MEDDEV ADVISORY

SAMPLE PREVIEW

Endpoint Waiver & No-New-Testing Justification Toolkit

Endpoint applicability, evidence bridges, jurisdiction-specific rationale, limitations, stress testing, and qualified scientific approval

An honest buyer view of the fail-closed dashboard, endpoint register, jurisdiction controls, and actual justification-record completeness logic

MDA-TLK-WAIVER-BIO-10993-01 • v3.0 • PUBLIC PRODUCT PREVIEW

PRE-PURCHASE TOUR — COMPLETE PAID FILES NOT INCLUDED

Help medical-device teams prepare traceable, endpoint-specific records explaining why an endpoint is not applicable, why existing evidence may support a proposal not to generate new test data, or why additional evidence or testing remains necessary.

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

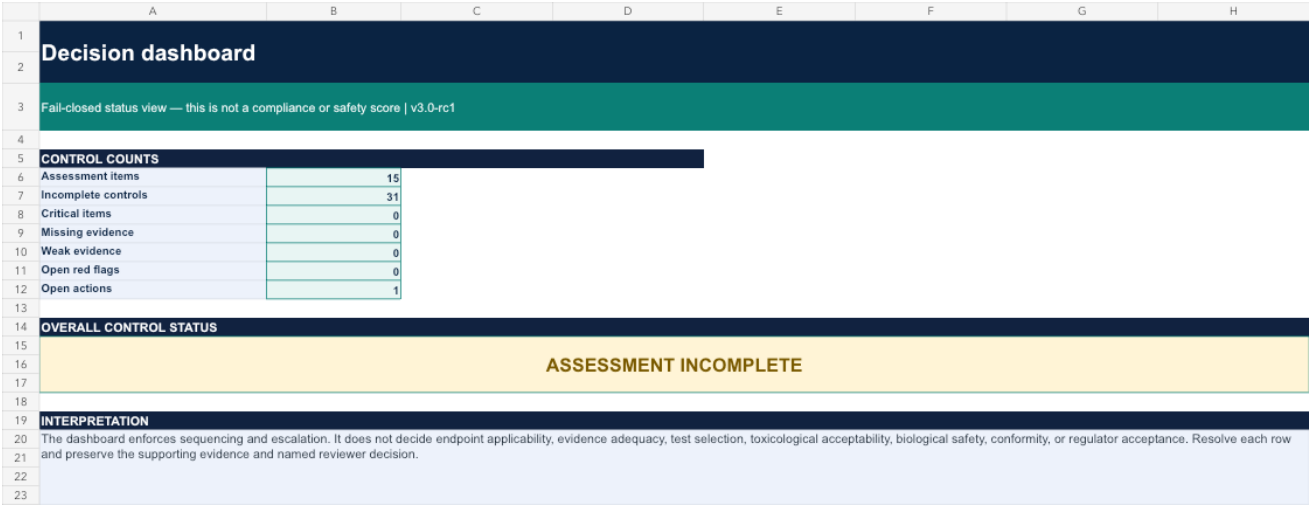
What this resource helps a team produce

- A controlled question tied to the exact final finished device, intended use, contact route, cumulative duration, population, materials, processing, sterilization, packaging, shelf life, and jurisdiction.
- An endpoint register that separates applicability from evidence sufficiency and never turns a generic table into an automatic test plan.
- A provenance-controlled evidence inventory and an explicit comparison showing what each prior report, chemistry record, TRA, publication, clinical/PMS source, or risk record can and cannot support.
- A clear distinction among endpoint not applicable, endpoint addressed without new testing, testing or other evidence required, and unresolved qualified-review escalation.
- A jurisdiction matrix that keeps ISO publication, FDA recognition, FDA guidance, EU law and harmonisation, and CDSCO rules or FAQ status from being blended into one claim.
- An editable no-new-testing rationale containing the device-specific question, evidence chain, comparison basis, limitations, unfavorable information, residual uncertainty, and re-opening trigger.
- A stress-tested reviewer handoff with predictable objections, owned gaps, proportionate alternatives, and named scientific, regulatory, toxicology, and risk decisions.
- A fail-closed release record in which neither formulas nor administrative completion can approve a scientific conclusion or regulator outcome.

SCOPE This toolkit organizes device facts, evidence, jurisdictional status, draft rationale, limitations, red flags, actions, and review records. It does not determine endpoint applicability, decide that testing is unnecessary, establish biological safety, perform toxicological calculations, prove equivalence, create a declaration of conformity, replace lawfully obtained standards, or predict FDA, notified-body, CDSCO, or other regulator acceptance. Each conclusion requires the current device record, current market requirements, controlled evidence, and named qualified review.

