MEDDEV ADVISORY

SAMPLE PREVIEW

ISO 10993-1:2025 Biological Evaluation Plan Builder

Traceable device scope, biological-hazard, evidence-route, test-planning, and qualified-decision controls

A candid pre-purchase view of the files, controls, workflow, fictional example, and professional-judgment boundary

MDA-TLK-BEP-10993-2025-01 • v3.0 • PUBLIC PRODUCT PREVIEW

PRE-PURCHASE TOUR — COMPLETE PAID FILES NOT INCLUDED

Help medical-device teams assemble a controlled Biological Evaluation Plan working package that links the final finished device, biological hazards, endpoint questions, evidence routes, study plans, risk records, and qualified decisions without automating scientific or regulatory judgment.

A structured working aid. It does not determine biological safety, compliance, or regulatory acceptance.

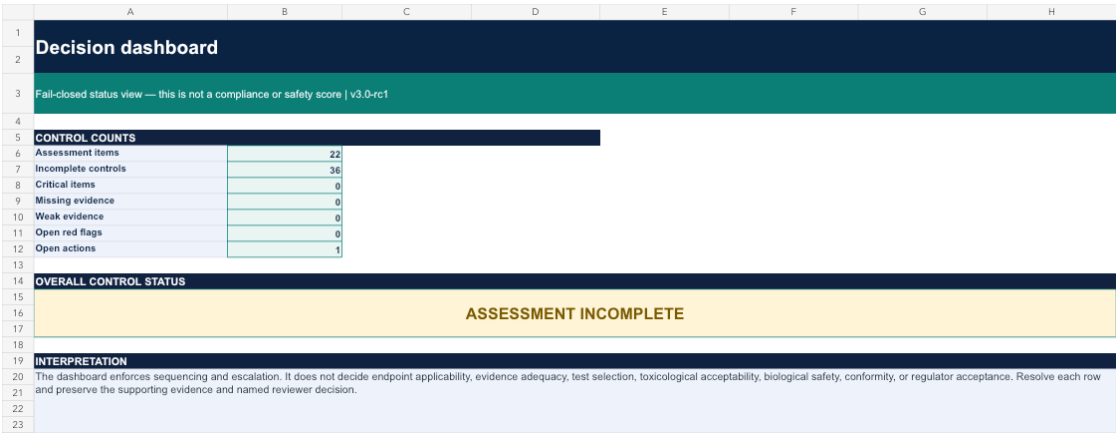
What this resource helps a team produce

- A controlled BEP scope record tied to one final finished device configuration, intended use, contact profile, population, markets, and decision request.
- A biological-hazard and endpoint-question map that starts with device mechanisms and exposure instead of copying a generic test list.
- A traceable evidence-route plan showing existing evidence, applicability limits, gaps, proposed studies, and the qualified decision owner for each question.
- A final-finished-device, test-article, sample-preparation, protocol, chemistry, toxicology, and animal-welfare planning record with explicit stop conditions.
- A source-dated FDA, EU MDR, and CDSCO working bridge that keeps ISO publication, regulator recognition, draft guidance, and legal requirements separate.
- A fail-closed assessment and red-flag system that preserves missing evidence, weak evidence, contrary findings, unresolved actions, and reviewer reservations.
- A reusable BEP assembly and handoff structure with stable IDs linking evidence, risks, endpoints, studies, decisions, actions, changes, and post-market triggers.
- A segregated fictional example that demonstrates record linkage without contaminating a live device file or implying a favorable conclusion.

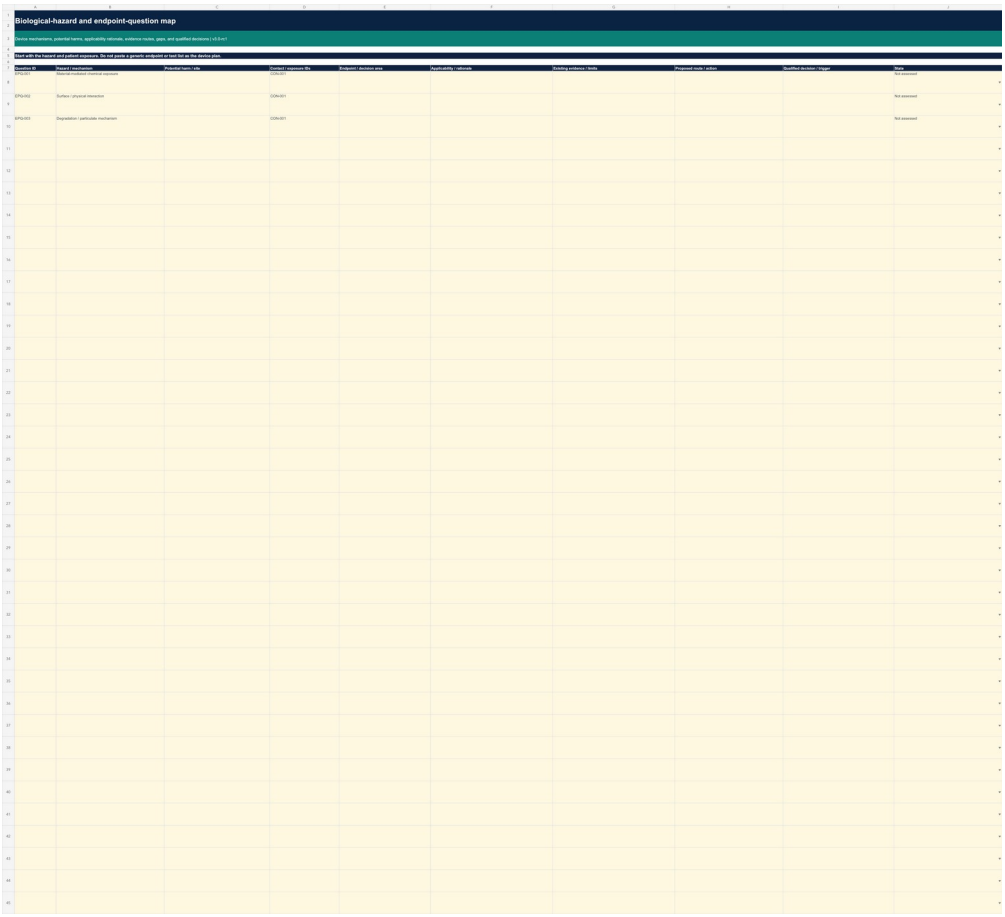
SCOPE This resource structures a Biological Evaluation Plan working record. It is not a Biological Evaluation Report, test prescription, waiver generator, safety conclusion, conformity assessment, submission, or regulator-acceptance prediction. It does not decide endpoint applicability, evidence sufficiency, representative or worst-case articles, toxicological acceptability, biological safety, or whether new testing is required. Device-specific conclusions require appropriately qualified biological-safety, toxicology, laboratory, risk-management, clinical, quality, and jurisdiction-specific regulatory review.

