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Packaging for terminally sterilized medical devices —

Part 3: Requirements for process development for forming, sealing and assembly

Emballages des dispositifs médicaux stérilisés au stade terminal —

Partie 3: Exigences relatives à la mise au point des procédés de formage, scellage et assemblage

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Foreword

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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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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).

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

ISO 11607-1 and ISO 11607-2 specify requirements for the design and validation of sterile barrier systems for terminally sterilized medical devices, and the validation requirements for manufacturing processes of sterile barrier systems, respectively. The heat sealing of a sterile barrier system is critical to the maintenance of sterile barrier integrity to the point of use; however, there is little content available for process development in the current edition of ISO 11607-2.

This document specifies requirements for the development of heat sealing processes to meet sterile barrier seal design requirements. A thorough development process with a high-quality output is an important input to an efficient validation of the process. While a successful validation is essential to ensure the safety of terminally sterilized medical devices, there is no intention to imply that the process development approach proposed in this document is the only valid approach. Users of this document can use the activities described in this document to control risks associated with heat sealing processes, if they find it appropriate. Additionally, this document specifies a process for documenting the equivalence of heat sealing processes which can be a benefit to users in support of change control activities since it can create the basis to leverage the efforts over a range of heat sealing equipment or over a sterile barrier system family.

This document is intended for use by industrial manufacturers engaged in the design and development of sterile barrier systems and heat sealing processes. Effective application of the requirements described in this document requires proficiency in design of experiment (DOE) methodologies and access to the requisite testing resources for result evaluation. Producers of preformed sterile barrier systems, as well as medical device manufacturers, rely heavily on heat sealing, among other techniques, to create sterile barrier systems that ensure device integrity and sterility at various stages of distribution and handling of sterile devices until the point of use and aseptic presentation. This process often involves the operation of multiple, interchangeable heat sealers to produce commercial quantities of sterile barrier systems.

For healthcare facilities (e.g. hospitals), ISO/TS 16775:2021, Annex B contains all relevant guidance for sterile barrier system closure technologies including sealing, reusable container closures and wrapping processes.

Packaging for terminally sterilized medical devices —

Part 3:
Requirements for process development for forming, sealing and assembly

1 Scope

This document specifies requirements for process development for forming, sealing and assembly of packaging for medical devices to be terminally sterilized, when utilizing heat sealing technologies.

This document recommends minimum heat sealing equipment features to support subsequent validation, process control and monitoring.

This document applies to both preformed sterile barrier systems and sterile barrier systems.

This document utilizes the sterile barrier system specification to develop the process specification using the principles of risk management.

This document is intended to be used prior to process validation.

NOTE ISO 11607-2 provides requirements for process specification and process validation.

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

ISO 11607-2:2019/Amd 1:2023, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes — Amendment 1: Application of risk management*

3 Terms and definitions

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

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

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

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

3.1
assembly
<packaging> process of putting together all components of a sterile barrier system, including packaging materials and contents

3.2
control
regulation of variables within specified limits

[SOURCE: ISO 11139:2018, 3.63]

3.3
forming
<packaging> process of bringing materials into contact with each other or into the necessary position for heat sealing or closure processes to create a sterile barrier system

Note 1 to entry: Forming in this context does not include thermoforming, cold-forming, forming the thermoform portion of form-fill-seal, fabrication of the material.

3.4
monitoring
continual checking, supervising, critically observing or determining the status in order to identify change from the performance level required or expected

[SOURCE: ISO 11139:2018, 3.180]

3.5
process parameter
specified value for a process variable

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

[SOURCE: ISO 11139:2018, 3.211]

3.6
process specification
documented procedure that includes all equipment, process parameters, monitors and materials required to manufacture a product that consistently meets requirements

[SOURCE: ISO 11607-2:2019, 3.15]

3.7
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]

3.8
seal
<packaging> result of joining surfaces together by fusion to form a microbial barrier

Note 1 to entry: For sealing by thermal fusion, this can include multiple heat sealing equipment technologies, but not cold sealing.

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

3.9
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]

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

4.2 Risk management

A risk management process conforming with the requirements of ISO 11607-2/Amd 1:2023 shall be implemented.

4.3 Sampling

Sampling plans based upon a statistically valid rationale are required for validation per ISO 11607-2. Application of statistical aspects for sampling plans used in development of heat sealing processes is helpful. This can include a rationale on statistical aspects regarding the materials, risks and sterile barrier systems being evaluated.

NOTE Statistically valid indicates the use of a methodology that ensures the sample size and selection process are appropriate for drawing reliable and accurate conclusions.

4.4 Test methods

Test methods used for activities described in this document shall meet the test method validation requirements of ISO 11607-2. Process development may include preliminary evaluation methods which do not require validation.

NOTE Preliminary evaluation methods focus on understanding the characteristics, attributes, or qualities of a product or process (e.g. visual scoring method for heat seals which includes estimating attributes of a heat seal). See Annex A, particularly A.2.4.

4.5 Documentation

Documentation of activities described in this document shall meet the documentation requirements of ISO 11607-2:2019, 4.5.

5 Process development

5.1 General

5.1.1 The requirements of this document are intended to be applied to heat sealing processes that have not yet been validated. Existing SBS and preformed SBS heat sealing processes that have successfully met the validation requirements of ISO 11607-2 may be regarded as sufficient evidence that appropriate process development has occurred; therefore, no additional process development activities according to this document shall be required.

NOTE 1 The heat sealing processes of interest are those for SBS seals that establish a microbial barrier. Other types of seals, such as those used for containment or spot welds for wraps bonding, are not used to create a microbial barrier and are not covered in this document.

NOTE 2 This document provides an approach that meets the process development requirements for consistency; however, there can be other valid approaches.

5.1.2 When process development is conducted prior to installation qualification (IQ), a documented rationale should assess any risk with production equivalence and impact to process input and design output.