The working sequence

Step	Action	Output
1	Freeze the exact device, decision event, endpoint question, and market.	Controlled scope baseline
2	Identify every endpoint that requires a documented disposition.	Endpoint register
3	Inventory the evidence and control its provenance before interpreting it.	Evidence inventory
4	Compare each evidence subject with the current device and exact biological question.	Applicability and change-impact record
5	Separate the market-specific rule, guidance, recognition, or technical position.	Jurisdiction matrix
6	Draft the endpoint disposition and rationale with limitations and contrary evidence visible.	Justification record
7	Stress-test the rationale and convert uncertainty into proportionate actions or alternatives.	Reviewer challenge and remediation record
8	Obtain named qualified decisions and bind them to the exact candidate.	Qualified review handoff



Decision dashboard

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

CONTROL COUNTS

Assessment items	15
Incomplete controls	31
Critical items	0
Missing evidence	0
Weak evidence	0
Open red flags	0
Open actions	1

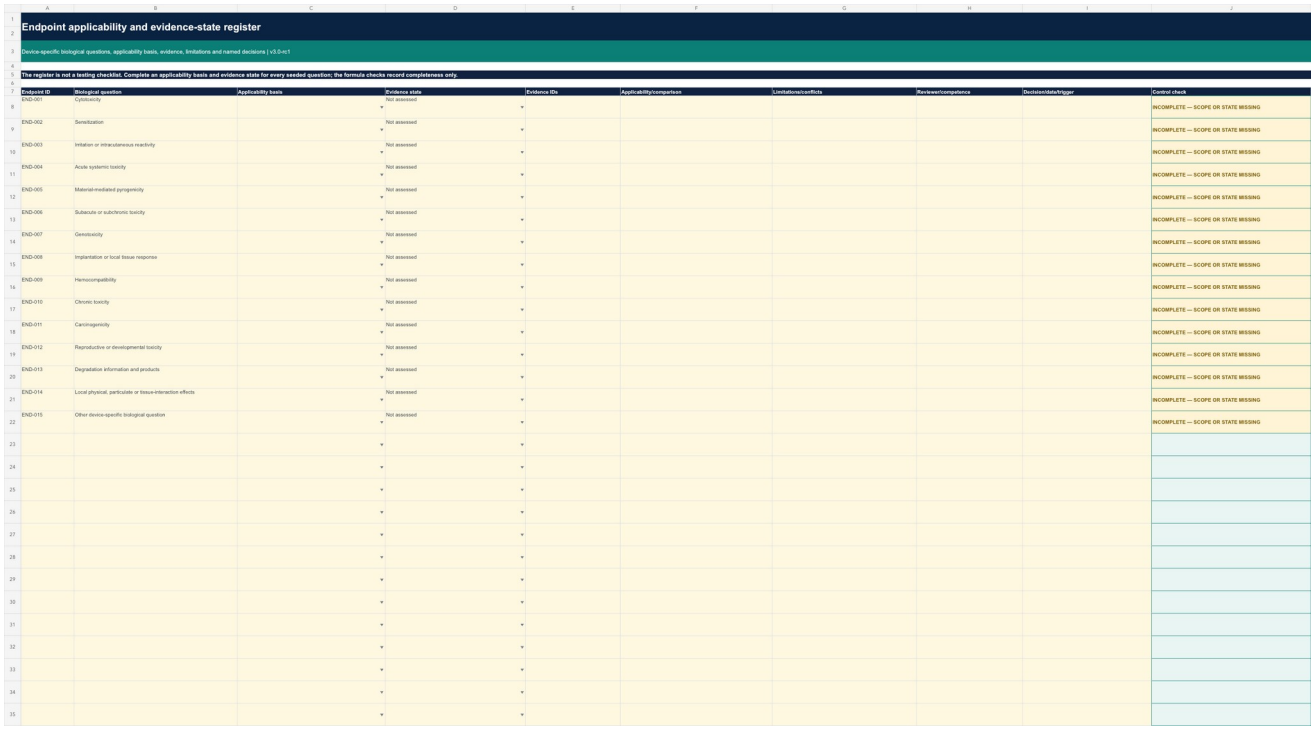
OVERALL CONTROL STATUS

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 dashboard from the actual candidate workbook - workflow control, not a safety or waiver score



