MEDDEV ADVISORY

SAMPLE PREVIEW

Biocompatibility Test Strategy & Test Article Preparation Pack

Final-finished-device scope, endpoint rationale, worst-relevant article selection, unit-controlled extraction inputs, and laboratory evidence QC

An honest buyer view of the controlled scope, endpoint rationale, article selection, and unit-labelled arithmetic

MDA-TLK-TEST-ART-10993-01 • v3.0 • PUBLIC PRODUCT PREVIEW

PRE-PURCHASE TOUR — COMPLETE PAID FILES NOT INCLUDED

Help medical-device teams convert a device-specific biological-evaluation question into a controlled test strategy, a justified final-finished or representative test article, traceable preparation inputs, and a reviewer-ready laboratory evidence record.

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

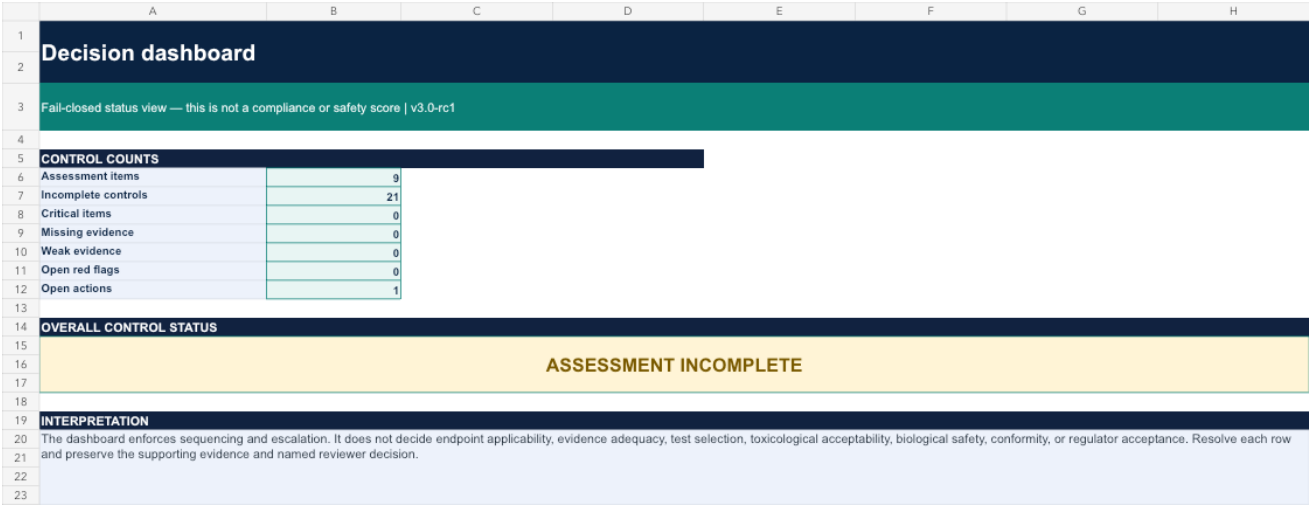
What this resource helps a team produce

- A controlled evaluation question tied to the exact final finished device, variants, intended use, contact route, cumulative duration, population, manufacturing state, sterilization, packaging, and shelf-life state.
- An endpoint-rationale matrix that distinguishes device facts, biological questions, existing evidence, remaining uncertainty, and qualified decisions instead of treating a regulator table as a test checklist.
- A candidate test-article comparison that identifies the final finished article when feasible and documents why any coupon, component, pooled set, aged unit, or worst-relevant configuration answers the intended question.
- A traceable article and preparation record covering configuration, revision, lot, quantity, processing, sterilization, packaging, age, handling, conditioning, surface area, pooling, exclusions, controls, and deviations.
- Unit-labelled extraction inputs and transparent arithmetic for area and mass ratios, with no automatic scientific recommendation or pass/fail conclusion.
- A protocol-quality review that aligns purpose, article, method, controls, acceptance criteria, data capture, GLP or ASCA status where applicable, deviations, and sponsor authorization before work begins.
- A report-quality review connecting every result to the authorized protocol, tested article, preparation record, raw-data summary, deviations, limitations, and named interpretation owner.
- A fail-closed handoff containing gaps, red flags, change impact, actions, source status, and qualified approval records bound to the exact candidate files.

