



Biocompatibility Planning Kit (ISO 10993)

Plan, justify and track biological evaluation for your device.

What's inside

File	What it is / how to use it
01_Biocompatibility_ISO10993_Workbook.xlsx	Endpoint planning matrix, materials inventory and test tracker with flags.
02_Biological_Evaluation_Plan.docx	Plan template structured on the ISO 10993-1 risk-based evaluation process.
03_Biological_Evaluation_Report.docx	Report shell to summarize evidence and conclude.

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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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Biological Evaluation Plan (BEP)

Biocompatibility Planning Kit (ISO 10993) - Document 02 - Rev A (2026-10)

Device		Document no.	
Author		Date	

1. Device description and categorization

[Describe the device, its patient-contacting materials, contact type and duration. Reference the Device Profile sheet.]

2. Evaluation strategy

Follow a risk-based approach (ISO 10993-1, clause 4 and Annex A as navigation): gather material and manufacturing information, perform chemical characterization where useful, and select only the endpoints needed to close the remaining risk.

3. Endpoint plan

Endpoint	Approach	Test standard (part no.)	Lab	Justification

4. Acceptance and review

[Who reviews results; toxicologist sign-off; link to the ISO 14971 risk file.]

Role	Name	Signature	Date
Author			
Toxicologist / reviewer			
Quality			