
**Packaging for terminally sterilized
medical devices —**

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

iTeh STANDARD PREVIEW
*Emballages des dispositifs médicaux stérilisés au stade terminal —
Partie 2: Exigences de validation pour les procédés de formage,
scellage et assemblage*
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Foreword

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

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

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

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html. (standards.iteh.ai)

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.
ISO 11607-2:2019

This second edition cancels and replaces the first edition (ISO 11607-2:2006), which has been technically revised. It also incorporates the amendment ISO 11607-2:2006/Amd.1:2014.

The main changes compared to the previous edition are as follows:

- terms and definitions for “process variable”, “process parameter” and “monitoring of processes” have been added;
- various definitions have been aligned with the latest version of ISO 11139;
- the terminology of “critical” process parameters has been discontinued and the concept of a process specification has been introduced to include all elements required to manufacture a product that consistently meets specifications.

A list of all parts in the ISO 11607 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Packaging for terminally sterilized medical devices should be designed and manufactured to ensure that the medical device can be sterilized and remain sterile under documented storage and transport conditions until the sterile barrier system is damaged or opened.

One of the most critical characteristics of a sterile barrier system and packaging system for sterile medical devices is the assurance of sterility maintenance. Medical devices delivered in a sterile state should have been manufactured, packed and sterilized by appropriate, validated methods. The development and validation of packaging processes are crucial to ensure that sterile barrier system integrity is attained and will remain so until opened by the users of sterile medical devices.

There should be a documented process validation programme demonstrating the efficacy and reproducibility of all packaging and sterilization processes. Along with the sterilization process, some of the packaging operations that can affect sterile barrier system integrity are sealing, capping or other closure systems, cutting, form/fill/seal, assembly processes and subsequent handling. This document provides the framework of activities and requirements to develop and validate the process used to make and assemble the packaging system. Guidance for ISO 11607 series can be found in ISO/TS 16775.

The term “sterile barrier system” was introduced in 2006 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.

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 health care facilities for use in internal sterilization are considered medical devices in many parts of the world.

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Packaging for terminally sterilized medical devices —

Part 2:

Validation requirements for forming, sealing and assembly processes

1 Scope

This document specifies requirements for the development and validation of processes for packaging medical devices that are terminally sterilized. These processes include forming, sealing and assembly of preformed sterile barrier systems, sterile barrier systems and packaging systems.

It is applicable to industry, to health care facilities, and to wherever medical devices are packaged and sterilized.

It does not cover all requirements for packaging medical devices that are manufactured aseptically. Additional requirements can be necessary for drug/device combinations.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11607-1:2018, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

3 Terms and definitions

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

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

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

aseptic presentation

transfer of sterile contents from its sterile barrier system using conditions and procedures that minimize the risk of microbial contamination

[SOURCE: ISO 11139:2018, 3.13]

3.2

closure

<packaging> means used to complete a sterile barrier system where no seal is formed

EXAMPLE By a reusable container gasket or sequential folding to construct a tortuous path.

[SOURCE: ISO 11139:2018, 3.51, modified — The example has been added.]

3.3

control

regulation of variables within specified limits

[SOURCE: ISO 11139:2018, 3.63]

3.4

expiry date

date by which product should be used

Note 1 to entry: For the purpose of this document and ISO 11607-1, expiry date refers to the medical device in a sterile barrier system. The term “use by date” is used to describe the shelf life of packaging materials and *performed sterile barrier systems* (3.13) prior to assembly into a *sterile barrier system* (3.25).

[SOURCE: ISO 11139:2018, 3.110, modified — The Note 1 to entry has been added.]

3.5

installation qualification

IQ

process of establishing by objective evidence that all key aspects of the process equipment and ancillary system installation comply with the approved specification

[SOURCE: ISO 11139:2018, 3.220.2]

3.6

labelling

label, instructions for use and any other information that is related to identification, technical description, intended purpose and proper use of the health care product but excluding shipping documents

[SOURCE: ISO 13485:2016, 3.8, modified — The term “medical device” has been replaced by “health care product”.]

<https://standards.iteh.ai/catalog/standards/sist/a28314ef-7d5c-401e-9366-c76f64cc7e33/iso-11607-2-2019>

3.7

medical device

instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical 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 by means of *in vitro* examination of specimens derived from the human body;

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

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- items specifically intended for cleaning or sterilization of medical devices;
- pouches, reel goods, sterilization wrap and reusable containers for packaging of medical devices for sterilization;

- disinfection substances;
- aids for persons with disabilities;
- devices incorporating animal and/or human tissues;
- devices for *in vitro* fertilization or assisted reproduction technologies.

[SOURCE: ISO 13485:2016, 3.11, modified — The first two list items in Note 1 to entry have been added.]