SCOPE This working aid organizes facts, arithmetic, evidence, gaps, and named decisions. It does not choose endpoints, prescribe a test method or extraction condition, establish sample size or acceptance criteria, interpret results, determine toxicological acceptability or biological safety, declare conformity, or predict regulator acceptance. Current requirements, the exact device, the qualified biological-safety and toxicology reviewers, and the authorized testing laboratory control every scientific conclusion.

The working sequence

Step	Action	Output
1	Freeze the exact evaluation question and final finished device configuration.	Controlled scope profile
2	Convert contact and risk facts into endpoint-specific questions and written rationales.	Endpoint-rationale matrix
3	Inventory existing evidence and define the unanswered question before commissioning work.	Evidence and test need plan
4	Compare candidate test articles with the current final finished device and relevant variants.	Representative or worst-relevant article decision
5	Record article identity, lot, state, quantity, handling, conditioning, preparation, extraction inputs, controls, and exclusions.	Article and preparation authorization
6	Have the qualified laboratory and scientific reviewers approve methods, conditions, sample counts, controls, criteria, and data requirements.	Authorized protocol candidate
7	Control execution changes, deviations, chain of custody, observations, and report completeness.	Traceable laboratory evidence record
8	Reconcile results, limitations, changes, gaps, red flags, actions, sources, and named decisions before handoff.	Qualified-review package



Decision dashboard

Fail-closed status view — this is not a compliance or safety score | v3.0-rc1

CONTROL COUNTS

Assessment items	9
Incomplete controls	21
Critical items	0
Missing evidence	0
Weak evidence	0
Open red flags	0
Open actions	1