The working sequence

Step	Action	Output
1	Freeze the exact device, final finished state, use, population, markets, decision request, exclusions, owners, and source date.	Controlled BEP charter
2	Map every direct and indirect contact path, tissue or fluid, duration, frequency, cumulative use, population, and configuration.	Contact and exposure profile
3	Describe component formulations, processing, cleaning, residues, surfaces, sterilization, packaging, ageing, degradation, and supplied state.	Material and process map
4	Identify biological hazards and device-specific questions; route endpoint applicability to qualified review.	Hazard and endpoint-question map
5	Register evidence, appraise quality, bridge each article to the candidate, preserve contrary data, and open every gap.	Evidence ledger and applicability bridge
6	Plan chemistry, toxicology handoff, articles, preparation, protocols, laboratories, and animal-welfare controls where justified.	Qualified evidence-generation plan
7	Link planned conclusions and uncertainties to risk, clinical, PMS, CAPA, change, jurisdiction, and lifecycle records.	Risk and regulatory bridge
8	Recheck sources, reconcile IDs, remove fictional content, resolve actions, and route the exact candidate for independent review.	Controlled BEP review candidate



Decision dashboard - the blank production workbook correctly starts in a fail-closed incomplete state



Biological-hazard and endpoint-question map - device mechanisms, evidence routes, gaps, actions, and qualified decisions remain distinct

WHAT THE PREVIEW DEMONSTRATES The product controls the BEP boundary, sources, device and exposure facts, hazards, endpoint questions, evidence routes, studies, risk links, actions, and qualified decisions. It does not provide a prewritten endpoint, waiver, testing, toxicology, biological-safety, conformity, submission, or acceptance conclusion.

Exactly what is included

File	Use it for	Complete when
Quick Start PDF	Define the exact candidate, follow the eight-step safe sequence, and recognize stop conditions before entering conclusions.	The team knows the device boundary, owners, source date, workflow, review sequence, and non-conclusions.
Implementation Guide PDF	Apply the device, hazard, endpoint, evidence, study, risk, lifecycle, and jurisdiction controls with current source-status boundaries.	The team can explain every planned route, limitation, action, reserved decision, and reopening trigger.
Editable Working Templates DOCX	Draft the BEP charter, source record, device/exposure profile, hazard map, endpoint schedule, evidence bridge, study controls, regulatory bridge, and decision memo.	Every response is device specific, traceable, reviewed, and free of fictional or unresolved instruction text.
Operational Workbook XLSX	Control project facts, official sources, contact, materials/process, hazards/endpoints, evidence, articles, chemistry/TRA, studies, assessment, risk/regulatory links, red flags, actions and decisions.	No invalid or incomplete control remains, every open/blocked action is resolved, and every terminal decision is fully evidenced and reviewed.
Source Status and Release Notes PDF	Verify current ISO publication, FDA recognition, final/draft guidance, dynamic template, EU MDR, and CDSCO status.	The source register matches the exact controlled standards and official sources used for the candidate event.
Customer README, responsible-use terms, and CSV source register	Orient recipients, preserve identity and boundaries, and support controlled internal use.	Title, IDs, version, files, source date, support route, restrictions, and use boundaries agree.

What is deliberately not promised

- No automated endpoint applicability, test selection, waiver, no-new-testing, representative or worst-case, toxicological-acceptability, or biological-safety decision.
- No completed BER, risk-management file, clinical evaluation, laboratory report, TRA, submission, eSTAR, GSPR checklist, Device Master File, or regulator response.
- No FDA clearance, EU conformity, CE marking, CDSCO licence, notified-body acceptance, submission readiness, or regulator-acceptance prediction.
- No reproduction of ISO standards or replacement for lawfully obtained standards, current legal text, guidance, recognition records, device-specific requirements, ethics approval, or qualified professional review.
- No guarantee that prior evidence applies to a changed material, supplier, process, sterilization, package, age, use, population, configuration, market, or source environment.

AVAILABILITY Current customer edition — available by request. Online checkout, payment collection, public buyer-file download, and automatic delivery are not enabled.