CUSTOMER EDITION — CONTROLLED COPY | PURPOSE AND BOUNDARY | v5.0 | Official sources last checked 31 July 2026

Legacy Biological Evaluation Gap-Assessment Toolkit

ISO 10993-1:2025 orientation for existing biological evaluation files

SAMPLE PREVIEW This six-page preview is drawn from the v5.0 guide, workflow, market notices, and fictional example. It is a public sample preview for evaluating the workflow before requesting the current customer edition.

What the toolkit is designed to organize

Legacy biological-evaluation files can contain useful evidence while still making it difficult to trace the current device, its changes, the evidence reviewed, the unresolved questions, and the approved decisions. The toolkit provides a controlled structure for rebuilding that traceability and preparing the work for qualified review.

Working outputs

- Review scope and device/configuration register.
- Evidence genealogy with independent source-location, applicability-review, and decision/action fields.
- Action-based 2018-to-2025 orientation record used with appropriately licensed sources.
- Separate FDA, EU MDR, CDSCO, and other-market overlays.
- BEP/BER working drafts, decision records, and qualified-review handoff index.

PRODUCT BOUNDARY This toolkit organizes existing evidence and review work. It does not reproduce or replace ISO 10993-1:2025, perform a device-specific biological evaluation or toxicological risk assessment, determine testing, establish conformity or compliance, provide legal advice, or guarantee acceptance.

The eight-stage review sequence

Stage	Action	Output
1	Confirm device, configuration, purpose, evidence cut-off, and target markets.	Review Scope Record
2	List controlled records without judging adequacy.	Evidence Inventory
3	Link sources to the represented article and current device.	Evidence Genealogy
4	Reopen edition-change questions with licensed source material.	Orientation Record
5	Record contact/exposure, materials/processes, and changes.	Context Records
6	Create one distinct overlay per target market.	Market Overlay
7	Assign owners, authorities, dates, and closure evidence.	Action/Decision Registers
8	Deliver indexed evidence and numbered questions to reviewers.	Handoff Index

Three fields that must not be blended

Source location	Where the controlled source is, or why it has not been retrieved.
Applicability review	Whether a named qualified reviewer has assessed the source for the current device and question.
Decision/action	What decision or information is required, who owns it, and how closure will be evidenced.

NO SCORE Workbook counts are workload indicators only. Source location, applicability review, and decision/action are recorded as three independent fields and reported separately. A located source may still have applicability review pending and an open decision/action. The workbook does not calculate regulatory readiness, compliance, defensibility, biological risk, or authority acceptance, and it does not make automatic test, endpoint, waiver, bridge, equivalence, or no-new-testing decisions.

Questions to reopen — selected examples

ORIENTATION BOUNDARY The 2018-to-2025 material is an orientation aid based on publicly accessible status descriptions and regulator notices. It is not a clause concordance and does not reproduce or replace the standard. Use lawfully obtained standards and obtain qualified scientific and regulatory review for device-specific decisions.

Change area	Question to reopen	Controlled action
Risk-management architecture	Can a reviewer trace each biological question, evidence item, uncertainty, decision, and control into the approved risk process?	Build an interface map; do not create a separate workbook risk score.
Contact/exposure	Are frequency, recurrence, intermittency, cumulative use, and changing device state described for the actual use?	Record facts and ambiguous scenarios for qualified review; do not calculate a category.
Material characterization	Does the file connect current formulation, suppliers, processing, sterilization, surface, geometry, and relevant residuals to the evidence?	Refresh the register and represented-article links.
Biological considerations	Is the file driven by an old test list rather than device-specific questions, evidence, uncertainty, and decisions?	Reframe the map around questions; do not generate a universal test list.
Market transition	Has one status or transition date been assumed for every jurisdiction?	Create a separate, dated source-status record for each market and intended use.

STANDARDS USE Use lawfully obtained standards within the applicable licence terms. This toolkit does not reproduce or replace a standard; record the source version reviewed and do not paste protected standards text into the files.

Keep each jurisdiction separate

UNITED STATES Verified 31 July 2026: FDA recognition 2-313 partially recognizes ISO 10993-1 sixth edition 2025-11. The stated exclusions and implementation cautions must be assessed. FDA will accept declarations of conformity to recognition 2-258 for the 2018 edition until 1 July 2029.

EUROPEAN UNION Commission Implementing Decision (EU) 2026/1231, as corrected on 22 June 2026, added EN ISO 10993-1:2025 as entry 54 to the MDR harmonised-standards list. The decision was published and entered into force on 17 June 2026. The corrigendum changes only the deferred date for Annex point (5), not the effective date of entry 54. Any presumption of conformity is limited to the MDR requirements covered by the harmonised standard.