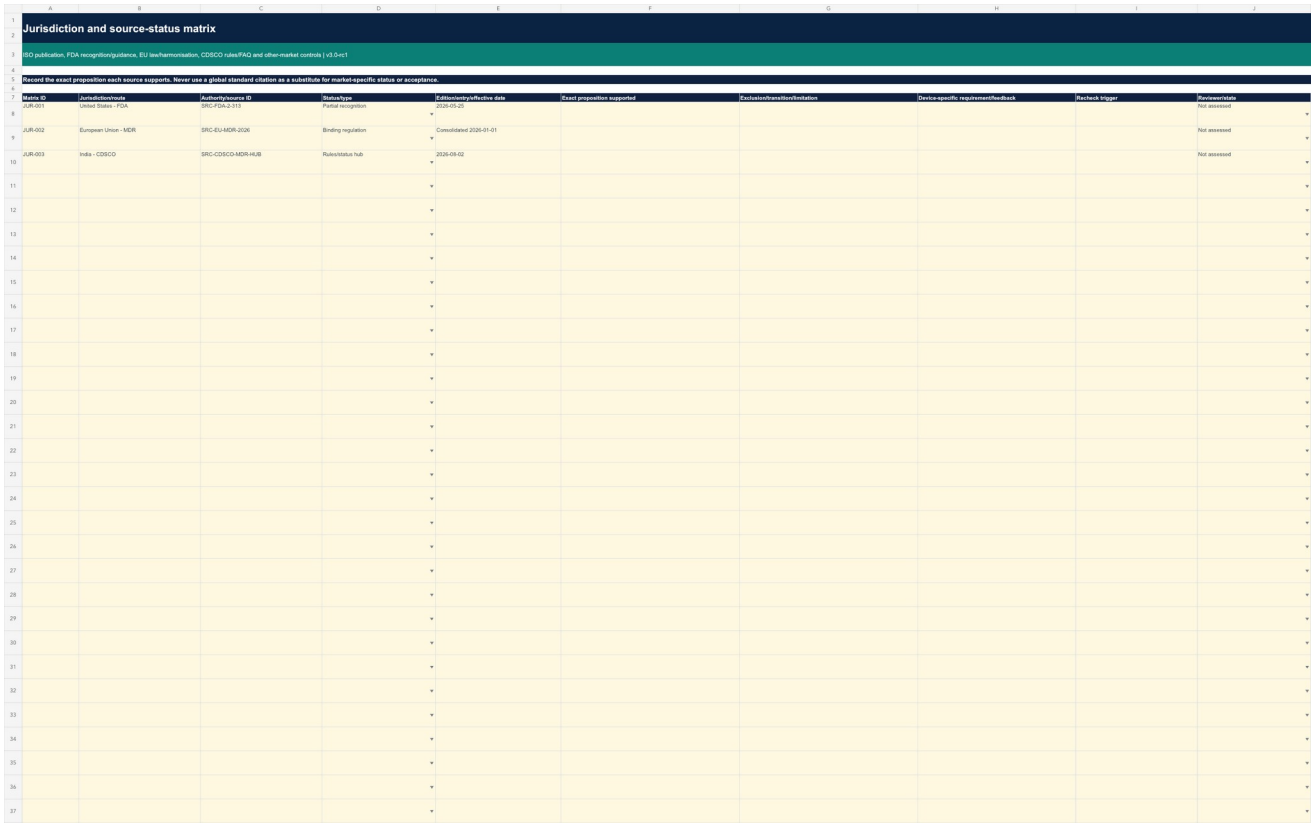
Endpoint applicability and evidence-state register

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

The register is not a testing checklist. Complete an applicability basis and evidence state for every seeded question; the formula checks record completeness only.

Endpoint ID	Biological question	Applicability basis	Evidence state	Evidence IDs	Applicability comparison	Limitations/conflicts	Reviewer/competence	Decision/date/trigger	Control check
END-001	Cytotoxicity		Not assessed						INCOMPLETE — SCOPE OR STATE MISSING
END-002	Sensitization		Not assessed						INCOMPLETE — SCOPE OR STATE MISSING
END-003	Irritation or intracutaneous reactivity		Not assessed						INCOMPLETE — SCOPE OR STATE MISSING
END-004	Acute systemic toxicity		Not assessed						INCOMPLETE — SCOPE OR STATE MISSING
END-005	Material-mediated pyrogenicity		Not assessed						INCOMPLETE — SCOPE OR STATE MISSING
END-006	Subacute or subchronic toxicity		Not assessed						INCOMPLETE — SCOPE OR STATE MISSING
END-007	Genotoxicity		Not assessed						INCOMPLETE — SCOPE OR STATE MISSING
END-008	Implantation or local tissue response		Not assessed						INCOMPLETE — SCOPE OR STATE MISSING
END-009	Hemocompatibility		Not assessed						INCOMPLETE — SCOPE OR STATE MISSING
END-010	Chronic toxicity		Not assessed						INCOMPLETE — SCOPE OR STATE MISSING
END-011	Carcinogenicity		Not assessed						INCOMPLETE — SCOPE OR STATE MISSING
END-012	Reproductive or developmental toxicity		Not assessed						INCOMPLETE — SCOPE OR STATE MISSING
END-013	Degradation information and products		Not assessed						INCOMPLETE — SCOPE OR STATE MISSING
END-014	Local physical, particulate or tissue-interaction effects		Not assessed						INCOMPLETE — SCOPE OR STATE MISSING
END-015	Other device-specific biological question		Not assessed						INCOMPLETE — SCOPE OR STATE MISSING