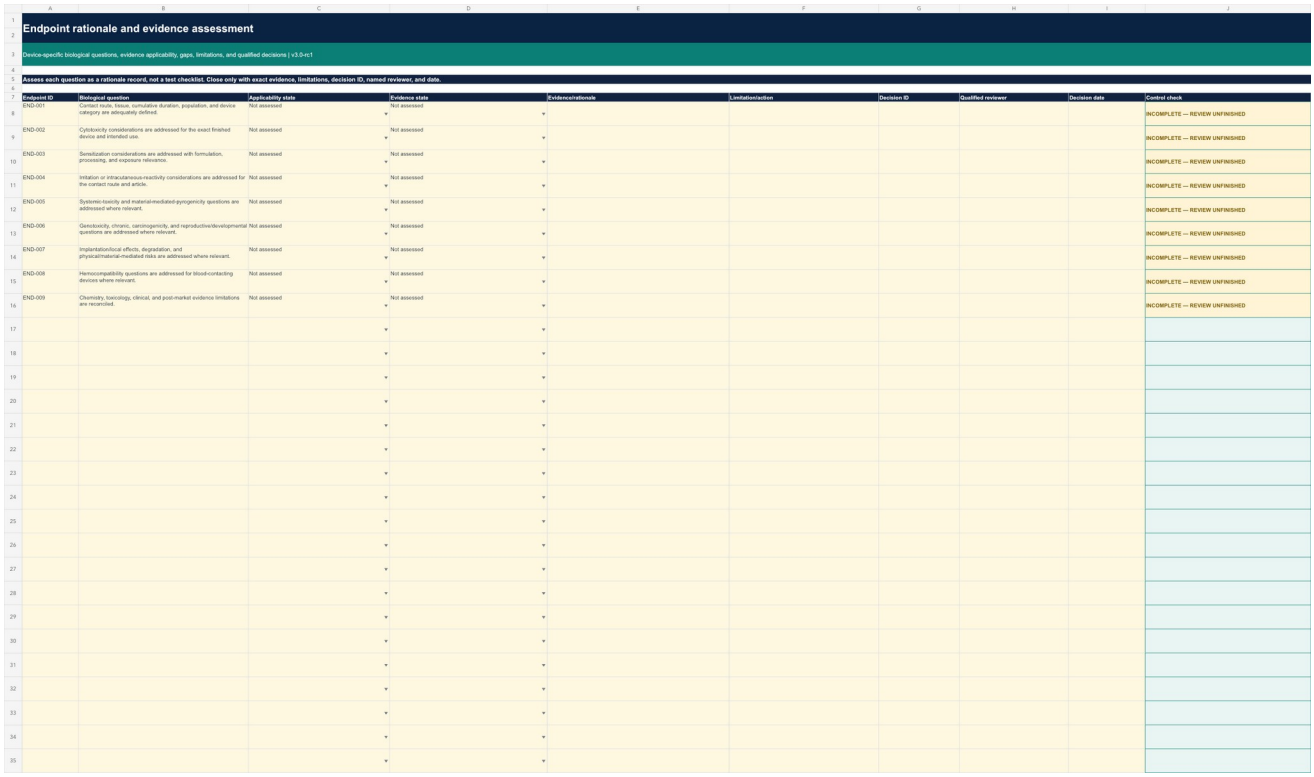
OVERALL CONTROL STATUS

ASSESSMENT INCOMPLETE

INTERPRETATION

The dashboard enforces sequencing and escalation. It does not decide endpoint applicability, evidence adequacy, test selection, toxicological acceptability, biological safety, conformity, or regulator acceptance. Resolve each row and preserve the supporting evidence and named reviewer decision.

Fail-closed decision dashboard from the actual candidate workbook — workflow control, not a safety score



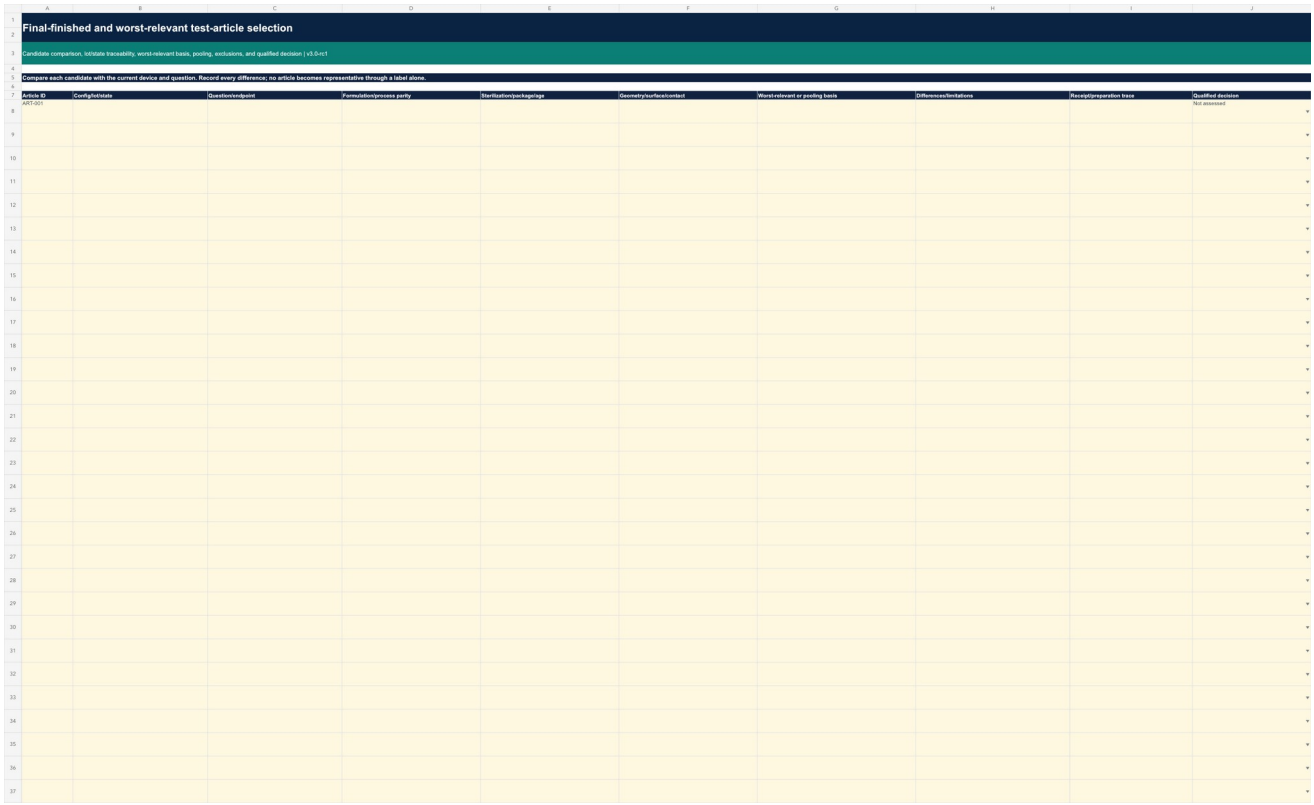
Endpoint rationale and evidence assessment

Device-specific biological questions, evidence applicability, gaps, limitations, and qualified decisions | v3.0-rc1

Assess each question as a rationale record, not a test checklist. Close only with exact evidence, limitations, decision ID, named reviewer, and date.

