by ISO Technical Committee 198, *Sterilization of health care products*, to fill a need for international standards for packaging for terminally sterilized medical devices. U.S. participation in ISO/TC 198 is organized through the U.S. Technical Advisory Group (TAG) for ISO/TC 198, administered by the Association for the Advancement of Medical Instrumentation (AAMI) on behalf of the American National Standards Institute (ANSI). The United States made a considerable contribution to this standard.

AAMI encourages its committees to harmonize their work with international standards as much as possible. Upon review of the final Draft International Standard (FDIS) of ISO 11607-1:2006, the AAMI Packaging Working Group (WG) decided to adopt ISO 11607-1 verbatim as a revision, with 11607-2:2006, of ANSI/AAMI/ISO 11607:2000, now split into two parts—this Part 1 on general requirements, and Part 2 on packaging validation.

ANSI/AAMI/ISO 11607-1 specifies the basic attributes required of materials and pre-formed systems intended for use in packaging systems for terminally sterilized medical devices, while considering a wide range of potential materials, medical devices, packaging system designs, and sterilization methods. The goal of a terminally sterilized medical device packaging system is to allow sterilization, provide physical protection, maintain sterility to the point of use, and allow aseptic presentation. The specific nature of the medical device, the intended sterilization methods(s), the intended use, expiry date, transport and storage all influence the packaging system design and choice of materials.

The first and second editions of the ISO packaging standard consisted of only one document, but with the third edition, ISO/TC 198 decided to create two parts. This document, or Part 1, deals with requirements for materials, sterile barrier systems, and packaging systems. Part 2 deals with requirements for forming, sealing and assembly processes**.** The change that is perhaps the most significant and the one which cleared the way for harmonization was the establishment of new definitions for four key concepts. The definitions of “Sterile barrier system,” “preformed sterile barrier system,” “protective packaging,” and “packaging system” provide for more specific descriptions and eliminate any confusion due to the way the work packaging is used in different languages. It is hoped that this new vocabulary is adopted throughout the industry and that it makes for clearer communication, especially when international collaboration is required.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the ISO foreword on page x, this American National Standard is identical to ISO 11607-1:2006.

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 11607-1 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

ISO 11607-1 and ISO 11607-2 cancel and replace ISO 11607:2003, which has been technically revised.

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*

Introduction

The process of designing and developing a packaging system for terminally sterilized medical devices is a complicated and critical endeavor. The device components and the packaging system should be combined to create a product that performs efficiently, safely, and effectively in the hands of the user.

This part of ISO 11607 specifies the basic attributes required of materials and pre-formed systems intended for use in packaging systems for terminally sterilized medical devices, while considering the wide range of potential materials, medical devices, packaging system designs, and sterilization methods. ISO 11607-2 describes the validation requirements for forming, sealing and assembly processes. This part of ISO 11607 is harmonized with EN 868-1 and specifies general requirements for all packaging materials whereas EN 868 Parts 2 to 10 specify particular requirements for a range of commonly used materials. Both parts of ISO 11607 were designed to meet the Essential Requirements of the European Medical Device Directives.

European standards that provide requirements for particular materials and preformed sterile barrier systems are available and known as the EN 868 series. This part of ISO 11607 has been developed as a means to show compliance with the relevant Essential Requirements of the European Directives concerning medical devices. Compliance with EN 868 Parts 2 to 10 can be used to demonstrate compliance with one or more of the requirements of this part of ISO 11607.

The goal of a terminally sterilized medical device packaging system is to allow sterilization, provide physical protection, maintain sterility up to the point of use and allow aseptic presentation. The specific nature of the medical device, the intended sterilization methods(s), the intended use, expiry date, transport, and storage all influence the packaging system design and choice of materials.

One significant barrier to harmonization was terminology. The terms “package,” “final package,” “final pack,” “primary pack,” and “primary package” all have different connotations around the globe, and choosing one of these terms to be the harmonized basis for this part of ISO 11607 was considered a barrier to successful completion of this document. As a result, the term “sterile barrier system” was introduced to describe the minimum packaging required to perform the unique functions required of medical packaging: to allow sterilization, to provide an acceptable microbial barrier, and to allow for aseptic presentation. “Protective packaging” protects the sterile barrier system, and together they form the packaging system. “Preformed sterile barrier systems” would include any partially assembled sterile barrier systems such as pouches, header bags or hospital packaging reels. An overview of sterile barrier systems can be found in Annex A.

The sterile barrier system is essential to ensure the safety of terminally sterilized medical devices. Regulatory authorities recognize the critical nature of sterile barrier systems by considering them as an accessory or a component of a medical device. Preformed sterile barrier systems sold to healthcare facilities for use in internal sterilization are considered as medical devices in many parts of the world.

Packaging for terminally sterilized medical devices —Part 1: Requirements for materials, sterile barrier systems, and packaging systems

1 Scope

This part of ISO 11607 specifies the 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 until the point of use.

This part of ISO 11607 is applicable to industry, to health care facilities, and wherever medical devices are placed in sterile barrier systems and sterilized.

This part of ISO 11607 does not cover all requirements for sterile barrier systems and packaging systems for medical devices that are manufactured aseptically. Additional requirements might also be necessary for drug/device combinations.

This part of ISO 11607 does not describe a quality assurance system for control of all stages of manufacture.

2 Normative references

The following referenced documents are indispensable for the application 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.

ISO 5636-5:2003, *Paper and board — Determination of air permeance and air resistance (medium range) — Part 5: Gurley method*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
aseptic presentation
introduction and transfer of a sterile product using conditions and procedures that exclude microbial contamination

3.2
bioburden
population of viable microorganisms on or in a product or sterile barrier system

[ISO/TS 11139:2006]

3.3
closure
means used to close a sterile barrier system where no seal is formed

NOTE For example, a sterile barrier system can be closed by a reusable container gasket or sequential folding to construct a tortuous path.

3.4
closure integrity
characteristics of the closure, which ensures that it prevents the ingress of microorganisms under specified conditions

NOTE See also 3.8.

3.5
expiry date
indication of the date, by which the product should be used, expressed at least as the year and month

3.6
labeling
written, printed, electronic or graphic matter affixed to a medical device or its packaging system; or accompanying a medical device

NOTE Labeling is related to identification, technical description and use of the medical device but excludes shipping documents.

