MEDDEV ADVISORY

SAMPLE PREVIEW

Catheter, Tubing & Fluid-Path Device Biocompatibility Documentation Pack

Traceable device, flow-path, evidence, test-article, and review controls

An honest view of the working sequence, files, controls, and professional-judgment boundary

MDA-TLK-CATH-FLUID-10993-01 • v3.0 • PUBLIC PRODUCT PREVIEW

PRE-PURCHASE TOUR — COMPLETE PAID FILES NOT INCLUDED

Help medical-device teams define catheter and fluid-path exposure, connect device-specific evidence to biological-evaluation decisions, and prepare a traceable working package for qualified review.

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

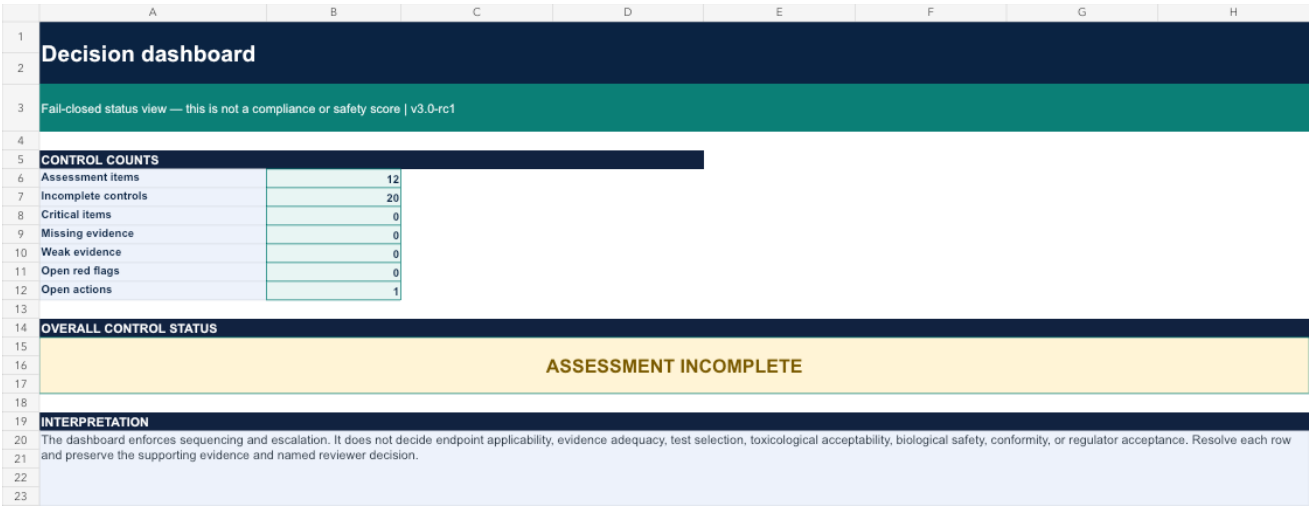
What this resource helps a team produce

- A controlled final-finished-device scope, including variants, accessories, sterilization, packaging, ageing, coatings, lubrication, and use conditions.
- A component-level direct and indirect patient-contact map covering lumens, hubs, connectors, valves, seals, ports, reservoirs, filters, adhesives, coatings, and delivered-fluid routes.
- A material, formulation, processing, residue, and surface-state map linked to drawings, bills of material, supplier controls, and change history.
- A reviewable contact and exposure model that addresses cumulative, repeated, intermittent, and reasonably foreseeable use.
- An endpoint-by-endpoint evidence strategy that separates tested evidence, prior-device evidence, chemistry or toxicology support, device-specific rationale, unresolved applicability, and gaps.
- Separate hemocompatibility and pyrogen/endotoxin decision records with explicit triggers and escalation paths.
- A test-article release record demonstrating representativeness of the final finished configuration and documenting any limitation or deviation.
- A decision and handoff package that identifies residual uncertainty, actions, owners, evidence locations, named reviewers, and dates.