Endpoint ID	Biological question	Applicability state	Evidence state	Evidence/rationale	Limitation/action	Decision ID	Qualified reviewer	Decision date	Control check
END-001	Contact mode, tissue, cumulative duration, population, and device category are adequately defined.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-002	Cytotoxicity considerations are addressed for the exact finished device and intended use.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-003	Sensitization considerations are addressed with formulation, processing, and exposure relevance.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-004	Irritation or intracutaneous-reactivity considerations are addressed for the contact route and article.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-005	Systemic-toxicity and material-mediated-pyrogenicity questions are addressed where relevant.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-006	Genotoxicity, chronic, carcinogenicity, and reproductive/developmental questions are addressed where relevant.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-007	Implantation/local effects, degradation, and physical/material-mediated risks are addressed where relevant.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-008	Hemocompatibility questions are addressed for blood-contacting devices where relevant.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-009	Chemistry, toxicology, clinical, and post-market evidence limitations are reconciled.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED

Endpoint-rationale matrix from the actual workbook — questions, evidence, gaps, and qualified decisions



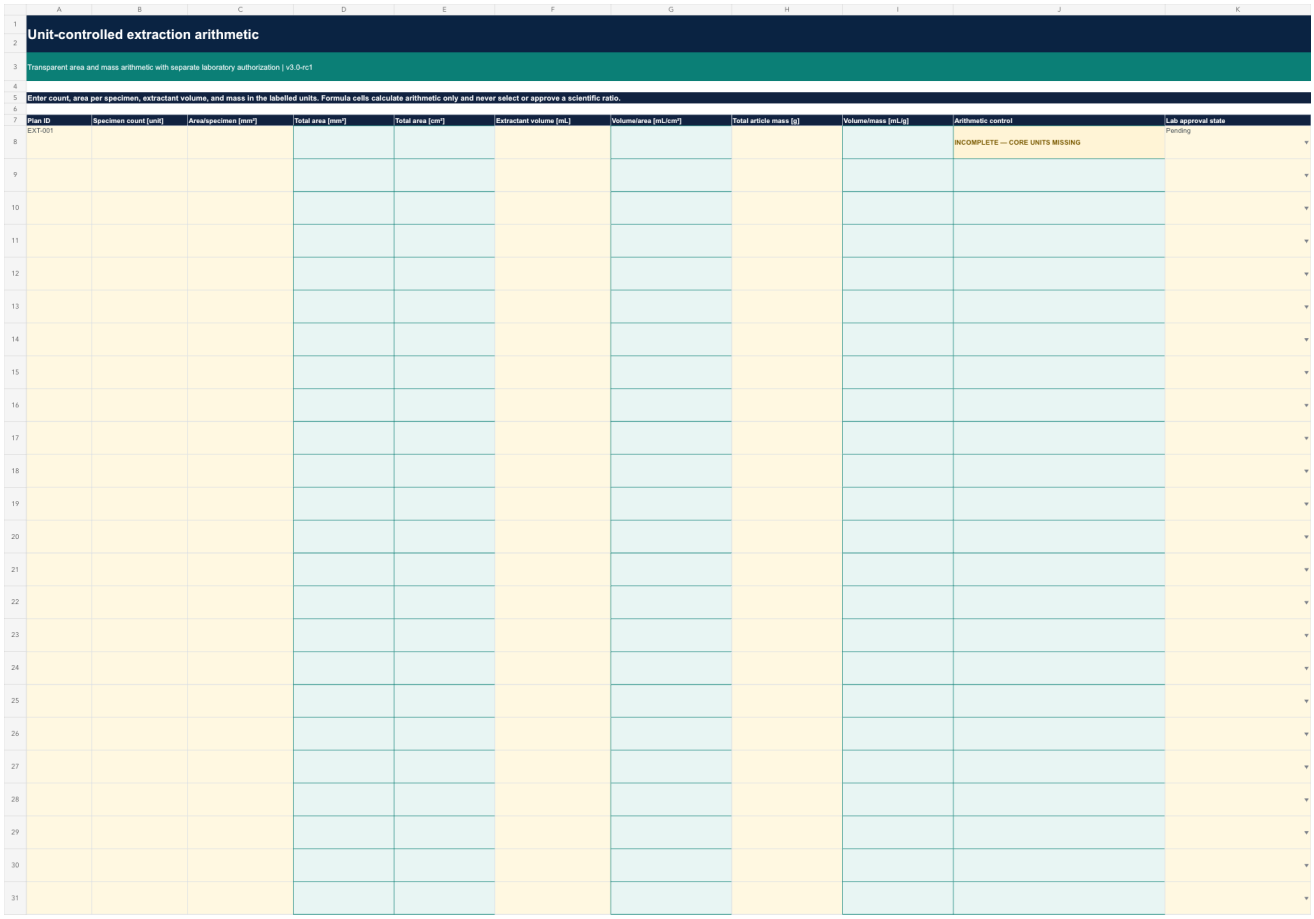
Final-finished and worst-relevant test-article selection