3.7
medical device
any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

— investigation, replacement, modification or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices,

— providing information for medical purposes by means of in vitro examination of specimens derived from the human body;

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

[ISO 13485:2003]

NOTE This definition from ISO 13485:2003 has been developed by the Global Harmonization Task Force (GHTF 2002).

3.8
microbial barrier
property of the sterile barrier system that prevents the ingress of microorganisms under specified conditions

3.9
packaging material
any material used in the fabrication or sealing of a packaging system

3.10
packaging system
combination of the sterile barrier system and protective packaging

[ISO/TS 11139:2006]

3.11
preformed sterile barrier system
sterile barrier system (3.22) that is supplied partially assembled for filling and final closure or sealing

EXAMPLE Pouches, bags, and open reusable containers.

[ISO/TS 11139:2006]

3.12
product
result of a process

[ISO 9000:2000]

NOTE For the purpose of sterilization standards, product is tangible and can be raw material(s), intermediate(s), sub-assembly(ies) and health care product(s).

[ISO/TS 11139:2006]

3.13
protective packaging
configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use

NOTE Adapted from ISO/TS 11139:2006.

3.14
recycled material
material that has been reprocessed through a production process of waste materials for their original purpose or for other purposes

3.15
repeatability
closeness of the agreement between the results of successive measurements of the same particular quantity subject to measurement (measurand) carried out under the same conditions of measurement

NOTE 1 These conditions are called repeatability conditions.

NOTE 2 Repeatability conditions can include the following:

— the same measurement procedure;

— the same observer;

— the same measuring instrument, used under the same conditions;

— the same location;

— repetition over a short period of time.

NOTE 3 Repeatability may be expressed quantitatively in terms of the dispersion characteristics of the results.

NOTE 4 Adapted from *International Vocabulary of Basic and General Terms in Metrology*, 1993, definition 3.6.

3.16
reproducibility
closeness of the agreement between the results of measurements of the same particular quantity subject to measurement (measurand) carried out under changed conditions of measurement

NOTE 1 A valid statement of reproducibility requires specification of the conditions changed.

NOTE 2 The changed conditions can include:

— principle of measurement;

— method of measurement;

— observer;

— measuring instrument;

— reference standard;

— location;

— conditions of use;

— time.

NOTE 3 Reproducibility may be expressed quantitatively in terms of the dispersion characteristics of the results.

NOTE 4 Adapted from *International Vocabulary of Basic and General Terms in Metrology*, 1993, definition 3.7.

3.17
reusable container
rigid sterile barrier system designed to be repeatedly used

3.18
seal
result of joining surfaces together

NOTE For example, surfaces can be jointed together by use of adhesives or thermal fusion.

3.19
seal integrity
characteristics of the seal, which ensures that it prevents the ingress of microorganisms under specified conditions

NOTE See also 3.8.

3.20
seal strength
mechanical strength of the seal

3.21
sterile
free from viable microorganisms

[ISO/TS 11139:2006]

3.22
sterile barrier system
minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use

[ISO/TS 11139:2006]

3.23
sterile fluid-path packaging
system of protective port covers and/or packaging designed to ensure sterility of the portion of the medical device intended for contact with fluids

NOTE An example of sterile fluid-path packaging would be the interior of the tubing for administration of an intravenous fluid.

3.24
sterilization compatibility
attributes of the packaging material and/or system that allow it to both withstand the sterilization process and attain the required conditions for sterilization within the packaging system

3.25
sterilizing agent
physical or chemical entity, or combination of entities having sufficient microbicidal activity to achieve sterility under defined conditions

[ISO/TS 11139:2006]

3.26
terminal sterilization
process whereby product is sterilized within its sterile barrier system

3.27
useful life
the time period during which all the performance requirements are met

3.28
validation
⟨general⟩ confirmation by examination and provision of objective evidence that the particular requirement for a specific intended use can be consistently fulfilled

NOTE This definition is applicable to validation of test methods and design.

3.29
validation
⟨process⟩ documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

NOTE Adapted from ISO/TS 11139:2006.

4 General requirements

4.1 General

Compliance with one or more requirements of this part of ISO 11607 may be demonstrated by using one or more parts of the series EN 868-2 to EN 868-10.

4.2 Quality systems

4.2.1 The activities described within this part of ISO 11607 shall be carried out within a formal quality system.

NOTE ISO 9001 and ISO 13485 contain requirements for suitable quality systems. Additional requirements may be specified by a country or region.

4.2.2 It is not necessary to obtain third-party certification of the quality system to fulfill the requirements of this part of ISO 11607.

4.2.3 Health care facilities may use the quality system required by their country or region.

4.3 Sampling

The sampling plans used for selection and testing of packaging systems shall be applicable to packaging systems being evaluated. Sampling plans shall be based upon statistically valid rationale.

NOTE Examples of suitable sampling plans are given in ISO 2859-1 or ISO 186. Additional sampling plans may be specified by countries or regions.

4.4 Test methods

4.4.1 All test methods used to show compliance with this part of ISO 11607 shall be validated and documented.

NOTE Annex B contains a list of suitable test methods.

4.4.2 The test method validation shall demonstrate the suitability of the method as used. The following elements shall be included:

— establishment of a rationale for the selection of the appropriate tests for the packaging system;

— establishment of acceptance criteria;

NOTE Pass/fail is a type of acceptance criterion.

— determination of test method repeatability;

— determination of test method reproducibility; and

— establishment of test method sensitivity for integrity tests.

4.4.3 Unless otherwise specified in the test methods, test samples shall be conditioned at (23 ± 1) °C and (50 ± 2) % relative humidity for a minimum of 24 h.

4.5 Documentation

4.5.1 Demonstration of compliance with the requirements of this part of ISO 11607 shall be documented.

4.5.2 All documentation shall be retained for a specified period of time. The retention period shall consider factors such as regulatory requirements, expiry date and traceability of the medical device or sterile barrier system.

4.5.3 Documentation of compliance with the requirements may include, but is not limited to, performance data, specifications and test results from validated test methods.