SCOPE This resource supports structured documentation and review preparation. It does not select tests, determine endpoint applicability, establish toxicological acceptability or biological safety, prove conformity, or predict regulator acceptance. Device-specific decisions require qualified biological-safety, toxicology, laboratory, risk-management, clinical, and market-specific regulatory review as applicable.

The working sequence

Step	Action	Output
1	Freeze the marketed or submitted configuration and intended-use boundary.	Controlled device scope
2	Map every component and surface that can contact the patient directly or through fluid, blood, gas, drainage, or delivered substance.	Contact and flow-path map
3	Record materials, grades, additives, colorants, coatings, adhesives, lubricants, processing aids, residues, sterilization, and ageing state.	Material and process map
4	Define contact nature, anatomical site, duration, frequency, flow, volume, delivered fluid, and foreseeable exposure extensions.	Exposure model
5	Build the endpoint strategy and identify the evidence route and residual uncertainty for each decision area.	Endpoint evidence matrix
6	Resolve hemocompatibility, pyrogen/endotoxin, chemistry/toxicology, and test-article triggers in separate controlled records.	Specialist decision records
7	Link every conclusion to a controlled evidence location and open an owned action for each unresolved limitation.	Evidence, actions, and decisions
8	Assemble the reviewer handoff and perform the final cross-file identity, scope, source, and decision check.	Qualified-review package



Decision dashboard

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

CONTROL COUNTS

Assessment items	12
Incomplete controls	20
Critical items	0
Missing evidence	0
Weak evidence	0
Open red flags	0
Open actions	1