3.8

microbial barrier

property of a sterile barrier system to minimize the risk of ingress of microorganisms

[SOURCE: ISO 11139:2018, 3.169]

3.9

monitoring

continual checking, supervising, critically observing or determining the status in order to identify change from the performance level required or expected

[SOURCE: ISO Guide 73:2009, 3.8.2.1, modified — The note has been deleted.]

3.10

operational qualification

OQ

process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[SOURCE: ISO 11139:2018, 3.220.3]

3.11

packaging system <https://standards.iteh.ai/catalog/standards/sist/a28314ef-7d5c-401e-9366-c708c2253130-iso-11607-2-2019> combination of a *sterile barrier system* (3.25) and *protective packaging* (3.18)

[SOURCE: ISO 11139:2018, 3.192]

3.12

performance qualification

PQ

process of establishing by objective evidence that the process, under anticipated conditions, consistently produces a *product* (3.17) which meets all predetermined requirements

[SOURCE: ISO 11139:2018, 3.220.4]

3.13

preformed sterile barrier system

sterile barrier system (3.25) that is supplied partially assembled for filling and final closure or sealing

EXAMPLE Pouches, bags and open *reusable containers* (3.21).

[SOURCE: ISO 11139:2018, 3.201, modified — The example has been added.]

3.14

process parameter

specified value for a *process variable* (3.16)

Note 1 to entry: The specification for a process includes the process parameters and their tolerances.

[SOURCE: ISO 11139:2018, 3.211]

3.15

process specification

documented procedure that includes all equipment, process parameters, monitors and materials required to manufacture a product that consistently meets requirements

3.16

process variable

chemical or physical attribute within a cleaning, disinfection, packaging or sterilization process, changes in which can alter its effectiveness

EXAMPLE Time, temperature, pressure, concentration, humidity, wavelength.

[SOURCE: ISO 11139:2018, 3.213]

3.17

product

tangible result of a process

EXAMPLE Raw material(s), intermediate(s), sub-assembly(ies), healthcare product(s).

Note 1 to entry: For the purposes of this document and ISO 11607-1, products include *performed sterile barrier systems* (3.13), *sterile barrier systems* (3.25) and contents within them.

[SOURCE: ISO 11139:2018, 3.217, modified — Note 1 to entry has been added.]

3.18

protective packaging

configuration of materials designed to prevent damage to the *sterile barrier system* (3.25) and its contents from the time of their assembly until the point of use

[SOURCE: ISO 11139:2018, 3.219]

3.19

repeatability

condition of measurement, out of a set of conditions that includes the same measurement procedure, same operators, same measuring system, same operating conditions and same location, and replicate measurements on the same or similar objects over a short period of time

[SOURCE: ISO/IEC Guide 99:2007, 2.20, modified — The term name has been simplified and the notes omitted.]

3.20

reproducibility

condition of measurement, out of a set of conditions that includes different locations, processors, measuring systems, and replicate measurements on the same or similar objects

Note 1 to entry: The different measuring systems may use different measurement procedures.

Note 2 to entry: A specification should give the conditions changed and unchanged to the extent practical.

[SOURCE: ISO/IEC Guide 99:2007, 2.24, modified — The term has been simplified.]

3.21

reusable container

rigid *sterile barrier system* (3.25) designed to be used repeatedly

[SOURCE: ISO 11139:2018, 3.235]

3.22

seal

<packaging> result of joining surfaces together by fusion to form a microbial barrier

Note 1 to entry: Surfaces can be joined together by, for example, adhesives or thermal fusion.

[SOURCE: ISO 11139:2018, 3.244 modified — The Note 1 to entry has been added.]

3.23

seal strength

mechanical capacity of the seal to withstand force

[SOURCE: ISO 11139:2018, 3.246]

3.24

sterile

free from viable microorganisms

[SOURCE: ISO 11139:2018, 3.271]

3.25

sterile barrier system

SBS

minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use

[SOURCE: ISO 11139:2018, 3.272]

3.26

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

EXAMPLE The interior of the tubing for administration of an intravenous fluid.

[SOURCE: ISO 11139:2018, 3.273]

3.27

terminally sterilized

condition of a product that has been exposed to a sterilization process in its sterile barrier system

[SOURCE: ISO 11139:2018, 3.296]

3.28

validation

confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word “validated” is used to designate the corresponding status.

Note 3 to entry: The use conditions for validation can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13, modified — “process” has been added to the definition.]

4 General requirements

4.1 Quality systems

The activities described within this document shall be carried out within a formal quality system.

NOTE ISO 9001, ISO 13485, and ANSI/AAMI ST90 contain requirements for suitable quality systems. Additional requirements can be specified by a country or region.