4.5.4 Electronic records, electronic signatures and handwritten signatures executed to electronic records that contribute to validation, process control or other quality decision-making processes shall be reliable.

5 Materials and preformed sterile barrier systems

5.1 General requirements

5.1.1 The requirements on materials referenced shall apply to those used in preformed sterile barrier systems, as well as sterile barrier systems.

5.1.2 The requirements listed in this subclause (5.1) are not intended to be all-inclusive. Materials which have characteristics not listed in this subclause may be evaluated using the performance criteria given in Clause 6.

5.1.3 The conditions under which the material and/or preformed sterile barrier system are produced and handled shall be established, controlled and recorded, if applicable, in order to ensure that:

a) the conditions are compatible with the use for which the material and/or sterile barrier system is designed;

b) the performance characteristics of the material and/or sterile barrier system are maintained.

5.1.4 As a minimum, the following shall be considered:

a) temperature range;

b) pressure range;

c) humidity range;

d) maximum rate of change of the above, where necessary;

e) exposure to sunlight or UV light;

f) cleanliness;

g) bioburden;

h) electrostatic conductivity.

5.1.5 The source, history and traceability of all materials, especially recycled materials, shall be known and controlled to ensure that the finished product will consistently meet the requirements of this part of ISO 11607.

NOTE With current commercial technologies, it is unlikely that anything other than virgin manufacturing waste will be used in recycled materials, due to insufficient controls to allow the safe use of other recycled material in sterile barrier systems.

5.1.6 The following properties shall be evaluated:

a) microbial barrier (see 5.2);

b) biocompatibility and toxicological attributes;

NOTE This is usually restricted to material in contact with the device. Guidance on biocompatibility is given in ISO 10993-1.

Sterilization effects on biocompatibility should be evaluated.

c) physical and chemical properties;

d) compatibility with respect to forming and sealing processes;

e) compatibility with respect to the intended sterilization process(es) (see 5.3);

f) any shelf-life limitations for pre-sterilization and post-sterilization storage.

5.1.7 Materials, e.g. wrapping materials, paper, plastic film, nonwovens or reusable fabrics, shall meet the following general performance requirements.

a) Materials shall be non-leaching and odorless under specified conditions of use, to such an extent that neither performance nor safety is impaired and the medical devices with which they are in contact are not adversely affected.

   NOTE Odor determination does not require a standardized test method, since objectionable odors are readily evident.

b) Materials shall be free of holes, cracks, tears, creases, or localized thickening and/or thinning sufficient to impair functioning.

c) Materials shall have a basis weight (mass per unit area) which is consistent with the specified value.

d) Materials shall exhibit acceptable levels of cleanliness, particulate matter and linting.

e) Materials shall comply with established specific or minimum physical properties, such as tensile strength, thickness variation, tear resistance, air permeance and burst strength.

f) Materials shall comply with established specific chemical characteristics (such as pH value, chloride, and sulfate content) to meet the requirements of the medical device, packaging system or sterilization process.

g) Materials shall not contain or release material known to be toxic in sufficient quantity to cause a health hazard either before, during or after sterilization under the conditions of use.

5.1.8 In addition to the requirements given in 5.1.1 through 5.1.7, adhesive-coated materials shall meet the requirements listed below.

a) Coating patterns shall be continuous without skips or breaks in the pattern sufficient to cause a discontinuity in the seal.

b) Coating mass shall be consistent with the stated value.

c) Materials shall demonstrate minimum specified seal strength when a seal is formed with another specified material under specified conditions.

5.1.9 In addition to the requirements given in 5.1.1 through 5.1.7 and, if appropriate, 5.1.8, sterile barrier systems and preformed sterile barrier systems shall meet the requirements listed below.

a) Materials and components, e.g. coatings, ink or chemical indicators, shall not adversely affect the medical device by reaction, contamination and/or transfer before, during or after the defined sterilization process.

b) If formed by sealing, the specified requirements for seal width and seal strength (tensile and/or burst) shall be met.

c) Peel-open characteristics shall be continuous and homogeneous, without delamination or tearing of the material that can affect aseptic opening and presentation.

NOTE 1 Paper bags and heat-sealable pouches and reels have construction and design requirements, as well as performance requirements.

NOTE 2 A maximum seal strength may be necessary, if seals are intended to be opened for aseptic presentation.

d) Seals and/or closures shall provide a barrier to microorganisms.

5.1.10 In addition to the requirements given in 5.1.1 through 5.1.7, reusable containers shall meet the requirements given below.

a) The container shall be fitted with a tamper-evident system to provide a clear indication when the closure integrity has been compromised.

b) The sterilizing agent port shall provide a barrier to microorganisms, during removal from the sterilizer, transport and storage (see 5.2).

c) After forming the sterile barrier system, the closure shall provide a barrier to microorganisms.

d) The container shall be constructed to facilitate inspection of all essential parts.

e) Acceptance criteria shall be established for inspection prior to each reuse.

NOTE 1 While visual inspection is the most common procedure, there could be other acceptable methods.

f) Individual components of the same model containers shall be either completely interchangeable or designed such that the components cannot be interchanged.

NOTE 2 Suitable coding and/or labeling can address this design requirement.

g) Service, cleaning procedures and the manner of inspection, maintenance and replacement of components shall be specified.

NOTE 3 For additional guidance on reusable containers, see EN 868-8.

5.1.11 In addition to the requirements given in 5.1.1 through 5.1.7 and, if appropriate, 5.1.8, reusable fabrics shall meet the requirements given below:

a) Performance requirements shall be met after any repairs to the material and after every sterilization cycle.

b) Processing procedures for laundering and refurbishing shall be established and documented.

NOTE This may include visual inspection, other test methods and acceptance criteria for reuse.

c) Processing procedures shall conform to the product labeling.

5.1.12 For reusable sterile barrier systems including containers and fabrics, it shall be determined if processing in accordance with the provided instruction leads to a degradation that will limit the useful life. Where such degradation is predicted, the number of reprocessing cycles that can be tolerated shall be stated in the product labeling, or the end of the useful life shall be detectable.

