



Sterilization Validation Kit (EO / Steam / Radiation)

Plan and track sterilization validation, requalification and routine release.

What's inside

File	What it is / how to use it
01_Sterilization_Validation_Workbook.xlsx	Method-selection checklist, validation activity tracker, requalification calendar and BI/dose results log.
02_Sterilization_Validation_Protocol.docx	Protocol template with method-specific sections.
03_Sterilization_Validation_Report.docx	Report template with results and conclusion.

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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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Sterilization Validation Protocol

Sterilization Validation Kit (EO / Steam / Radiation) - Document 02 - Rev A (2026-10)

Product family		Method	
Sterilizer / facility		Protocol no.	

1. Objective

Demonstrate the process reliably achieves the specified sterility assurance level (typically SAL 10⁻⁶ for terminally sterilized devices; state your target).

2. Product and load definition

Product, load, PCD

3. Qualification stages

Stage	Test	Acceptance criteria	Ref