MEDDEV ADVISORY

SAMPLE PREVIEW

ISO 10993-1:2025 BER Evidence & Literature Evaluation Toolkit

Device-specific evidence applicability, reproducible literature evaluation, endpoint synthesis, chemistry/TRA linkage, and qualified BER review

An honest buyer view of the fail-closed dashboard, endpoint evidence synthesis, literature screening, and critical appraisal controls

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

PRE-PURCHASE TOUR — COMPLETE PAID FILES NOT INCLUDED

Help medical-device teams turn controlled test reports, chemistry, toxicology, literature, legacy evidence, clinical and post-market information, and risk records into a traceable Biological Evaluation Report evidence argument for qualified review.

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

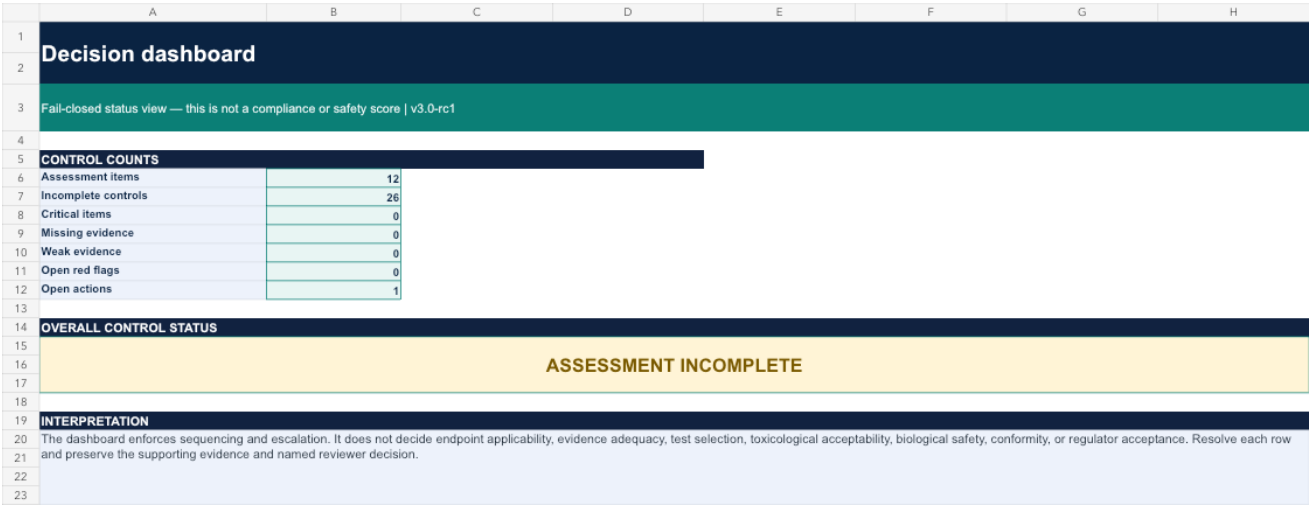
What this resource helps a team produce

- A controlled BER question tied to the exact final finished device, intended use, contact route, cumulative duration, population, materials, processing, sterilization, packaging, and life-cycle state.
- A provenance-controlled evidence inventory that distinguishes possession of a document from its applicability to the current device and question.
- An endpoint-by-endpoint synthesis linking biological questions to direct and indirect evidence, limitations, conflicts, residual uncertainty, and named qualified decisions.
- A reproducible literature mini-protocol, search log, deduplication record, screening trail, critical appraisal, and evidence-extraction record without an invented quality score.
- A chemistry and toxicological-risk bridge that identifies which exact reports, constituents, exposures, assumptions, and limitations support each proposed BER use.
- A legacy-evidence applicability record that tests device, material, process, sterilization, packaging, ageing, exposure, and intended-use differences instead of relying on age or product-family labels.
- A reconciled view of unfavorable or contradictory evidence, complaints, PMS/clinical signals, risk controls, changes, gaps, and required actions.
- A fail-closed qualified-review handoff in which no terminal conclusion is accepted without evidence, rationale, limitations, reviewer identity, competence, date, decision ID, and recheck trigger.

