



ISO 14971 Risk Management Kit

A risk management file a reviewer can follow, from plan to report.

What's inside

File	What it is / how to use it
01_Risk_Management_Workbook.xlsx	Editable acceptability matrix; hazard analysis with lookup-based risk levels; FMEA with RPN; controls with implementation/effectiveness verification; readiness summary.
02_Risk_Management_Plan.docx	Plan template.
03_Benefit-Risk_and_Risk_Management_Report.docx	Benefit-risk table and final report questions.

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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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Risk Management Plan

ISO 14971 Risk Management Kit - Document 02 - Rev A (2026-10)

Device / family	
Intended use / purpose	
Life-cycle phases covered	
Plan owner	
Revision	

1. Scope

Device description, accessories, users, use environments, life-cycle phases

2. Responsibilities and authorities

Role	Name	Responsibility
Risk management lead		Owns file
Design / engineering		Hazard analysis, controls
Clinical / user expert		Harm severity, benefit
Quality		Verification, reviews
Top management		Policy and criteria approval

3. Acceptability criteria

Per the Criteria sheet of 01_Risk_Management_Workbook (attach a print). Criteria derive from the company risk policy, considering applicable standards and the generally acknowledged state of the art.

4. Overall residual risk method

Describe how all residual risks together are evaluated (e.g., expert panel review of the full hazard table, comparison to similar marketed devices, benefit-risk).

5. Verification activities

How implementation and effectiveness of each control will be verified (tests, inspections, usability studies).