5.2 Microbial barrier properties

5.2.1 The impermeability of a material shall be determined in accordance with Annex C.

NOTE The microbial barrier properties of materials used in the construction of sterile barrier systems are critical for ensuring integrity and product safety. The methods used for evaluation of the microbial barrier properties are divided into two categories: those that are appropriate for impermeable materials, and those that are appropriate for porous materials.

5.2.2 Demonstrating that the material is impermeable shall satisfy the microbial barrier requirement.

5.2.3 Porous materials shall provide an adequate microbial barrier to microorganisms in order to provide integrity of the sterile barrier system and product safety.

NOTE There is no universally accepted method of demonstrating microbial barrier properties. Evaluation of the microbial barrier properties of porous materials is typically conducted by challenging samples with an aerosol of bacterial spores or particulates, under a set of test conditions which specify the flow rate through the material, microbial challenge to the sample, and duration of the test. The microbial barrier properties of the material, under these specified test conditions, are determined by comparing the extent of bacterial or particulate penetration through the material with the original challenge. Data from a validated physical test method that correlates with a validated microbiological challenge method are considered acceptable for determining the microbial barrier properties. As validated microbial challenge methods for materials and sterile barrier systems become available, they will be considered for inclusion in future editions of this part of ISO 11607. (For further information, see Sinclair and Tallentire 2002[41], Tallentire and Sinclair 1998[40], Scholla et. al 1995[39], and Scholla et al. 2000[38]).

5.3 Compatibility with the sterilization process

5.3.1 It shall be demonstrated that the materials and preformed sterile barrier system are suitable for use in the specified sterilization process(es) and cycle parameters.

5.3.2 Sterilization compatibility should be determined using a sterilizer designed, constructed and operated in accordance with the requirements of the relevant International or European Standards.

NOTE For example, see ISO 17665-1, ISO 11135, ISO 11137 (all parts), ISO 14937, EN 285, EN 550, EN 552, EN 554, EN 1422, or EN 14180. Efforts are under way to harmonize these International Standards and European Standards.

5.3.3 The performance of the materials shall be evaluated to ensure that the material performance remains within specified limits after exposure to all the specified sterilization processes.

5.3.4 Specified sterilization processes may include multiple exposures of the same or different sterilization processes.

5.3.5 Determination of suitability for the intended purpose shall include consideration of material variations that will occur during normal routine supply.

5.3.6 Where the product is enclosed by multiple wrappings or layers, different limits on material properties may be set for inner and outer layers.

5.3.7 Determination of suitability may be carried out concurrently with validation of the sterilization process(es) to be used.

5.4 Compatibility with the labeling system

The labeling system shall

a) remain intact and legible until the point of use,

b) be compatible with the materials, sterile barrier system and medical device during and after the specified sterilization process(es) and cycle parameters and shall not adversely affect the sterilization process, and

c) not be printed or written in ink of a type which can be transferred to the medical device nor react with the packaging material and/or system to impair the utility of the packaging material and/or system, nor change color to an extent which renders the label illegible.

NOTE Labeling systems can take a number of forms, including printing or writing directly on the material and/or sterile barrier system, or labels consisting of another layer of material attached to the surface of the material and/or system by adhesion, fusion or other means.

5.5 Storage and transport

5.5.1 Materials and preformed sterile barrier systems shall be packaged to provide the protection necessary to maintain the performance characteristics during transport and storage.

5.5.2 Materials and preformed sterile barrier systems shall be transported and stored under conditions that ensure that the performance characteristics remain within specified limits (see 5.1).

This can be accomplished by:

a) demonstrating retention of these characteristics under defined storage conditions, and

b) ensuring that storage conditions remain within specified limits.

6 Design and development requirements for packaging systems

6.1 General

6.1.1 The packaging system shall be designed to minimize the safety hazard to the user and patient under the intended specified conditions of use.

6.1.2 The packaging system shall provide physical protection and maintain integrity of the sterile barrier system.

6.1.3 The sterile barrier system shall allow for sterilization and be compatible with the chosen process(es).

6.1.4 The sterile barrier system shall maintain sterility until the point of use or until the expiry date.

NOTE See also 6.4.1.

6.1.5 Maintenance of sterile barrier integrity may be used to demonstrate maintenance of sterility.

NOTE See ANSI/AAMI ST65:2000 and Hansen et al. 1995[36]. The loss of sterility is regarded as event-related rather than time-related.

6.1.6 When similar medical devices use the same packaging system, a rationale for establishing similarities and identifying the worst-case configuration shall be documented. As a minimum, the worst-case configuration shall be used to determine compliance with this part of ISO 11607.

NOTE For example, similarity could be established by different sizes of the same product.

6.2 Design

6.2.1 There shall be documented procedures for the design and development of packaging systems.

6.2.2 The sterile barrier system shall allow the product to be presented in an aseptic manner.

6.2.3 The design and development of a package system shall consider many factors that include, but are not limited to:

a) customer requirements;

b) the mass and configuration of the product;

c) the presence of sharp edges or protrusions;

d) the need for physical and other protection;

e) the sensitivity of the product to particular risks, e.g. radiation, moisture, mechanical shock, static discharge;

f) the number of products per package system;

g) package labeling requirements;

h) environmental limitations;

i) expiry date limitations of the product;

j) distribution, handling, storage environment;

k) sterilization compatibility and residuals.

6.2.4 The product components and constructions which constitute sterile fluid-path closure assemblies shall be identified and specified. These should include, but are not limited to:

— materials;

— finish;

— component dimensions;

— assembly dimensions (e.g. tolerances for interference fits).

6.2.5 The results of the design and development process (6.2.1, 6.2.3 and 6.2.4) shall be recorded, verified and approved prior to release of the product.

6.3 Packaging-system performance testing

6.3.1 Integrity of the sterile barrier system shall be demonstrated after sterilization and subsequent performance testing.

6.3.2 Physical tests, along with microbial barrier testing of porous packaging materials, can be used to establish the capability of the sterile barrier system to maintain sterility. For a review of this topic, refer to ANSI/AAMI ST65:2000 and Hansen et al. 1995[36].

6.3.3 Standardized test methods for evaluating the integrity of the sterile barrier system are preferred. However, in the absence of applicable validated sterile barrier system integrity tests, microbial barrier performance characteristics can be established by testing the microbial barrier properties of materials and the integrity of the seals and closures.