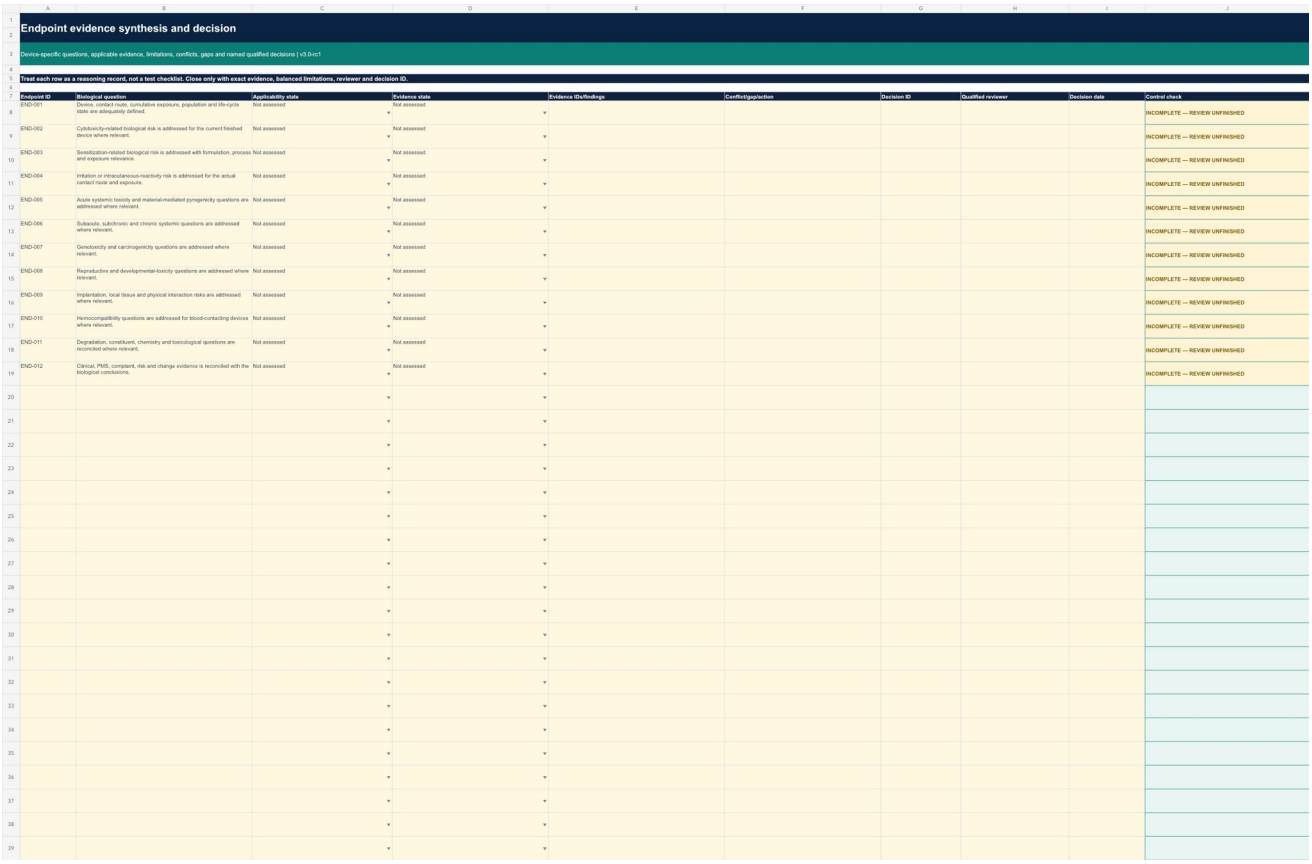
SCOPE This toolkit organizes evidence provenance, applicability, literature work, gaps, and draft reasoning. It does not perform a systematic review, decide endpoint applicability, establish equivalence, interpret toxicology, determine biological safety or residual-risk acceptability, author a final BER, declare conformity, or predict regulator acceptance. The current device, lawful controlled standards, applicable regulator instructions, and named qualified reviewers govern every conclusion.

