SLOVENSKI STANDARD
SIST EN ISO 11607-1:2020/oprA1:2022

01-oktober-2022

Embalaža za končno sterilizirane medicinske pripomočke - 1. del: Zahteve za materiale, sterilne pregradne sisteme in sisteme embalaže - Dopolnilo A1 (ISO 11607-1:2019/DAM 1:2022)

Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems - Amendment 1 (ISO 11607-1:2019/DAM 1:2022)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 1: Anforderungen an Materialien, Sterilbarrieresysteme und Verpackungssysteme - Änderung 1 (ISO 11607-1:2019/DAM 1:2022)

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage - Amendement 1 (ISO 11607-1:2019/DAM 1:2022)

Ta slovenski standard je istoveten z: **EN ISO 11607-1:2020/prA1**

ICS:

11.080.30	Sterilizirana embalaža	Sterilized packaging

SIST EN ISO 11607-1:2020/oprA1:2022 **en,fr,de**

DRAFT AMENDMENT
ISO 11607-1:2019/DAM 1

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

Voting begins on: **2022-08-02** Voting terminates on: **2022-10-25**

Packaging for terminally sterilized medical devices —

Part 1: Requirements for materials, sterile barrier systems and packaging systems

AMENDMENT 1

Emballages des dispositifs médicaux stérilisés au stade terminal —

Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage

AMENDEMENT 1

ICS: 11.080.30

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO 11607-1:2019/DAM 1:2022(E)

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Foreword

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

This amendment to ISO 11607-1:2019 revises the introduction, Clause 3, 4.2 and 6.1.1 and adds a normative Annex F on risk management as well as an informative annex G with guidance on packaging 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.

Introduction

Add the following as the last paragraph:

Packaging for terminally sterilized medical devices —

Part 1: Requirements for materials, sterile barrier systems and packaging systems

AMENDMENT 1

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 3

3.7

Replace term and definition with the definition from ISO 13485:2016, 3.8 as follows:

3.7

labelling

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

[SOURCE: ISO 13485:2016, 3.8]

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

reasonably foreseeable misuse

use of a product or system in a way not intended by the manufacturer, but which can result from readily predictable human behaviour

Note 1 to entry: Readily predictable human behaviour includes the behaviour of all types of users, e.g. lay and professional users.

Note 2 to entry: Reasonably foreseeable misuse can be intentional or unintentional.

[SOURCE: ISO/IEC Guide 63:2019, 3.8]

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 F shall be implemented.

NOTE Annex F details requirements for the packaging risk management process which is a subset of risk management for medical devices. Annex G provides background information on risk management for medical device packaging. 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.

6.1.1

Replace the text with the following:

6.1.1 The packaging system shall be designed to minimize the risks as specified in Annex F to the user and patient during intended use/purpose and/or reasonably foreseeable misuse.

NOTE 1 The requirement under 6.1.1 combines intended use as used in the United States and intended purpose which is the term in the European Union. These terms have essentially the same meaning.

NOTE 2 See also 4.2 as well as Annex G for guidance on packaging risk management.

Annex F, Annex G

Add the following annex F and annex G after Annex E.

Annex F
(normative)

Risk management

F.1 Risk management process

An ongoing risk management process applicable to packaging systems shall be established, implemented, documented and maintained. This process shall include:

a) identification of hazards and hazardous situations associated with the packaging system (see F.4, G.2.1, G.2.2, and G.2.3);

b) estimation (see F.5) and evaluation (see F.6) of the associated risks (see G.2.4 and G.2.5);

c) risk control (see F.7 and G.2.6);

d) monitoring of the effectiveness of the risk control measures (see F.8, G.2.7 and G.2.8).

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.

F.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 packaging system. The following shall be included:

a) Design and development phase

— Packaging system design (see Clause 6, G.2.6.1, G.2.6.2, G.2.6.3 and G.2.7.2).

NOTE Sealing and assembly process development is addressed in G.2.6.4 and ISO 11607-2.

b) Validation phase

— Performance and stability testing (see Clause 8 and G.2.7.3);

— Usability evaluation (see Clause 7 and G.2.7.2).

NOTE Process validation is addressed in G.2.7.4 and ISO 11607-2.

c) Production phase

— Packaging system changes (see Clause 9 and G.2.9).

NOTE Process control and monitoring, assembly, use of reusable sterile barrier systems, process changes and revalidation are addressed in ISO 11607-2 and G.2.8.

d) Post-production phase

— If post-production information is available on the performance of the packaging system, 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 11607-1 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.

F.3 Risk management plan

F.3.1 General

A risk management plan shall be documented in accordance with the risk management process for each packaging system including as 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 packaging systems may be combined with those for the medical device.

F.3.2 Criteria for risk acceptability

Criteria for risk acceptability shall be developed based on the following principles (see also G.2.5):

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

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

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

— consider the hazards defined in Table F.1, taking into account generally acknowledged state-of- the-art acceptance criteria as applicable (e.g. biocompatibility).

F.3.3 Similar packaging systems

Risk management plans for similar packaging systems may be combined, in which case the rationale for these similarities shall be documented.

F.4 Specific hazards and hazardous situations to be addressed

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

— Microbial contamination;

— Chemical contamination;

— Adverse environmental, processing and use conditions;

— Misleading information.

Table F.1 provides examples of hazards and contributing factors.

Table F.1 — Hazards and contributing factors

Hazard	Possible contributing factors
Microbial contamination	Airborne, surface or material microbial contamination