6.3.4 Performance testing shall be conducted on the worst-case sterile barrier system produced at the specified process limits of forming and sealing and after exposure to all the specified sterilization processes.

NOTE Specified sterilization processes may include multiple exposures of the same or different sterilization processes.

6.3.5 The packaging system shall provide adequate protection to the product through the hazards of handling, distribution and storage.

6.4 Stability testing

6.4.1 Stability testing shall demonstrate that the sterile barrier system maintains integrity over time.

6.4.2 Stability testing shall be performed using real-time aging.

6.4.3 Stability testing, using accelerated aging protocols, shall be regarded as sufficient evidence for claimed expiry dates until data from real-time aging studies are available.

6.4.4 Real-time and accelerated aging tests should begin simultaneously.

NOTE Stability testing and performance testing are separate entities. Performance testing evaluates the interaction between the packaging system and the products in response to the stresses imposed by the manufacturing and sterilization processes and the handling, storage and shipping environment.

6.4.5 When expiry dates are based upon product performance, stability testing for expiry dating should be conducted along with package stability testing.

6.4.6 If accelerated aging tests are performed, a documented rationale for the accelerated aging conditions and test duration chosen shall be established.

6.4.7 When it is demonstrated that the product does not interact with the specified sterile barrier system over time, previously documented data for stability testing shall be sufficient to be in accordance with 6.4.1.

7 Information to be provided

7.1 The following information shall be provided with the material, preformed sterile barrier system or sterile barrier system:

— the type, size or grade;

— batch number or other means of tracing the manufacturing history;

— the intended sterilization process(es);

— the expiry date, if applicable;

— any specific storage conditions, if applicable;

— any known restrictions on handling or use (e.g. environmental conditions), if applicable;

— for reusable materials and/or preformed sterile barrier systems, the frequency and nature of maintenance.

7.2 When national or regional regulations require additional information for preformed sterile barrier systems which are placed on the healthcare market, this additional information shall be provided.

Annex A
(informative)

Guidance on medical packaging

A.1 Factors influencing the choice of the materials and design of the packaging system

The specific nature of the medical device, the intended sterilization methods(s), and the intended use, expiry date, transport and storage all influence the packaging system design and choice of materials. Choosing appropriate materials for terminally sterilized medical device packaging systems is influenced by the inter-relationships that are illustrated in Figure A.1.

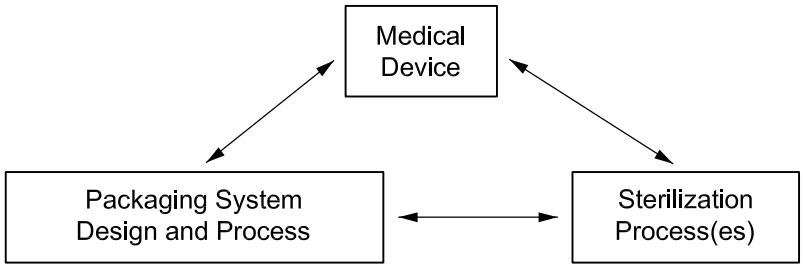

Figure A.1 — Interrelationships influencing the choice of appropriate materials for terminally sterilized medical packaging systems

A.2 Sterilization processes and considerations

A.2.1 The choice of sterilization processes include, but are not limited to, ethylene oxide (EO), gamma irradiation (γ), electron beam (e-beam), steam, and low-temperature oxidative sterilization processes. If the device is intended to be sterilized by EO, steam, or oxidizing processes, the sterile barrier system has a permeable component to allow the sterilizing gases to enter, kill the microorganisms, and escape without significant residual concentrations.

A.2.2 If the device is to be sterilized by irradiation (γ or e-beam), a permeable component may not be required and the sterile barrier system can be made entirely of impermeable materials. The manufacturer of a medical device chooses the appropriate sterilization processes for each device and their choice is dependent upon several factors. If the device is constructed of materials that are not irradiation stable, EO, steam, and oxidizing agents are typically used. Alternatively, if a device tends to retain high residual concentrations of EO, the device manufacturer may choose irradiation.

A.3 Sterile barrier systems

A.3.1 Sterile barrier systems for medical devices can have many characteristics in common. The majority have a top-web, a bottom web, and a means to join the webs together. In the case where a peelable seal is required, a sealant layer is applied to allow heat-sealing of the two layers together. The sealant layer, which is commonly known as coating, has traditionally been applied to the permeable web.

Today, many films incorporate the sealant layer as (a) layer(s) in the film construction. Where a weld seal is required, compatibility of the webs is required to allow joining by heat, or other methods such as ultrasonic welding.

A.3.2 There are many types and variations of sterile barrier systems used to package sterile medical devices. The first type is the pre-formed rigid tray with a die-cut lid. The tray is usually preformed by a thermoforming or pressure-forming process. The die-cut lid can be permeable or impermeable and typically will have a sealant layer used to heat-seal the lid to the tray. Rigid trays with die-cut lids are commonly used for large profile and heavy devices, such as orthopedic implants and pacemakers, as well as surgical kits.

A.3.3 The second type is the flexible peel pouch. A pouch is typically constructed of a film on one side and either film, paper, or nonwoven on the other. Pouches are typically supplied as preformed sterile barrier systems where all the seals have been formed except for one (typically at the bottom). This remains open so that the device can be placed inside and then the final seal applied prior to sterilization. Vast arrays of different medical devices use pouches as the sterile barrier system, due to their wide availability in a variety of sizes. These devices are typically low profile and lightweight. Pouches can come with a variety of design features. (For example, gussets may be included to allow for higher profile devices.)

A.3.4 The third type is the sterilization bag. A sterilization bag is constructed from a single web of porous medical-grade paper that has been folded to form a long tube with or without side gussets. The tube is sealed along its length by a double line of adhesive. It is then cut to the required size and one end is sealed by one or more applications of adhesive. Additional folds may also be used to further strengthen the closure. The open end normally has either a lip or a thumb cut to facilitate ease of opening. Final closure of the bags is applied prior to sterilization.