EU ISO 10993-17 STATUS Commission Implementing Decision (EU) 2026/1231, as corrected on 22 June 2026, deletes the earlier entry 20 and inserts entry 20a for EN ISO 10993-17:2023 together with EN ISO 10993-17:2023/A1:2025. ISO lists ISO 10993-17:2023/Amd 1:2025 as published in November 2025. This records status only; technical implementation requires appropriately licensed source material and qualified review.

EU ANNEX ZA BOUNDARY Do not state that EN ISO 10993-1:2025 proves MDR compliance or that Annex I sections 10.1 to 10.6 are supported as one block. Determine covered requirements, conditions, and limitations from an appropriately licensed EN ISO 10993-1:2025, including Annex ZA, current Official Journal sources, and qualified EU review. Do not infer coverage from the title, OJ entry, or toolkit.

INDIA India’s Medical Devices Rules, 2017 establish a standards hierarchy. Applicable standards, schedule provisions, device classification, application route, and final Gazette notifications must be confirmed for the actual device. The Gazette watch is non-exhaustive; a title-level index review does not determine route relevance or legal effect, and a draft notification is not law.

Market record minimum

- Device, classification, route, regulatory purpose, authority, and qualified market reviewer.
- Legal instrument/guidance/standard status, extent, exclusions, deviations, dates, official URL, checked date, and recheck date.
- Device-specific requirements or questions, supporting evidence, covered boundary, limitations, and decision requested.
- Authority or conformity-assessment interaction, commitments, actions, owners, and closure evidence.

FICTIONAL WORKED EXAMPLE All names, device facts, records, and decisions on this page are invented. This is not a model conclusion. Project Alder is the guide/preview scenario; the workbook contains a separate fictional Nereid training case.

Project Alder — unresolved applicability

A fictional sterile hydrogel wound dressing changed from an uncolored Site North formulation to a blue Site East formulation with a revised mixing and curing sequence. The legacy BER and biological studies represent the earlier configuration. A current-device chemistry report is referenced in an email but has not been retrieved, and the controlled formulation/process comparison is absent.

Source location	Legacy reports: Located and linked. Current-device chemistry report: Referenced; source unavailable.
Applicability review	Legacy reports: Potentially applicable; limitations unresolved. Unavailable chemistry report: Not assessed.
Decision/action	Information requested and Scientific review pending. Retrieve the source and comparison; route representativeness and applicability to qualified review.
Market overlays	US and EU records are separate and remain Market confirmation pending for device-specific application.

DECISION REMAINS OPEN The example does not conclude that the legacy studies apply, does not propose a no-new-testing rationale, and does not state that the device is acceptable for either market.

The handoff asks for decisions, not suggested answers

The reviewer receives the confirmed scope, represented-article links, missing-record request, market sources, open limitations, and two numbered questions: whether the existing evidence applies to the current device, and what additional evaluation, if any, is justified after the missing facts are reviewed.

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WHAT THE CUSTOMER RECEIVES | v5.0 | Official sources last checked 31 July 2026

Customer-delivery file set

Included file	How it helps
00_Quick_Start_v5.0.pdf	Sets up the first working session and directs the user to the right review route.
01_Customer_README_v5.0.pdf	Maps the package and shows how to begin, work, and hand off the review.
01_Customer_README_v5.0.txt	Maps the package and shows how to begin, work, and hand off the review.
02_Customer_License_and_Responsible_Use_v5.0.pdf	Explains permitted use, sharing limits, responsible-use controls, and support.
03_Source_Status_and_Release_Notes_v5.0.pdf	Summarizes dated source positions, limitations, and the pre-use refresh steps.
MANIFEST.csv	Lists every delivered file so the package can be checked at a glance.
CHECKSUMS_SHA256.txt	Provides integrity hashes for verifying that delivered files are unchanged.
MDA-TLK-10993-2025-01_Implementation_Guide_v5.0.pdf	Explains the workflow, record logic, market boundaries, and worked example.
MDA-TLK-10993-2025-01_Editable_Working_Templates_v5.0.docx	Provides structured drafts and reviewer-ready records for the core outputs.
MDA-WBK-10993-2025-01_Gap_Assessment_Workbook_v5.0.xlsx	Captures scope, evidence genealogy, market overlays, actions, decisions, and handoff.
MDA-TLK-10993-2025-01_Official_Source_Register_v5.0.csv	Links dated market statements to the official sources used for orientation.

Delivery folders keep the working files, guidance, source notes, and verification records easy to navigate.

What this preview does not claim

- It does not replace the complete toolkit, the applicable order terms, or qualified review.
- It does not reproduce ISO text or replace appropriately licensed standards.
- It does not promise a regulatory outcome or decide whether evidence applies to a specific device.

PUBLIC PREVIEW Assess the workflow before requesting the current customer edition. Available by request; checkout, payment, public buyer-file download, and automatic delivery are not enabled.

Product support — include the SKU and version; do not send confidential device records