TECHNICAL SPECIFICATION

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Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2

Emballages des dispositifs médicaux stérilisés au stade terminal — Lignes directrices relatives à l'application de l'ISO 11607-1 et l'ISO 11607-2

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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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers and associated equipment for processing of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO/TS 16775:2014), which has been technically revised.

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

— updates to reflect ISO 11607-1:2019 and ISO 11607-2:2019 editions;

— intent and guidance is provided for each clause of the standard to improve usability of this document.

— new annexes have been added;

— some annexes have been removed.

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

Sterile barrier systems are intended to allow for sterilization, provide physical protection, maintain the sterility of their contents until the point of use and ensure aseptic presentation. The sterile barrier system, depending on conditions of handling, distribution or storage, can be combined with additional protective packaging to create a packaging system.

ISO 11607-1 specifies the requirements for materials, sterile barrier systems, and packaging systems, including the validation of the packaging system design while ISO 11607-2 specifies the requirements for packaging process validation. The requirements outlined in these standards are generic and are applicable to healthcare facilities and wherever medical devices are packaged and sterilized. It is recognized that the circumstances of the application of these standards will be different when they are used in a healthcare facility, by a medical device manufacturer or reprocessor.

This document provides guidance on the application of ISO 11607-1 and ISO 11607-2. This latest revision has been completely reorganised following the structure of ISO 11607-1 and ISO 11607-2 and referring to individual or groups of clauses or subclauses while indicating the intent of the requirements followed by relevant guidance. It can be used for the systematic application of ISO 11607-1 and ISO 11607-2 or as a reference when questions come up about specific requirements. Clause 4 covers the general requirements that are identical in ISO 11607-1 and ISO 11607-2, while Clause 5 applies to ISO 11607-1:2019 and Clause 6 to ISO 11607-2:2019. Guidance on the application of risk management over the packaging life cycle has been added in anticipation of the upcoming amendments to ISO 11607 (all parts).

This guidance document is applicable to healthcare facilities and to industry while differences for the two environments are addressed as necessary. Although healthcare facilities are usually not involved in sterile barrier system design tasks, their part in the sterile barrier system and packaging system design process consists of carefully selecting an appropriate sterile barrier system and protective packaging based on the identified risks related to the content, sterilization method, transport, storage and aseptic presentation. Sterile barrier and packaging systems and the related processes must then be properly validated, and sealing, closure and assembly processes must be controlled and monitored. To ensure patient safety, healthcare facilities should develop written procedures to be implemented by adequately trained personnel. Guidance given in the annexes of this document is applicable to healthcare facilities and/or industry, as indicated.

The conditions of use of this guidance can vary widely around the world and can be subject to interpretation by circumstances and regulatory environments.

Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2

1 Scope

This document provides guidance for the application of the requirements contained in ISO 11607-1 and ISO 11607-2. It does not add to, or otherwise change, the requirements of ISO 11607-1 and ISO 11607-2. This is an informative document, not normative. It does not include requirements to be used as basis of regulatory inspection or certification assessment activities.

The guidance can be used to better understand the requirements of ISO 11607-1 and ISO 11607-2 and illustrates the variety of methods and approaches available for meeting the requirements of those International Standards. It is not required that this document be used to demonstrate conformity with them.

Guidance is given for evaluation, selection and use of packaging materials, preformed sterile barrier systems, sterile barrier systems and packaging systems. Guidance on validation requirements for forming, sealing and assembly processes is also given.

This document provides information for both healthcare facilities and the medical devices industry for terminally sterilized medical devices.

This document does not provide guidance for applications of packaging materials and systems after their opening. In the use of packaging for other purposes such as a "sterile field" or transport of contaminated items, other regulatory standards will apply.

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 11607-1:2019, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2:2019, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11607-1:2019 and ISO 11607-2:2019 and the following apply.

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
process
set of interrelated or interacting activities that use inputs to deliver an intended result

Note 1 to entry: Whether the "intended result" of a process is called output, product or service depends on the context of the reference.

Note 2 to entry: Inputs to a process are generally the outputs of other processes and outputs of a process are generally the inputs to other processes.

