MEDDEV ADVISORY

SAMPLE PREVIEW

Wound Dressing & Adhesive Skin-Contact Biological Evaluation Evidence Pack

Route-gated wound-contact, material, active-agent, evidence, and reviewer controls

An honest buyer view of the route gate, working files, live controls, and professional-judgment boundary

MDA-TLK-WOUND-SKIN-10993-01 • v3.0 • PUBLIC PRODUCT PREVIEW

PRE-PURCHASE TOUR — COMPLETE PAID FILES NOT INCLUDED

Help medical-device teams define the final finished wound-dressing configuration, distinguish wound-bed and intact-skin exposure, determine the applicable regulatory route, and assemble traceable biological-evaluation evidence for qualified review.

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

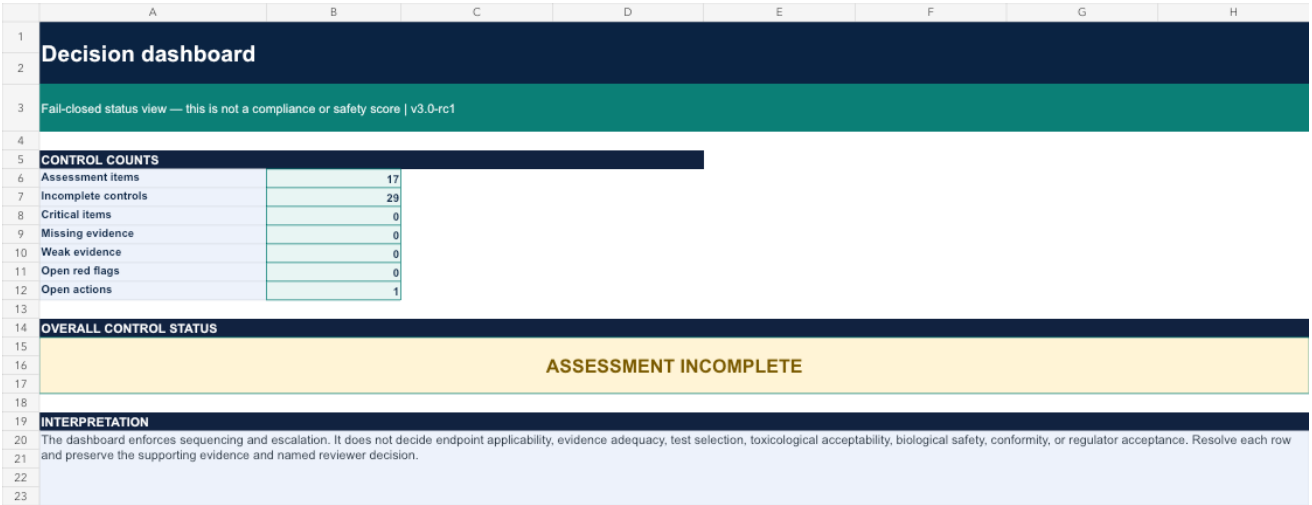
What this resource helps a team produce

- A controlled device and claims profile tied to the final finished, sterilized, packaged, and aged configuration.
- A route decision that distinguishes exempt or non-exempt FDA pathways, EU MDR Rules 4, 13, and 21, India classification orientation, and combination-product uncertainty.
- A zone-level contact and exposure map covering wound bed, breached dermis, exudate, peri-wound skin, adhesive border, backing, liner, secondary dressings, and indirect transfer routes.
- A material, formulation, active-agent, process, residue, sterilization, packaging, shelf-life, and supplier-change record.
- An endpoint evidence strategy that records the device-specific question, evidence route, limitations, residual uncertainty, action, and qualified decision for each area.
- A test-article and sample-preparation release record that compares the proposed article with the current finished product and worst-case marketed variants.
- Separate FDA, EU, and India evidence maps that activate only after the applicable classification and regulatory route are confirmed.
- A reviewer handoff with controlled evidence locations, stop conditions, actions, decisions, named reviewers, dates, source status, and change triggers.

SCOPE This structured working aid is limited to externally applied, non-resorbable wound dressings and adhesive skin-contact components. It does not determine product classification, combination-product jurisdiction, endpoint applicability, test selection, toxicological acceptability, biological safety, conformity, submission or export readiness, or regulator acceptance. Drug- or biologic-releasing, resorbable, implantable, haemostatic, tissue-adhesive, animal- or human-derived, living-cell or tissue-engineered, internal or mucosal products—and any product with an unclear principal mode of action—require a separately confirmed specialist route before use.