The working sequence

Step	Action	Output
1	Freeze the exact BER question and final finished device baseline.	Controlled device and evaluation scope
2	Inventory every candidate source and control provenance before drafting conclusions.	Evidence inventory
3	Compare each evidence item with the current device and the biological question it is meant to answer.	Applicability record
4	Define and execute the literature work from a dated protocol.	Search, screening, appraisal, and extraction trail
5	Build endpoint-specific evidence syntheses and reconcile limitations and conflicts.	Endpoint evidence map
6	Connect chemistry, TRA, legacy, clinical/PMS, and risk-management evidence to the exact claims they support.	Cross-evidence bridge
7	Record gaps, deviations, red flags, changes, actions, and reopening triggers.	Close-out and change-control register
8	Prepare the draft BER evidence handoff and obtain named qualified approval.	Hash-bound review candidate



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



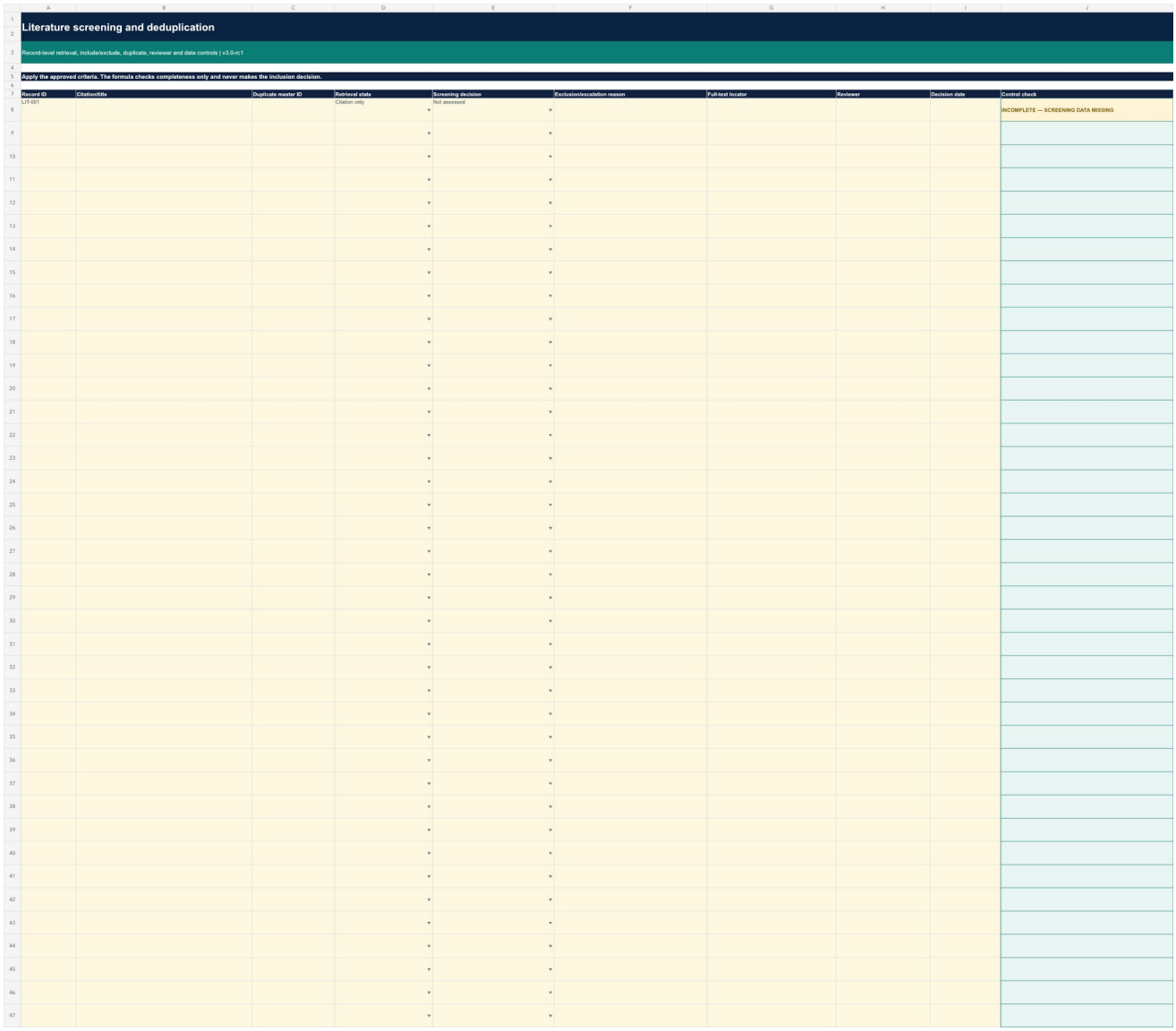
Endpoint evidence synthesis and decision

Device-specific questions, applicable evidence, limitations, conflicts, gaps and named qualified decisions | v3.0-rc1

Treat each row as a reasoning record, not a test checklist. Close only with exact evidence, balanced limitations, reviewer and decision ID.