Note 3 to entry: Two or more interrelated and interacting processes in series can also be referred to as a process.

[SOURCE: ISO 9000:2015, 3.4.1, modified — Notes to entry 4, 5 and 6 are deleted.]

3.2
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO/IEC Guide 63: 2019, 3.10, modified — Note 1 to entry deleted.]

3.3
risk control
process (3.1) in which decisions are made and measures implemented by which *risks* (3.2) are reduced to, or maintained within, specified levels

[SOURCE: ISO/IEC Guide 63: 2019, 3.12]

3.4
risk estimation
process (3.1) used to assign values to the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO/IEC Guide 63: 2019, 3.13]

3.5
risk evaluation
process (3.1) of comparing the estimated *risk* (3.2) against given risk criteria to determine the acceptability of the risk

[SOURCE: ISO/IEC Guide 63: 2019, 3.14]

4 Guidance on Clauses 1-4 of ISO 11607-1:2019 and ISO 11607-2:2019

4.1 Scope (ISO 11607-1:2019, Clause 1 and ISO 11607-2:2019, Clause 1)

4.1.1 Intent

The objective of the scope is to outline the purpose of the standard, its applicability, as well as any exclusions or limitations.

4.1.2 Guidance

ISO 11607-1:2019 and ISO 11607-2:2019 are "group standards" as defined in ISO 16142-1[1] as it applies to a wide range of packaging types that are intended to maintain sterility of terminally sterilized medical devices until the point of use**.** Group standards are horizontal in nature within the medical device sector and are developed to address the essential principles that are applicable to a wide range of medical devices. Furthermore, as defined by ISO 16142-1, ISO 11607-1:2019 and ISO 11607-2:2019 are also process standards. Process standards provide the requirements for manufacturers to develop, implement, and maintain processes applicable to all stages of the lifecycle of a medical device. These processes are typically established in the frame of a quality management system like ISO 13485[2] or

ISO 9001[3], although these standards are not a normative requirement as outlined in Clause 4 of this document.

The scopes of ISO 11607-1 and ISO 11607-2 apply to healthcare facilities, medical device manufacturers and wherever medical devices are placed in sterile barrier systems (SBSs), packaged and sterilized. It is recognized that the circumstances of the application of these documents will be different when they are used in a healthcare facility compared with when they are used by a medical device manufacturer or reprocessor.

ISO 11607-1:2019 and ISO 11607-2:2019 can also be applied by any suppliers of packaging materials or preformed SBSs. In this case the conformity statements will be limited to what the manufacturer can claim since full conformance is only possible for the completely sealed or closed SBS validated for a specific device or family of devices. Manufacturers of materials and preformed SBSs should clearly indicate what is covered and not covered in their conformity statements.

As a summary, ISO 11607-1:2019 and ISO 11607-2:2019 are horizontal group standards and process standards applicable to several stages of the lifecycle of sterile medical packaging providing the requirements for:

a) packaging materials, preformed SBSs and SBSs (ISO 11607-1:2019, Clause 5);

b) the development process of the SBSs and the packaging system including:

- the required forming, sealing and assembly processes;
- the design validations;
- the process validations;
- revalidations, periodic, if applicable, and in case of changes;
- change controls;
- the controls during routine operations.

It addresses materials, packaging, and also combination of packaging and device. It covers also sterile fluid path packaging where the SBS functionality is integrated with the construction of the device. ISO 11607-2 is applicable wherever a seal or closure is formed and was never intended to cover manufacturing of materials like sheets of sterilization wrap or rigid trays that are manufactured outside of a form-fill-seal process.

4.2 Normative references (ISO 11607-1:2019, Clause 2 and ISO 11607-2:2019, Clause 2)

4.2.1 Intent

Normative references list standards which are required to understand and to apply the standard.

This clause provides the normative references to other standards that apply as well to conform with the requirements of ISO 11607-1:2019 and ISO 11607-2:2019.

4.2.2 Guidance

Normative references are referred to in the text of a standard in such a way, that some or all of the cited content constitutes requirements for the document. In order to be able to apply the standard, all normatively cited references should be available to the user.