Candidate comparison, lot/state traceability, worst-relevant basis, pooling, exclusions, and qualified decision | v3.0-rc1

Compare each candidate with the current device and question. Record every difference; no article becomes representative through a label alone.

Article ID	Config/lot/state	Question/endpoint	Formulation/process parity	Sterilization/package/age	Geometry/surface/contact	Worst-relevant or pooling basis	Differences/limitations	Receipt/preparation trace	Qualified decision
ART-001									Not assessed

Final-finished and worst-relevant article comparison from the actual workbook



Unit-controlled extraction arithmetic

Transparent area and mass arithmetic with separate laboratory authorization | v3.0-rc1

Enter count, area per specimen, extractant volume, and mass in the labelled units. Formula cells calculate arithmetic only and never select or approve a scientific ratio.

Plan ID	Specimen count [unit]	Area/specimen [mm²]	Total area [mm²]	Total area [cm²]	Extractant volume [mL]	Volume/area [mL/cm²]	Total article mass [g]	Volume/mass [mL/g]	Arithmetic control	Lab approval state
EXT-001									INCOMPLETE — CORE UNITS MISSING	Pending

Unit-labelled extraction arithmetic from the actual workbook — no automated scientific recommendation

WHAT THE PREVIEW DEMONSTRATES The product links final-device scope, endpoint rationale, evidence, article selection, unit-controlled arithmetic, laboratory QC, deviations, changes, sources, and named decisions. It does not provide a prewritten test plan or biological-safety conclusion.

Exactly what is included

File	Use it for	Complete when
Quick Start PDF	Set the scope, stop conditions, and eight-step working sequence.	The team knows which device and question are controlled, where qualified review is mandatory, and what cannot be concluded automatically.
Implementation Guide PDF	Apply the full endpoint-rationale, article-selection, preparation, protocol, report, deviation, and change-control method.	A reviewer can reconstruct why the work was proposed, what was tested, how it was prepared, what changed, and who owns each decision.
Editable Working Templates DOCX	Draft ten controlled narratives and review records.	All blank and fictional fields are replaced with device-specific, approved information.
Operational Workbook XLSX	Control scope, endpoints, evidence, articles, extraction arithmetic, laboratory QC, gaps, red flags, changes, sources, and decisions.	Every seeded control is assessed, no stop condition is hidden, and scientific approvals are named outside the arithmetic.
Source Status and Release Notes PDF	Verify the official FDA, ISO, eCFR, and EU source status used by the candidate.	Edition, recognition extent, transition, publication status, checked date, and recheck trigger match the intended market use.
README, responsible-use terms, source register, manifest, and checksums	Orient the buyer and preserve package identity and integrity.	Product ID, version, inventory, hashes, use boundary, and support route agree across the controlled delivery.

What is deliberately not promised

- No automatic endpoint selection, test battery, waiver, method, vehicle, extraction ratio, condition, sample count, or acceptance criterion.
- No automatic representative or worst-case article conclusion; every selection requires device- and question-specific qualified review.
- No toxicological-acceptability, biological-safety, GLP-compliance, ASCA-eligibility, conformity, submission-readiness, or regulator-acceptance claim.
- No reproduction of ISO standards or replacement for lawfully obtained controlled standards, device-specific requirements, laboratory procedures, and current regulator instructions.
- No assumption that legacy evidence remains applicable after a material, supplier, process, sterilization, packaging, shelf-life, geometry, use, population, clinical, or regulatory change.
- No personalized consulting, legal advice, or final commercial terms in this preview.

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