Endpoint ID	Biological question	Applicability state	Evidence state	Evidence IDs/findings	Conflict/gap/action	Decision ID	Qualified reviewer	Decision date	Control check
END-001	Device, contact route, cumulative exposure, population and life-cycle state are adequately defined.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-002	Cytotoxicity-related biological risk is addressed for the current finished device where relevant.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-003	Sensitization-related biological risk is addressed with formulation, process and exposure relevance.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-004	Irritation or intracutaneous-reactivity risk is addressed for the actual contact route and exposure.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-005	Acute systemic toxicity and material-mediated pyrogenicity questions are addressed where relevant.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-006	Subacute, subchronic and chronic systemic questions are addressed where relevant.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-007	Genotoxicity and carcinogenicity questions are addressed where relevant.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-008	Reproductive and developmental-toxicity questions are addressed where relevant.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-009	Implantation, local tissue and physical interaction risks are addressed where relevant.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-010	Hemocompatibility questions are addressed for blood-contacting devices where relevant.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-011	Degradation, constituent, chemistry and toxicological questions are reconciled where relevant.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
END-012	Clinical, PMS, complaint, risk and change evidence is reconciled with the biological conclusions.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED

Endpoint evidence synthesis from the actual workbook - questions, evidence, gaps, limitations and named decisions



