



Medical Device Design Controls Kit

Plan, trace and transfer a medical device design without gaps.

What's inside

File	What it is / how to use it
01_Design_Traceability_Matrix.xlsx	User needs and design inputs with outputs, verification/validation results, broken-link and gap flags, coverage % and transfer readiness.
02_Design_Plan_Review_VV_Transfer_Templates.docx	Design plan, inputs approval, design review record, V&V protocol and report, transfer checklist.

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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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Design Controls Templates

Medical Device Design Controls Kit - Document 02 - Rev A (2026-10)

Design & Development Plan

Project / device		Design owner	
Classification / regulatory path		Plan revision	

Phase	Deliverables	Review / gate	Planned date
Planning	Plan, team, risk plan	DR-0	
Inputs	User needs, design inputs, standards list	DR-1	
Design & outputs	Drawings, specs, software, labeling	DR-2	
Verification	Protocols and reports	DR-3	
Validation	Simulated/clinical use, usability	DR-4	
Transfer	Transfer checklist, DMR/MDF complete	DR-5	

Update this plan as the project evolves. Interfaces between groups: [list].

Role	Name	Signature	Date
Design owner			
Quality			