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ISO 11607-2: 2019, IDT
(ICS 11.080.30)

SINGAPORE STANDARD

Packaging for terminally sterilised medical devices

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

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The content of this Singapore Standard was approved on 30 August 2019 by the Biomedical and Health Standards Committee (BHSC) under the purview of the Singapore Standards Council.

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The organisations in which the experts of the National Mirror Working Group are involved are:

Access-2-Healthcare

BioPharmaSpec UK Ltd

Edwards Lifesciences (Singapore) Pte Ltd

Sanmina Corporation Singapore

Singapore Manufacturing Federation (Medical Technology Industry Group)

Stendard

SystemED Pte Ltd

TÜV SÜD PSB Pte Ltd

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Contents

National Foreword	6
Foreword	7
Introduction	8
1 Scope	9
2 Normative references	9
3 Terms and definitions	9
4 General requirements	14
4.1 Quality systems	14
4.2 Risk management	14
4.3 Sampling	15
4.4 Test methods	15
4.5 Documentation	15
5 Validation of packaging processes	16
5.1 General	16
5.2 Installation qualification	16
5.3 Operational qualification	17
5.4 Performance qualification	18
5.5 Formal approval of the process validation	19
5.6 Process control and monitoring	19
5.7 Process changes and revalidation	19
6 Assembly	20
7 Use of reusable sterile barrier systems	20
8 Sterile fluid-path packaging	20
Annex A (informative) Process development	21
Bibliography	22

National Foreword

This Singapore Standard was prepared by the National Mirror Working Group on ISO/TC 210 set up by the Technical Committee on Quality Management Systems under the purview of BHSC.

This standard is identical with ISO 11607-2:2019, “Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes”, published by the International Organization for Standardization.

NOTE – Reference to International Standards are replaced by applicable Singapore Standards/Technical References.

Attention is drawn to the possibility that some of the elements of this Singapore Standard may be the subject of patent rights. Enterprise Singapore shall not be held responsible for identifying any or all of such patent rights.

NOTE

- 1. Singapore Standards (SSs) and Technical References (TRs) are reviewed periodically to keep abreast of technical changes, technological developments and industry practices. The changes are documented through the issue of either amendments or revisions. Where SSs are deemed to be stable, i.e. no foreseeable changes in them, they will be classified as “Mature Standards”. Mature Standards will not be subject to further review, unless there are requests to review such standards.*
- 2. An SS or TR is voluntary in nature except when it is made mandatory by a regulatory authority. It can also be cited in contracts making its application a business necessity. Users are advised to assess and determine whether the SS or TR is suitable for their intended use or purpose. If required, they should refer to the relevant professionals or experts for advice on the use of the document. Enterprise Singapore and the Singapore Standards Council shall not be liable for any damages whether directly or indirectly suffered by anyone or any organisation as a result of the use of any SS or TR. Although care has been taken to draft this standard, users are also advised to ensure that they apply the information after due diligence.*
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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).

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

For an explanation 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.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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.

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*