Endpoint register from the actual workbook - applicability, evidence state, limitations and named decisions kept separate



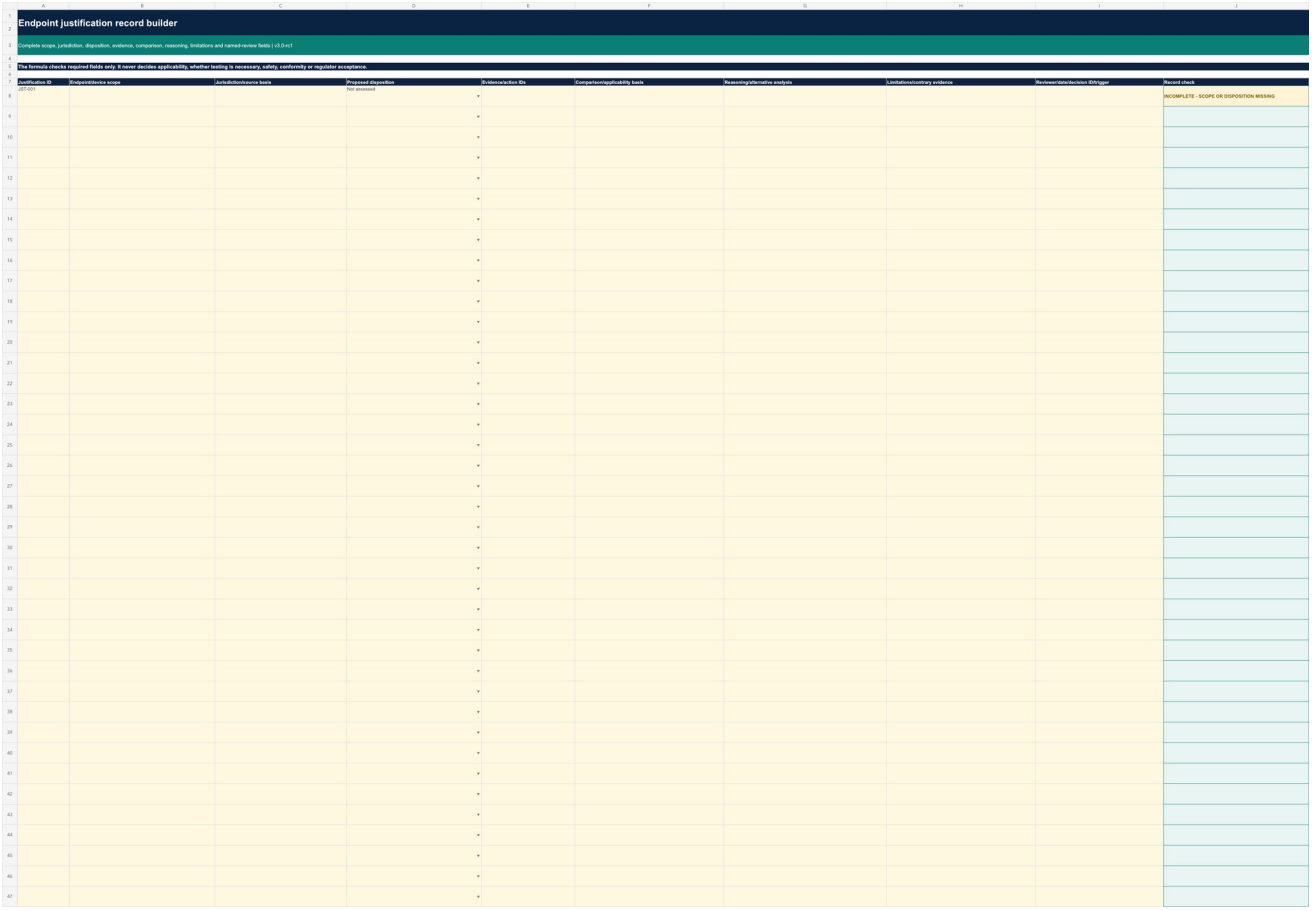
Jurisdiction and source-status matrix

ISO publication, FDA recognition/guidance, EU law/harmonisation, CDSCO rules/FAQ and other-market controls | v3.0-rc1

Record the exact proposition each source supports. Never use a global standard citation as a substitute for market-specific status or acceptance.