A.3.5 The fourth type is the header bag. The header bag is primarily a welded seal bag fabricated from two impermeable but compatible film webs. One of the webs is usually offset by several inches. Across this offset area, a permeable material, with adhesive, is heat-sealed. This permeable material can later be peeled off allowing access to the interior of the bag. Header bags are popular for bulky items such as kits.

A.3.6 The fifth type is the process known as form/fill/seal (FFS). The sterile barrier systems that are manufactured via FFS can look just like pouches, rigid trays with lids, or can have a flexible film bottom web that has been drawn or shaped. In FFS, the top and bottom web materials are placed on the FFS machine. The machine manufactures the sterile barrier system by forming the bottom web, filling the form with the device, and applying the top-web and sealing the sterile barrier system.

A.3.7 The sixth type is the four-side-sealing (4SS) process. 4SS is a non-stop packaging process like flowpack. Most commonly it employs rotary sealing equipment to form the seal. In the 4SS process, the bottom and top webs are placed on the 4SS machine. The product is placed onto the bottom web. The top web is applied above it and, finally, all four sides are sealed. 4SS is used for packaging of gloves and wound-care products, for instance.

A.3.8 The above list of sterile barrier systems is not meant to be all inclusive. Other constructions can be acceptable as sterile barrier systems.

A.3.9 Medical devices with a sterile fluid path may use unique sterile fluid-path packaging systems directly affixed to the device fluid-path access points. These may consist of caps, plugs, covers, or other device-specific closure designs. In these cases, the primary layer of product packaging may be represented by one of the four styles discussed above, but may not be required to provide a microbial barrier for the devices.

A.3.10 Healthcare facilities typically use sterile barrier systems in the form of pouches, reels, paper bags, sterilization wrap or reusable containers.

A.3.11 Sterilization wrap is used to provide a sterile barrier system for many devices sterilized in healthcare facilities. Instead of forming a heat or adhesive seal, the wrapping and folding process provides a tortuous path that maintains sterility. Devices are typically contained in organizing instrument trays prior to wrapping and subsequent sterilization.

A.3.12 Reusable containers are constructed of metal or synthetic polymeric materials capable of withstanding repeated exposures to hospital sterilization cycles. These containers typically have matched tops and bottoms with a gasket that provides an impervious seal between the two parts. A venting system allows the sterilizing agent gasses to enter and escape from the container. The vent design and materials used for providing microbial filtration vary widely. Devices sterilized in containers may require specific preconditioning or a longer exposure time to ensure that the sterilization process is complete.

A.3.13 Terminal sterilization and sterility maintenance are essential for patient safety, irrespective of the facility that conducts these processes. This part of ISO 11607 provides minimum requirements for using packaging systems that provide appropriate sterile barrier systems.

Annex B
(informative)

Standardized test methods and procedures that may be used to demonstrate compliance with the requirements of this part of ISO 11607

B.1 General

The following documents contain provisions that may be used to demonstrate compliance with provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications should be considered. Specific requirements for the use of test methods are found in 4.4.

The criteria for inclusion of test methods and procedures in this annex are that they must be nominated for inclusion and commercially available from a standards development organization, trade association or national standards body. Consequently, the Bibliography contains additional test methods that were published in the literature. This annex is not intended to be all-inclusive and the development of new test methods is known to be underway at the time of publication.

B.2 Packaging materials and preformed sterile barrier systems

Accelerated aging	ASTM F1980:2002	Standard guide for accelerated aging of sterile medical device packages
	EN 868-8:1999	Packaging materials and systems for medical devices which are to be sterilized — Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 — Requirements and test methods
Air permeance	ISO 5636-2:1984	Paper and board — Determination of air permeance (medium range) — Part 2: Schopper method
	ISO 5636-3:1992	Paper and board — Determination of air permeance (medium range) — Part 3: Bendtsen method
	ISO 5636-5:2003	Paper and board — Determination of air permeance and air resistance (medium range) — Part 5: Gurley method
	EN 868-2:1999	Packaging materials and systems for medical devices which are to be sterilized — Part 2: Sterilization wrap — Requirements and test methods (Annex C: Method for the determination of the pore size)
	ASTM D 737-04	Standard test method for air permeability of textile fabrics
Basis weight	ISO 536:1995	Paper and board — Determination of grammage
	ASTM D4321:1999	Standard test method for package yield of plastic film

	ASTM D3776:1996	Standard test methods for mass per unit area (weight) of woven fabric
Biocompatibility	ISO 10993-1:2003	Biological evaluation of medical devices — Part 1: Evaluation and testing
	USP < 87>	Biological reactivity test, in vitro
Burst strength	ISO 2758:2001	Paper — Determination of bursting strength
Cleanliness	TAPPI T 437-OM-96	Dirt in paper and paperboard
Chlorides	ISO 9197:1998	Paper, board and pulps — Determination of water-soluble chlorides
Coat weight	ASTM F 2217:2002	Standard practice for coating/adhesive weight determination
Conditioning	ISO 187:1990	Paper, board and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples
	ASTM D4332: 2001	Standard practice conditioning containers, packages or packaging components for testing
	ISO 2233:2000	Complete, filled transport packages and unit loads — Conditioning for testing
Dimensions	ASTM F2203-02 (E01)	Standard test method for linear measurement using precision steel rule
Drapability	ISO 9073-9:1995	Textiles — Test methods for nonwovens — Part 9: Determination of drape coefficient
	ISO 2493:1992	Paper and board — Determination of resistance to bending
	DIN 53121:1978	Testing of paper and board — Determination of the bending stiffness by the beam method
Flexural durability	ASTM F392: 1999	Standard test method for flex durability of flexible barrier materials
Gas sensing	ASTM F2228-2002	Standard test method for non-destructive detection of leaks in medical packaging which incorporates porous barrier material by CO_2 tracer gas method
Integrity	ASTM F 1929:1998	Standard test method for detecting seal leaks in porous medical packaging by dye penetration
	ASTM F2227: 2002	Standard test method for non-destructive detection of leaks in non-sealed and empty medical packaging trays by CO_2 tracer gas method
Internal pressure	ASTM F2096:2002	Standard test method for detecting gross leaks in porous medical packaging by internal pressurization (Bubble test)
Low-tension surface liquid resistance	IST 80-8	Alcohol repellency on nonwoven fabrics
Microbial barrier	ASTM F1608: 2000	Standard test method for microbial ranking of porous packaging materials (Exposure chamber method)

