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**AMENDMENT 1**
**2023-09**

# Packaging for terminally sterilized medical devices —

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

## AMENDMENT 1: Application of risk management

*Emballages des dispositifs médicaux stérilisés au stade terminal —*

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

*AMENDEMENT 1: Application de la gestion des risques*



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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 for medical purposes,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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# Packaging for terminally sterilized medical devices —

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

## AMENDMENT 1: Application of risk management

*Clause 1, Scope*

Delete the following text:

> It is applicable to industry, to health care facilities, and to wherever medical devices are packaged and sterilized.

*Clause 2, Normative references*

> Correct ISO 11607-1:2018 to ISO 11607-1:2019 and ISO 11607-1:2019/Amd 1:2023.

*Clause 3*

Add the following:

**3.29**
**hazard**
potential source of harm

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

**3.30**
**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 were deleted.]

**3.31**
**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 was 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.

*4.4.3, NOTE*

Replace the NOTE with the following text:

NOTE ISO 11607-1:2019, 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.

*Clause 7*

Correct ISO 11607-1:2018 to ISO 11607-1:2019

*Bibliography*

Add the following new entry:

[17] ISO/TR 24971:2020, *Medical devices — Guidance on the application of ISO 14971*

*Annex B*

Add the following new 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 ISO/TR 24971:2020, Annex B provides examples of techniques that support risk analysis. FMEA is an example of a risk analysis tool.

## 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

— Forming, sealing and assembly process development (see 5.1).

NOTE 1 Process development includes defining required process elements (e.g. sealers, conveyers, forming equipment, assembly tools). See Annex A for information on process development.

NOTE 2 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.

c) 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.

d) 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 The corrective and preventive actions can include redesign, additional controls or revalidation.

NOTE 2 This document 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.

NOTE 3 For guidance on risk management for medical device packaging see ISO 11607-1:2019/Amd1:2023, Annex G.

## 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 least the following:

— the 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 records and 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**:**

— align with the device SBS specification or preformed SBS specification as applicable;

— differentiate between critical and essential 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.

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 The manufacturing of a preformed SBS will only need a preformed SBS specification.

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 from the process evaluated.

— microbial contamination;

— chemical contamination;

— adverse environmental and processing 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. lubricants), cleaning agents |
| Adverse environmental and processing conditions | Exposure of packaging materials to incompatible temperature / pressure / humidity or moisture / UV lighting / shock / vibration |
| | Inadequate or uncontrolled manufacturing process including the work environment and human factors |
| Misleading information | Labelling / printing application inadequate |
| | Misallocation (e.g. incorrect label, information, data) |

## 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 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 determine if the risk is acceptable or not and 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 and reduce risk through process development as well as consideration of potential design modifications of packaging or contents, to make the process inherently safe;

b) take adequate measures to control the process (e.g. process monitors, in-process controls, alarms, alignment aids/fixtures);

c) provide information on potential failure modes to operators and inspect the output.