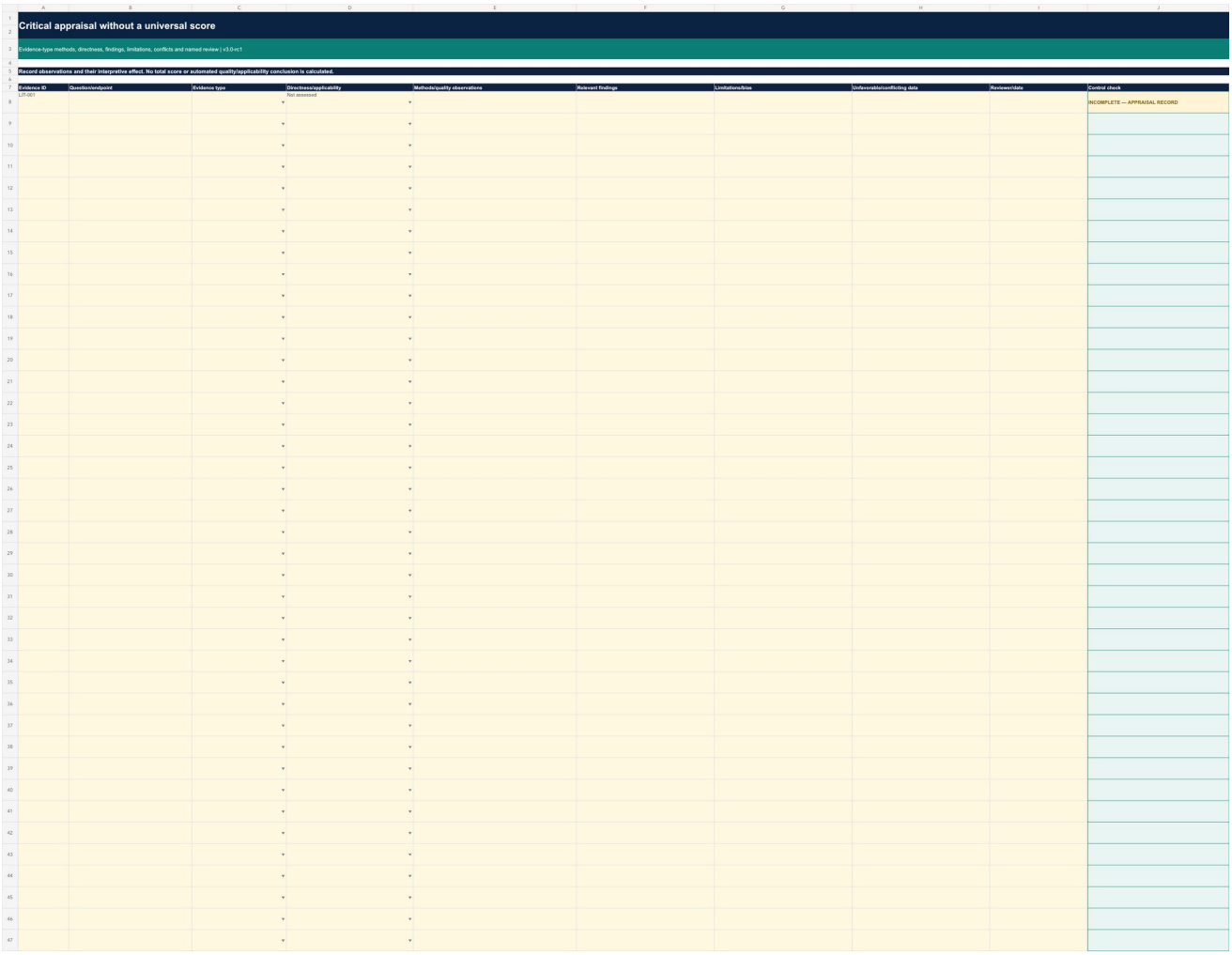
Literature screening and deduplication

Record-level retrieval, include/exclude, duplicate, reviewer and date controls | v3.0-rc1

Apply the approved criteria. The formula checks completeness only and never makes the inclusion decision.

Record ID	Citation/title	Duplicate master ID	Retrieval state	Screening decision	Exclusion/escalation reason	Full-text locator	Reviewer	Decision date	Control check
LIT-001			Citation only	Not assessed					INCOMPLETE — SCREENING DATA MISSING

Literature screening trail from the actual workbook - exact decisions, reasons, full-text control and reviewer dates



Critical appraisal without a universal score

Evidence-type methods, directness, findings, limitations, conflicts and named review | v3.0-rc1

Record observations and their interpretive effect. No total score or automated quality/applicability conclusion is calculated.

Evidence ID	Question/endpoint	Evidence type	Directness/applicability	Methods/quality observations	Relevant findings	Limitations/bias	Unfavorable/conflicting data	Reviewer/date	Control check
LIT-001			Not assessed						INCOMPLETE — APPRAISAL RECORD

Critical appraisal from the actual workbook - item-level observations with no universal evidence score

WHAT THE PREVIEW DEMONSTRATES The product connects a controlled device baseline, evidence provenance and applicability, literature work, endpoint reasoning, chemistry/TRA, legacy, PMS/risk, gaps, red flags and named decisions. It does not provide a prewritten BER conclusion.

Exactly what is included

File	Use it for	Complete when
Quick Start PDF	Run the first-pass evidence and literature workflow in the correct order.	The team knows the controlled question, minimum evidence set, literature route, stop conditions, and next qualified-review action.
Implementation Guide PDF	Apply the full evidence-applicability, literature-evaluation, endpoint-synthesis, chemistry/TRA, legacy, PMS/risk, and close-out method.	A reviewer can reconstruct what was searched, what was excluded, what evidence was used, why it applies, what conflicts remain, and who owns the conclusion.
Editable Working Templates DOCX	Draft thirteen controlled BER evidence and literature records.	Every instruction field is completed with device-specific information and each terminal record is linked to a named qualified reviewer.
Operational Workbook XLSX	Control scope, evidence, applicability, endpoints, literature work, cross-evidence bridges, gaps, red flags, changes, actions, sources, and decisions.	Every seeded control is assessed, screening and appraisal records are complete, and the dashboard remains fail-closed until qualified decisions exist.
Source Status and Release Notes PDF	Review the official ISO, FDA, EU, IMDRF, eCFR, and MDCG source status behind the candidate.	Edition, recognition extent, transition, guidance status, checked date, and recheck trigger agree with the intended use.
README, responsible-use terms, source register, manifest, and checksums	Orient the buyer and preserve controlled-package identity.	Product ID, version, inventory, hashes, professional-use boundary, and support route agree across delivery.

What is deliberately not promised

- No automated endpoint applicability, testing recommendation, evidence inclusion, evidence-quality score, equivalence decision or sufficiency conclusion.
- No claim that a targeted search is systematic unless the approved method and reporting support that description.
- No toxicological calculation, tolerable exposure, margin, constituent acceptability or biological-safety conclusion.
- No automatic use of legacy, predicate, equivalent, same-material, family, PMS or complaint evidence without device- and question-specific applicability review.
- No reproduction of ISO standards or replacement for lawfully obtained controlled standards, current law, regulator guidance, device-specific requirements and competent review.
- No conformity, submission-readiness, regulator-acceptance, personalized consulting or final commercial-availability promise in this preview.

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