Matrix ID	Jurisdiction/node	Authority/source ID	Status/type	Edition/entry/effective date	Exact proposition supported	Exclusion/transition/limitation	Device-specific requirement/feedback	Recheck trigger	Reviewer/state
JUR-001	United States - FDA	SRC-FDA-2-313	Partial recognition	2026-05-25					Not assessed
JUR-002	European Union - MDR	SRC-EU-MDR-2026	Binding regulation	Consolidated 2026-01-01					Not assessed
JUR-003	India - CDSCO	SRC-CDSCO-MDR-HUB	Rules/status hub	2026-08-02					Not assessed

Jurisdiction matrix from the actual workbook - ISO, FDA, EU and CDSCO authority and status are not blended



Endpoint justification record builder

Complete scope, jurisdiction, disposition, evidence, comparison, reasoning, limitations and named-review fields | v3.0-rc1

The formula checks required fields only. It never decides applicability, whether testing is necessary, safety, conformity or regulator acceptance.

Justification ID	Endpoint/device scope	Jurisdiction/source basis	Proposed disposition	Evidence/active IDs	Comparison/applicability basis	Reasoning/alternative analysis	Limitations/contrary evidence	Reviewer/date/decision ID/trigger	Record check
JST-001			Not assessed						INCOMPLETE - SCOPE OR DISPOSITION MISSING

Justification record from the actual workbook - formulas validate fields only and cannot decide testing necessity

WHAT THE PREVIEW DEMONSTRATES The product connects final-device scope, endpoint applicability, evidence provenance and comparison, chemistry/TRA, changes, literature/PMS, market status, draft rationale, challenges, gaps, red flags and named review. It does not provide a reusable no-testing conclusion.

Exactly what is included

File	Use it for	Complete when
Quick Start PDF	Run the controlled workflow in the correct order and understand every stop condition.	The device, endpoint, evidence, market, required records, and qualified-review route are clear.
Implementation Guide PDF	Apply the full endpoint-applicability, prior-evidence, chemistry/TRA, jurisdiction, rationale, stress-test, and close-out method.	A reviewer can reconstruct why the endpoint was considered, how the evidence applies, what remains uncertain, and who owns the decision.
Editable Working Templates DOCX	Draft thirteen controlled records for a real device without importing the fictional example into live evidence.	Every instruction field contains device-specific content and every terminal position is linked to a named qualified decision.
Operational Workbook XLSX	Control scope, endpoints, evidence, applicability, changes, chemistry/TRA, literature/PMS, jurisdictions, rationales, challenges, gaps, red flags, actions, reviews, and sources.	Every seeded endpoint and red flag is assessed and no formula has been mistaken for scientific approval.
Source Status and Release Notes PDF	Review the official ISO, FDA, EU, CDSCO, MDCG, and eCFR source status behind the candidate.	Edition, recognition extent, harmonisation, legal/guidance status, checked date, and recheck trigger fit the intended market.
README, responsible-use terms, source register, manifest, and checksums	Orient the buyer and preserve package identity and integrity.	Product ID, version, inventory, hashes, professional-use boundary, and support route agree across delivery.

What is deliberately not promised

- No automated endpoint applicability, evidence sufficiency, testing recommendation, waiver approval, toxicological conclusion or biological-safety decision.
- No claim that prior testing, same material, same family, predicate, CE marking, prior clearance, complaint history or a chemistry/TRA report automatically applies to the current device.
- No claim that ISO publication equals FDA recognition, EU harmonisation, CDSCO acceptance, regulator agreement or device conformity.
- No reproduction of protected standards text or replacement for controlled standards, current law, regulator guidance, device-specific requirements and qualified review.
- No guarantee of FDA clearance, De Novo authorization, PMA approval, CE marking, notified-body acceptance, CDSCO licence or any other regulator outcome.
- No personalized consulting, legal advice, final submission, final BER, or commercial-availability promise in this controlled preview.

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