NPG | Network Partners Group

NPG | Network Partners Group

# Executive Summary of Revisions

## ISO 11607-1 & 2:2019/Amd.1:2023(E)

# ISO 11607-1&2: 2019/Amd.1:2023(E)

## Summary

Amendment 1:2023 represents the first substantial revision to ISO 11607 Parts 1 and 2 since the 2019 release.

Other than a short list of administrative edits, the big news is the addition of two new Annexes (F and G) to Part 1 and one new Annex (B) to Part 2, all covering in-depth the important topic of Risk Management applied to Medical Device Packaging. Up until recently, the subject of Risk Management for Medical Devices was mostly found in ISO 14971 and its guidance document, ISO/TR 24971. As a result, risk management principles for medical device packaging had to be adapted with some interpretation. However, with Amendment 1:2023, the subject of risk management for medical device packaging has now been built directly into ISO 11607. (Hopefully this means less guesswork for us "packaging folks," going forward)!

What follows is an outline view of the changes plus table of contents for the above referenced Annexes contained in each Amendment.

Amendment 1:2023 for ISO 11607:1 and ISO 11607:2 are both copyrighted material, they must be purchased directly from ISO or other authorized sources.

Additional note: The Amendment text only shows revisions/additions that have been made. Neither Amendment is a “redline version” of the ISO 11607 text.

# ISO 11607-1: 2019/Amd.1:2023(E)

## Changes included in Amendment 1:2023 (English)

- 10 administrative edits
- 3 biographical references added
- 2 New Annexes covering Risk Management for Medical Device Packaging

**I. Ten Administrative edits:**

a. Redundant statement removed in Clause 1, Scope

b. Revised Terms and Definitions (6 definitions revised or added to harmonize with other ISO standards)

i. 3.7 labelling
ii. 3.32 hazard
iii. 3.33 intended use, intended purpose
iv. 3.34 process
v. 3.35 reasonably foreseeable misuse
vi. 3.36 risk

c. 4.2 Risk management

Internal references added directing reader to new Annexes F and G

d. 4.4.3 Test methods NOTE changed:

FROM:

"Annex B contains a list of test methods. Publication of a method by a standards body does not make it validated in any laboratory."

TO:
"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."

e. 6.1.1 Statement revised with "foreseeable misuse," plus references to Annex F and G added.

**II. Three new ISO references added to Bibliography list.**

**III. TWO NEW ANNEXES (F and G) added RE: Risk Management applied to Medical Device Packaging**

Reminder: "Normative" = required / "Informative" = Reference Only

## Annex F

(normative)

# Risk management

**Annex G**
(Informative)

Risk management for medical device packaging — Rationale for requirements

# ISO 11607-2: 2019/Amd.1:2023(E)

## Changes included in Amendment 1:2023 (English)

- 8 administrative edits.
- 1 biographical reference added.
- 1 New Annex covering Risk Management for Medical Device Packaging (virtually identical to Annex F of ISO 11607-1:2019/Amd1:2023).

**I. Eight Administrative edits:**

a. Clause 1, Scope: Redundant statement removed.
b. Clause 2: Administrative correction to ISO 11607-1:2019 reference.
c. Clause 3: Revised Terms and Definitions (3 definitions added to harmonize with other ISO standards).
    i. 3.29 hazard
    ii. 3.30 process
    iii. 3.31 risk
d. 4.2 Risk management
    i. Internal references added directing reader to new Annex B.
e. 4.4.3 Test methods NOTE changed:
    FROM:
    "Annex B of ISO 11607-1 contains a list of test methods. Publication of a method by a standards body does not make it validated in any laboratory."
    TO:
    "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."
f. Clause 7: Administrative correction to ISO 11607-1:2019 reference.

**II. One new ISO reference added to Bibliography list.**

**III. ONE NEW ANNEX (B) added RE: Risk Management applied to Medical Device Packaging Process.**

Reminder: "Normative" = required

## Annex B

(Normative)

# Risk management

B.1 General

B.2 Application of the risk management process

- B.2.1 Design and development phase
- B.2.2 Validation phase
- B.2.3 Production phase
- B.2.4 Post-production phase

B.3 Risk management plan

- B.3.1 General
- B.3.2 Criteria for risk acceptability

B.4 Specific hazards and hazardous situations to be addressed

Table B.1 — Hazards and contributing factors

B.5 Risk estimation

B.6 Risk evaluation

B.7 Risk control

B.8 Monitoring effectiveness of risk control measures