



ISO 11607 Sterile Packaging Validation Kit

Packaging validation master plan, sealer IQ/OQ/PQ protocols, seal test workbook with stats, accelerated-aging calculator and revalidation triggers for terminally sterilized devices.

What's inside

File	What it is / how to use it
01_ISO11607_Sterile_Packaging_Workbook.xlsx	Packaging gap tracker, seal strength data with mean/SD/Ppk on your limits, accelerated-aging calculator, test matrix, routine seal monitoring and revalidation trigger log.
02_Packaging_Validation_Master_Plan.docx	Scope, responsibilities and validation strategy.
03_Sealer_IQ_OQ_PQ_Protocol.docx	Protocol plus report shell.
04_Distribution_and_Aging_Plan.docx	Test plan shell.

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About the author

Built by Matt Norman, US Navy veteran and former SpaceX Falcon 9 quality inspector and QA supervisor. (Not affiliated with or endorsed by SpaceX.) Norman Quality Tools is Veteran-Owned & Operated. Contains no SpaceX, government, or customer proprietary information; all example data is made up.

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Packaging Validation Master Plan

ISO 11607 Sterile Packaging Validation Kit - Document 02 - Rev A (2026-10)

Company		Product family	
Sterilization method		Plan #	
Rev			

1. Scope

[Products, sterile barrier systems (SBS), protective packaging, sites and sealers covered.]

2. Sterile barrier system description

[Materials, configuration, preformed SBS supplier, sealing method.]

3. Strategy

- Material qualification and supplier controls
- Sealer IQ, OQ (lower/nominal/upper window), PQ (3 runs at nominal suggested)
- Performance testing after distribution simulation
- Stability: accelerated and real-time aging
- Usability for aseptic presentation
- Product family / worst-case rationale

4. Test methods and sampling

[List methods with revision and validation status; statistical rationale for sample sizes.]

5. Acceptance criteria

[Your criteria, with justification. This kit does not supply acceptance values.]

6. Change control and revalidation

[Triggers; see Revalidation Triggers sheet.]

Role	Name	Signature	Date
Packaging engineer			
Quality			

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