

ISO 11607: Packaging Validation Crosswalk (Part 1 ↔ Part 2)

LSO | Medical Package Testing — One-page map from requirements to process & evidence

Organization:		Project/VMF:					
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Topic / Clause (Part 1 or 2)	Part 1 — Evidence (SBS performance, materials, tests)	Part 2 — Process Validation (Form/Seal/Assemble)	Cross-Ref (SOP/Template/Doc ID or Link)	Example Record ID	Owner	Status	Notes
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Use this crosswalk to show traceability from ISO 11607 Part 1 requirements \rightarrow Part 2 process validation \rightarrow objective evidence (records).

- Suggested rows: SBS definition & aseptic presentation; Material specs/COAs; Seal strength & integrity (dye/bubble); Distribution & conditioning; Aging (accelerated/real).
- Sealing equipment IQ/OQ/PQ; Process window & routine checks; Sampling/acceptance criteria on batch records; Change control & re-qualification triggers; Labeling/IFU that affect packaging.
- Status: Planned / In-Progress / Complete. Keep entries concise; reference the exact SOP/template and one real record ID per row.

Tip: An auditor should be able to pick any row, open the cited SOP/template, and find a real example record in under 60 seconds.