	DIN 58953-6:1987	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
	BS 6256:1989	Specification for paper for steam sterilization paper bags, pouches and reels for medical use Appendix C: Methods for determination of methylene blue particulate penetration
	ASTM F 2101-01	Test method for evaluating the bacterial filtration efficiency (BFE) of medical face masks materials, using a biological aerosol of staphylococcus aureus
	SS 876 0019	Health care textiles — Bacterial penetration — Wet
Peel-open characteristic	EN 868-5:1999	Packaging materials and systems for medical devices which are to be sterilized — Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction — Requirements and test methods (Annex C: Determination of peel characteristics of paper/plastic laminate products)
Performance testing	ASTM D4169:2001	Practice for performance testing of shipping containers and systems
	ISTA 1,2, and 3 Series	International Safe Transit Association Preshipment Test Procedures
	ISO 4180-1:1980	Complete, filled transport packages — General rules for the compilation of performance test schedules — Part 1: General principles
	EN 868-8:1999	Packaging materials and systems for medical devices which are to be sterilized — Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 — Requirements and test methods
pH	ISO 6588-1:2005	Paper, board and pulps — Determination of pH of aqueous extracts — Part 1: Cold extraction
	ISO 6588-2:2005	Paper, board and pulps — Determination of pH of aqueous extracts — Part 2: Hot extraction
Pressure leak	ASTM F 2338:2003	Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay
Printing and coating	ASTM F2250:2003	Standard Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials
	ASTM F2252:2003	Standard Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials Using Tape
Puncture	ASTM D1709:2001	Standard test method for impact resistance of plastic film by free-falling dart method
	ASTM F1306:1998	Standard test method for slow rate penetration resistance of flexible barrier films and laminates
	ASTM D3420:2002	Standard test method for pendulum impact resistance of plastic film

Seal strength	ASTM F88:2000	Standard test method for seal strength of flexible Barrier materials
	ASTM F1140:2000	Standard test methods for failure resistance of unrestrained and nonrigid packages for medical applications
	ASTM F2054:2000	Standard test method for burst testing of flexible package seals using internal air pressurization within restraining plates
	EN 868-5:1999, Annex D	Packaging materials and systems for medical devices which are to be sterilized — Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction — Requirements and test methods
Static electricity	BS 6524:1989	Method for determination of the surface resistivity of a textile fabric
Sulfates	ISO 9198:2001	Paper, board and pulps — Determination of water-soluble sulfates
Tear resistance	ASTM D1922:2000	Standard test methods for propagation tear resistance of plastic film and thin sheeting by pendulum method
	ASTM D1938:2002	Standard test method for tear-propagation resistance (trouser tear) of plastic film and thin sheeting by a single tear-method
	ISO 1974:1990	Paper — Determination of tearing resistance (Elmendorf method)
Tensile properties	ISO 1924-2:1994	Paper and board — Determination of tensile properties — Part 2: Constant rate of elongation method
	ASTM D882:2002	Standard test method for tensile properties of thin plastic sheeting
Thickness/Density	ISO 534:2005	Paper and board — Determination of thickness, density and specific volume
	ASTM D645:1997	Standard test method for thickness of paper and paperboard
	ASTM F2251-03	Standard test method for thickness measurement of flexible packaging materials
Vacuum leak	ASTM D3078:1994	Standard test method for determination of leaks in flexible packaging by bubble emission
	EN 868-8:1999	Packaging materials and systems for medical devices which are to be sterilized — Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 — Requirements and test methods
Visual inspection	ASTM F1886:1998	Standard test method for determining integrity of seals for medical packaging by visual inspection
	EN 868-8: 1999	Packaging materials and systems for medical devices which are to be sterilized — Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 — Requirements and test methods

Water resistance	ISO 811:1981	Textile fabrics — Determination of resistance to water penetration — Hydrostatic pressure test
	EDANA 170-1-02:	Wet barrier — Mason Jar
	ASTM D779-03	Standard test method for water resistance of paper, paperboard, and other sheet materials by dry indicator method
	EN 20535:1994	Paper and board — Determination of water absorptiveness — Cobb method
Wet burst in wet condition	ISO 3689:1983	Paper and board — Determination of bursting strength after immersion in water
Wet tensile properties	ISO 3781:1983	Paper and board — Determination of tensile strength after immersion in water

Annex C
(normative)

Test method for resistance of impermeable materials to the passage of air

C.1 Impermeable materials for sterile barrier systems shall be tested for air permeance in accordance with ISO 5636-5.

Test criterion: After not less than 1 h there shall be no visible movement of the cylinder, within the tolerance of ± 1 mm.

C.2 Other test methods may be used for routine monitoring and production testing, however, these methods shall be validated against the reference test method (see C.1) for the material used.

NOTE Examples of such methods are listed in Annex B. Other methods for determining air permeance, such as the Schopper method for determination of air permeance, in accordance with ISO 5636-2 may be applicable. Conversion factors for different types of apparatus used in various methods for determination of air permeance are given in ISO 5636-1.

Bibliography

[1] ISO 186:2002, *Paper and board — Sampling to determine average quality*

[2] ISO 2859-1:1999, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

[3] ISO 5636-1:1984, *Paper and board — Determination of air permeance (medium range) — Part 1: General method*

[4] ISO 5636-2:1984, *Paper and board — Determination of air permeance (medium range) — Part 2: Schopper method*

[5] ISO 5636-5:2003, *Paper and board — Determination of air permeance and air resistance (medium range) — Part 5: Gurley method*

[6] ISO 9001:2000, *Quality management systems — Requirements*

[7] ISO 10993-1:2003, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

[8] ISO 11135:1994, *Medical devices — Validation and routine control of ethylene oxide sterilization*

[9] ISO 11137-1:2006, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

[10] ISO 11137-2:2006, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

[11] ISO 11137-3:2006, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects*

[12] ISO/TS 11139:2006, *Sterilization of health care products — Vocabulary*

[13] ISO 11607-2:2006, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

[14] ISO 13485:2003, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[15] ISO 13683:1997, *Sterilization of health care products — Requirements for validation and routine control of moist heat sterilization in health care facilities*

[16] ISO 14937:2000, *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*

[17] ISO 17665-1:—[1)], *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

1) To be published.

