



Medical Device Cybersecurity Documentation Kit (FD&C Act 524B)

Cybersecurity management plan, threat model, security risk assessment, SBOM inventory, vulnerability management and end-of-support register for cyber-device makers.

What's inside

File	What it is / how to use it
01_Med_Device_Cybersecurity_Workbook.xlsx	Threat model, security risk assessment, SBOM inventory, known-vulnerability log, postmarket vulnerability plan tracker, labeling checklist and submission checklist.
02_Cybersecurity_Management_Plan.docx	Plan template.
03_CVD_Policy_Template.docx	Public-facing CVD policy draft.
04_Security_Labeling_Checklist.docx	Labeling items to consider.

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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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Cybersecurity Management Plan

Medical Device Cybersecurity Documentation Kit (FD&C Act 524B) - Document 02 - Rev A (2026-10)

Device		Doc #	
Rev		Date	

1. Scope and cyber-device determination

[Does the device include software, connect to the internet, and have characteristics that could be vulnerable? Record your reasoning against 524B(c).]

2. Secure product development

[Framework you follow (e.g., your QMS design controls; IEC 81001-5-1 or AAMI TIR57 by number).]

3. Postmarket monitoring and CVD

[Sources monitored, intake channel for researchers, triage timeline, patch delivery.]

4. Roles

Role	Responsibility
Product security lead	[Define]
Regulatory	[Define]
Engineering	[Define]

Role	Name	Signature	Date
Product security lead			
Quality			

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