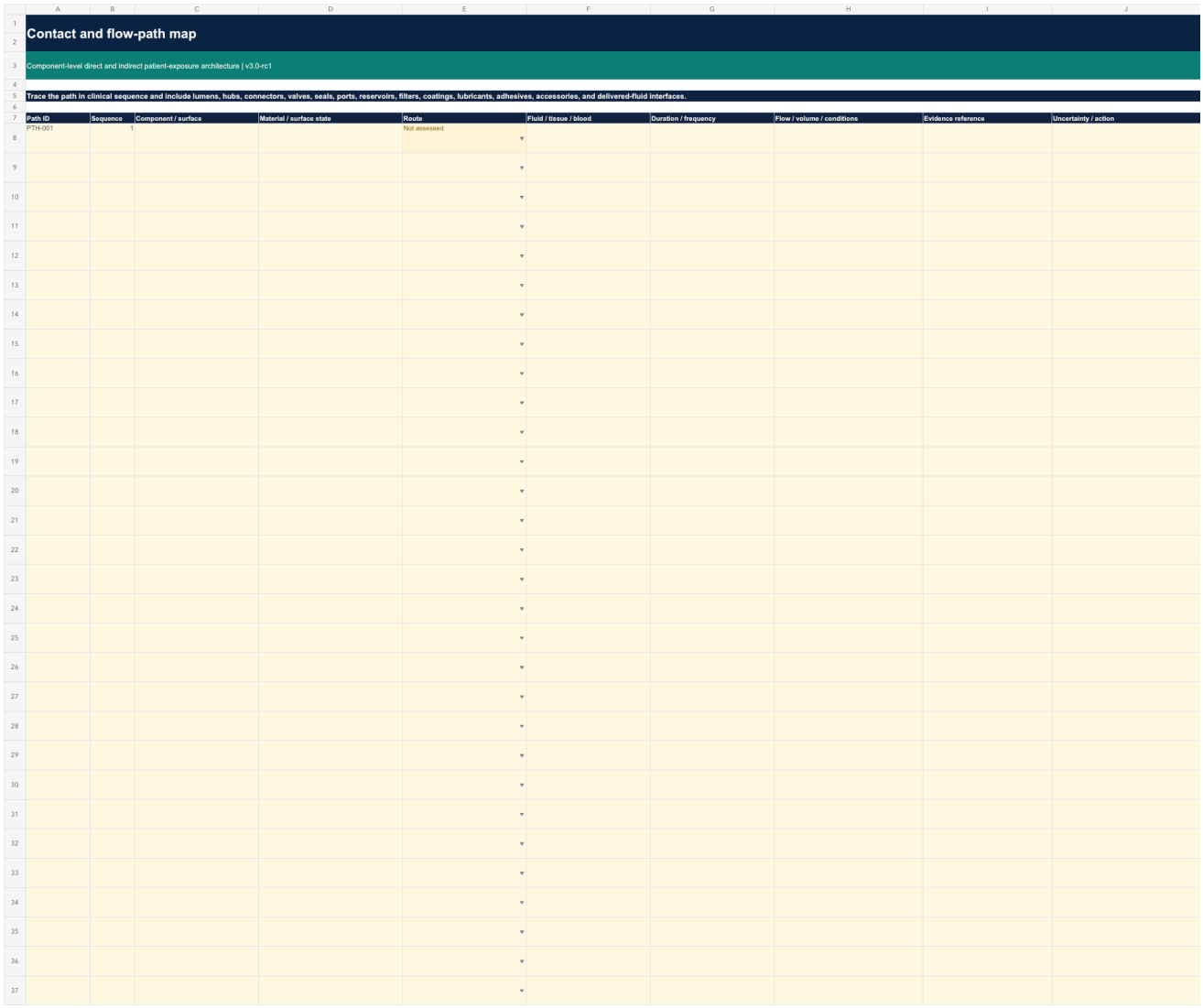
OVERALL CONTROL STATUS

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.

Decision dashboard — fail-closed control view from the current candidate build



Contact and flow-path map

Component-level direct and indirect patient-exposure architecture | v3.0-rc1

Trace the path in clinical sequence and include lumens, hubs, connectors, valves, seals, ports, reservoirs, filters, coatings, lubricants, adhesives, accessories, and delivered-fluid interfaces.

Path ID	Sequence	Component / surface	Material / surface state	Route	Fluid / tissue / blood	Duration / frequency	Flow / volume / conditions	Evidence reference	Uncertainty / action
PTH-001	1			Not assessed					

Contact and flow-path map — component-level direct and indirect exposure record

WHAT THE PREVIEW DEMONSTRATES The product controls device identity, exposure, evidence, specialist triggers, actions, sources, and qualified decisions. It does not supply a prewritten device conclusion.

Exactly what is included

File	Use it for	Complete when
Quick Start PDF	Run the safe workflow in the intended order and identify early stop conditions.	The team knows which artifact to use, who owns each step, and when to escalate.
Implementation Guide PDF	Understand the device-specific questions, evidence boundaries, market overlays, and reviewer expectations.	The selected approach and its limits can be explained without relying on generic material history.
Editable Working Templates DOCX	Draft the controlled scope, maps, evidence matrix, release memo, decisions, and handoff.	All response areas are replaced with device-specific content and open items are resolved or owned.
Operational Workbook XLSX	Control records, sources, status, actions, review evidence, and cross-functional handoff.	The dashboard has no incomplete controls or unowned stop conditions and named reviewers are recorded.
Source Status and Release Notes PDF	Verify public source status, recognition limits, transitions, jurisdiction, and recheck triggers.	The source register reflects the exact source versions used for the current decision.
README, responsible-use terms, manifest, and checksums	Orient the recipient, preserve package integrity, and control authorized use.	Identity, version, files, hashes, support route, and use boundaries agree.

What is deliberately not promised

- No automated selection of tests or endpoint applicability.
- No biological-safety, toxicological-acceptability, compliance, conformity, or regulator-acceptance determination.
- No reproduction of ISO standards or replacement for lawfully obtained standards and current regulator instructions.
- No guarantee that legacy evidence applies to a changed device, supplier, formulation, process, sterilization, ageing, surface, or use condition.
- This preview does not provide legal, privacy, refund, tax, processor, regulatory, scientific, or individualized commercial advice; the applicable order and terms control.

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