[18] EN 285:1996, *Steam sterilizers — Large sterilizers*

[19] EN 550:1994, *Sterilization of medical devices — Validation and routine control of ethylene oxide sterilization*

[20] EN 552:1994, *Sterilization of medical devices — Validation and routine control of sterilization by irradiation*

[21] EN 554:1994, *Sterilization of medical devices — Validation and routine control of sterilization by moist heat*

[22] EN 868-1:1997, *Packaging materials and systems for medical devices which are to be sterilized — Part 1: General requirements and test methods*

[23] EN 868-2:1999, *Packaging materials and systems for medical devices which are to be sterilized — Part 2: Sterilization wrap — Requirements and test methods*

[24] EN 868-3:1999, *Packaging materials and systems for medical devices which are to be sterilized — 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*

[25] EN 868-4:1999, *Packaging materials and systems for medical devices which are to be sterilized — Part 4: Paper bags — Requirements and test methods*

[26] EN 868-5:1999, *Packaging materials and systems for medical devices which are to be sterilized — Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction — Requirements and test methods*

[27] EN 868-6:1999, *Packaging materials and systems for medical devices which are to be sterilized — Part 6: Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation — Requirements and test methods*

[28] EN 868-7:1999, *Packaging materials and systems for medical devices which are to be sterilized — Part 7: Adhesive coated paper for the manufacture of heat sealable packs for medical use sterilization by ethylene oxide or irradiation — Requirements and test methods*

[29] EN 868-8:1999, *Packaging materials and systems for medical devices which are to be sterilized — Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 — Requirements and test methods*

[30] EN 868-9:2000, *Packaging materials and systems for medical devices which are to be sterilized — Part 9: Uncoated nonwoven materials of polyolefines for use in the manufacture of heat sealable pouches, reels and lids — Requirements and test methods*

[31] EN 868-10:2000, *Packaging materials and systems for medical devices which are to be sterilized — Part 10: Adhesive coated nonwoven materials of polyolefines for use in the manufacture of heat sealable pouches, reels and lids — Requirements and test methods*

[32] EN 1422:1997, *Sterilizers for medical purposes — Ethylene oxide sterilizers — Requirements and test methods*

[33] EN 13795-1:2002, *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*

[34] EN 14180:2003, *Sterilizers for medical purposes — Low temperature steam and formaldehyde sterilizers — Requirements and testing*

[35] ANSI/AAMI ST65:2000, *Processing of reusable surgical textiles for reprocessing in health care facilities*

[36] HANSEN, J., JONES, L., ANDERSON, H., LARSEN, C., SCHOLLA, M., SPITZLEY, J., and BALDWIN, A. 1995. In quest of sterile packaging: Part 1; Approaches to package testing. *Med. Dev. & Diag. Ind.* **17** (8): pp. 56-61

[37] JONES, L., HANSEN, J., ANDERSON, H., LARSEN, C., SCHOLLA, M., SPITZLEY, J., and BALDWIN, A. 1995. In quest of sterile packaging: Part 2; Approaches to package testing. *Med. Dev. & Diag. Ind.* **17** (9): pp. 72-79

[38] SCHOLLA, M., HACKETT, S., RUDYS, S., MICHELS, C. and BLETSOS, J. 2000. A potential method for the specification of microbial barrier properties. *Med. Dev. Technol.* **11** (3): pp. 12-16

[39] SCHOLLA, M., SINCLAIR, C.S., and TALLENTIRE, A. (1995). A European Consortium Effort to Develop a Physical Test for Assessing the Microbial Barrier Properties of Porous Medical Packaging Materials. In*: Pharm. Med. Packaging 95*, Copenhagen, Denmark

[40] TALLENTIRE, A. and SINCLAIR, C.S. (1996). A Discriminating Method for Measuring the Microbial Barrier Performance of Medical Packaging Papers. *Med. Dev. Diag. Ind.*, **18** (5), pp. 228-241

[41] SINCLAIR, C.S. and TALLENTIRE, A. (2002) Definition of a correlation between microbiological and physical articulate barrier performances for porous medical packaging materials. *PDA J. Pharm. Sci. Technol*. **56** (1): pp. 11-9

[42] JUNGHANNß, U., WINTERFELD, S., GABELE, L. and KULOW; U. Hygienic-Microbiological and Technical Testing of Sterilizer Container Systems, *Zentr. Steril.* 1999; **7** (3) pp. 154-162 under Sterile barrier systems, Package Integrity

[43] GABELE, L. and JUNGHANNß, U. Untersuchung zur Lagerdauer von Sterilgut unter Einbezug des Sterilcontainers; *Aseptica* **6**, 2000, pp. 5-7

[44] Merkblatt 45, Verpackungs-Rundschau 5/1982; Prüfung von Heißsiegelnähten auf Dichtigkeit, Herausgegeben von den Arbeitsgruppen der Industrievereinigung für Lebensmitteltechnologie und Verpackung e. V. am Fraunhofer-Institut für Lebensmitteltechnologie und Verpackung, Institut an der Technischen Universität München

[45] DUNKELBERG, H. and WEDEKIND, S. A New Method for Testing the Effectiveness of the Microbial Barrier Properties of Packaging Materials for Sterile Products; *Biomed. Technik*, **47** (2002), pp. 290-293

[46] *Test method for the microbial barrier properties of wrapping materials, new approach*; Report No. 319 011.007 RIVM (Rijksinstituut voor volksgezondheid en milieuhygiene), Netherlands

[47] *Test method for the microbial barrier properties of packaging for medical devices*; Report No. 31900, RIVM (Rijksinstituut voor volksgezondheid en milieuhygiene), Netherlands

[48] *International Vocabulary of Basic and General Terms in Metrology:* 1993, BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML

[49] AORN Journal 26 (21:334-350) *Microbiology of Sterilization*. Litsky, Bertha, Y. 1977

[50] USP 27<1031> *The biocompatibility of materials used in drug containers, medical devices and implants*