INTERNATIONAL STANDARD

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Packaging for terminally sterilized medical devices —

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

Emballages des dispositifs médicaux stérilisés au stade terminal — Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage

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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.

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 endeavour. 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
labelling
written, printed, electronic or graphic matter affixed to a medical device or its packaging system; or accompanying a medical device

NOTE Labelling 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 fulfil 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.