SLOVENSKI STANDARD
SIST EN ISO 11607-2:2020/oprA1:2022

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Embalaža za končno sterilizirane medicinske pripomočke - 2. del: Zahteve za validacijo pri procesih oblikovanja, označevanja in sestavljanja - Dopolnilo A1 (ISO 11607-2:2019/DAM 1:2022)

Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes - Amendment 1 (ISO 11607-2:2019/DAM 1:2022)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens - Änderung 1 (ISO 11607-2:2019/DAM 1:2022)

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage - Amendement 1 (ISO 11607-2:2019/DAM 1:2022)

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ICS:

11.080.30	Sterilizirana embalaža	Sterilized packaging

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DRAFT AMENDMENT
ISO 11607-2:2019/DAM 1

ISO/TC **198** Secretariat: **ANSI**

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Packaging for terminally sterilized medical devices —

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

AMENDMENT 1

Emballages des dispositifs médicaux stérilisés au stade terminal —

Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage

AMENDEMENT 1

ICS: 11.080.30

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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*.

This amendment revises Clause 3 and 4.2 and adds a normative Annex B on risk management.

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.

Packaging for terminally sterilized medical devices —

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

AMENDMENT 1

Introduction

Add the following as the last paragraph:

Amendment 1 expands on the application of risk management throughout the phases of design and development, validation and production of the packaging system.

Clause 1

Delete the following text from the scope: *It is applicable to industry, to health care facilities, and to wherever medical devices are placed in sterile barrier systems and sterilized.*

Clause 2

Correct the normative reference ISO 11607-1:2018 to ISO 11607-1:2019.

Clause 3

Add the following:

3.xx

hazard

potential source of harm

[SOURCE: ISO/IEC Guide 63: 2019, 3.2]

3.xx

intended use

intended purpose

use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer

Note 1 to entry: The intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the intended use.

[SOURCE: ISO/IEC Guide 63:2019, 3.4]

3.xx

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.xx

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]

4.2

Replace the text with the following:

4.2 Risk management

A risk management process conforming with the requirements of Annex B shall be implemented.

NOTE Annex B details requirements for the risk management process for forming, sealing and assembly of sterile barrier systems which is a subset of risk management for medical devices. Additional requirements for risk management of medical devices including sterile packaging can be specified by some regulatory jurisdictions. ISO 14971 covers application of risk management to medical devices and guidance on the application of ISO 14971 can be found in ISO/TR 24971[1].

4.4.3

Replace the NOTE to 4.4.3 with the following text:

NOTE Annex B contains a list of test methods. Publication of a method by a standards body does not make it validated by the user of the test method.

Annex B

Add the following Annex B after Annex A.

Annex B
(normative)

Risk management

B.1 General

An ongoing risk management process shall be established, implemented, documented and maintained to minimize the risk for the user and the patient. This process shall include:

a) identification of hazards and hazardous situations associated with the forming, sealing, and assembly processes for packaging (see B.4);

b) estimation (see B.5) and evaluation (see B.6) of the associated risks;

c) risk control (see B.7);

d) monitoring the effectiveness of the risk control measures (see B.8).

NOTE 1 Local regulatory requirements can provide mandatory criteria for risk acceptability or these criteria can be based on the generally accepted state of the art.

NOTE 2 FMEA is an example of risk analysis tool that is used widely in the industry.

B.2 Application of the risk management process

This process shall apply throughout the phases of design and development, validation, production and post-production of the process for forming, sealing and assembly of sterile barrier systems. The following shall be included:

a) Design and development phase

— Sealing and assembly process development (see 5.1).

NOTE Packaging system design is addressed in ISO 11607-1.

b) Validation phase

— Process validation (see 5.2, 5.3, 5.4 and 5.5).

NOTE Performance testing, stability testing and usability evaluation are addressed in ISO 11607-1.

b) Production phase

— Process control and monitoring (see 5.6);

— Assembly (see Clause 6);

— Use of reusable sterile barrier systems (see Clause 7) if applicable;

— Process changes and revalidation (see 5.7).

NOTE Packaging system changes are addressed in ISO 11607-1.

c) Post-production phase

— If post-production information is available which can be related to the performance of the process for forming, sealing and assembly of sterile barrier systems, it shall be analysed to

determine if risks are controlled appropriately or if unidentified hazards or hazardous situations are present. Consequent corrective and preventive actions shall be implemented as needed.

NOTE 1 This can include redesign, additional controls or revalidation.

NOTE 2 ISO 11607-2 does not include requirements for collecting post-production information or for reporting adverse events and field safety corrective actions to authorities or other related activities. This is typically established based on the requirements of the quality management system.

B.3 Risk management plan

B.3.1 General

A risk management plan shall be documented in accordance with the risk management process for each process for forming, sealing and assembly of sterile barrier systems including at a minimum

— scope of the planned risk management activities;

— criteria for risk acceptability;

— activities for verification of the implementation and effectiveness of risk control measures.

Risk management plans and related documentation for forming, sealing and assembly of sterile barrier systems may be combined with those for the medical device.

B.3.2 Criteria for risk acceptability

Criteria for risk acceptability shall be developed based on the following principles**:**

— aligned with the device to be packaged and its intended use;

— aligned with the intended use environment and related aseptic presentation;

— differentiate between critical and essential design requirements (e.g. integrity) and lesser impact requirements (e.g. dimensional variance);

— consider the hazards defined in Table B.1, taking into account generally acknowledged state-of- the-art acceptance criteria as applicable.

B.3.3 Similar processes for forming, sealing and assembly

Risk management plans for similar processes for forming, sealing and assembly of sterile barrier systems may be combined, in which case the rationale for these similarities shall be documented.

B.4 Specific hazards and hazardous situations to be addressed

For each of the following hazards, considering both normal and fault conditions, sequences of events shall be identified and the resulting hazardous situations evaluated.

— Microbial contamination;

— Chemical contamination;

— Adverse environmental, processing and use conditions;

— Misleading information.

See Table B.1 for examples of hazards and contributing factors:

Table B.1 — Hazards and contributing factors

Hazard	Possible contributing factors
Microbial contamination	Airborne, surface or material microbial contamination
Chemical contamination	process residuals (e.g. EO residual), cleaning agents,
Adverse environmental, processing and use conditions	Exposure to incompatible temperature / pressure / humidity or moisture / UV lighting / shock / vibration (all storage and transport conditions)
	Inadequate or uncontrolled manufacturing process including the work environment and human factors
Misleading information	Labeling / printing application inadequate
	Misallocation (incorrect label, information, data, etc.)

B.5 Risk estimation

For each identified hazardous situation, the associated risk(s) shall be estimated using available information or data.

Hazardous situations shall be assessed based on the probability of occurrence of that hazardous situation and the potential severity of related harm.

For hazardous situations for which the probability of the occurrence of harm cannot be estimated, the possible consequences shall be listed for use in risk evaluation and risk control.

The risk estimate may include detectability if the ability to detect the hazardous situation can be directly assessed.

B.6 Risk evaluation

Under risk evaluation, estimated risks shall be compared against criteria for risk acceptability defined in the risk management plan to identify risks to be controlled.

B.7 Risk control

Risk shall be controlled by implementing appropriate measures such that they are reduced to, or maintained within, levels as defined by the criteria for risk acceptability.

Risk control in packaging system forming, assembly and sealing for terminally sterilized medical devices shall be based on the following principles in the priority order listed:

a) eliminate or reduce risks as far as possible through use of validated and controlled processes for forming, assembly and sealing;

b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated;

c) provide information and training on risk control measures performed by process operators (e. g. inspections, maintenance, monitoring, etc).