The working sequence

Step	Action	Output
1	Confirm that the product is within the pack's intended scope and identify every out-of-scope or jurisdiction trigger.	Scope and specialist-route decision
2	Freeze the final finished device, variants, claims, sterile state, packaging, shelf life, wound indications, and assessment purpose.	Controlled device and claims profile
3	Determine the FDA, EU, and India route that actually applies before activating a market evidence map.	Regulatory route record
4	Map every wound-bed, breached-dermis, exudate, peri-wound, intact-skin, adhesive, backing, and indirect transfer route.	Contact-zone and cumulative-exposure map
5	Record materials, formulation, additives, active agents, processes, residues, sterilization, packaging, ageing, and supplier/change controls.	Material and finished-state map
6	Build an endpoint evidence strategy and separate existing evidence, chemistry/toxicology support, test data, rationale, and unresolved gaps.	Endpoint decision matrix
7	Release the test article and sample preparation only after comparing it with the current final finished and worst-case marketed configuration.	Test-article release record
8	Link every conclusion, gap, action, market output, and source to controlled evidence and a named qualified decision.	Reviewer handoff package



Decision dashboard

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

CONTROL COUNTS

Assessment items	17
Incomplete controls	29
Critical items	0
Missing evidence	0
Weak evidence	0
Open red flags	0
Open actions	1

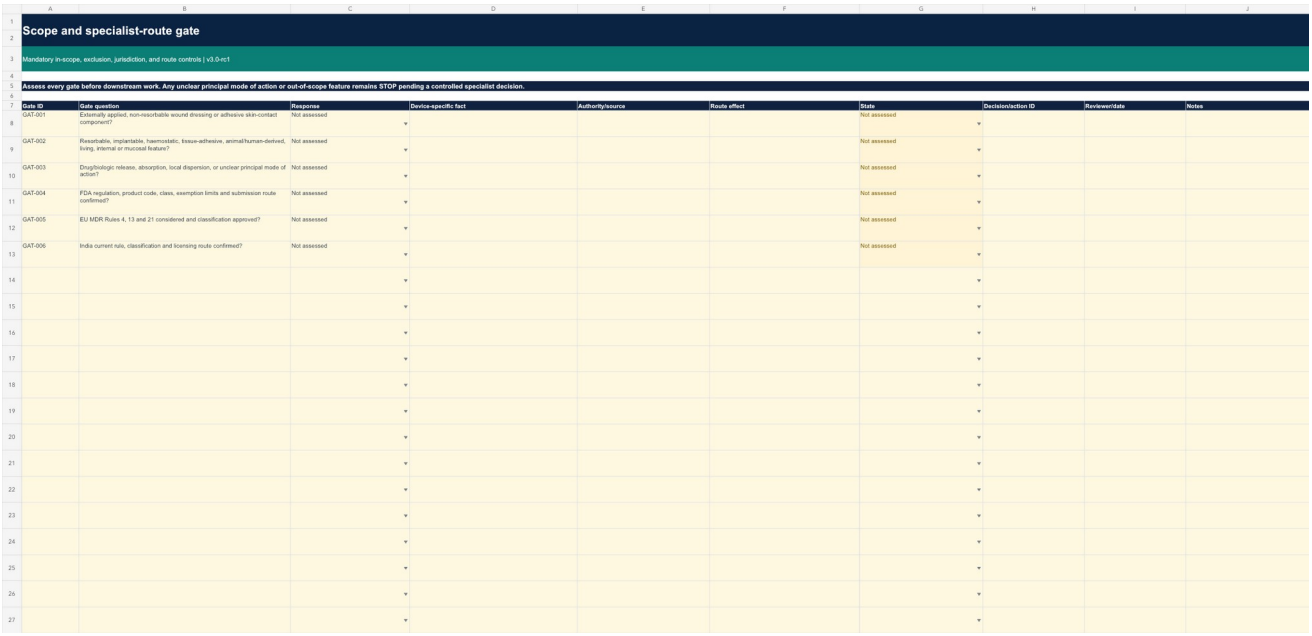
OVERALL CONTROL STATUS

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 from the current candidate - fail-closed control status, not a readiness score



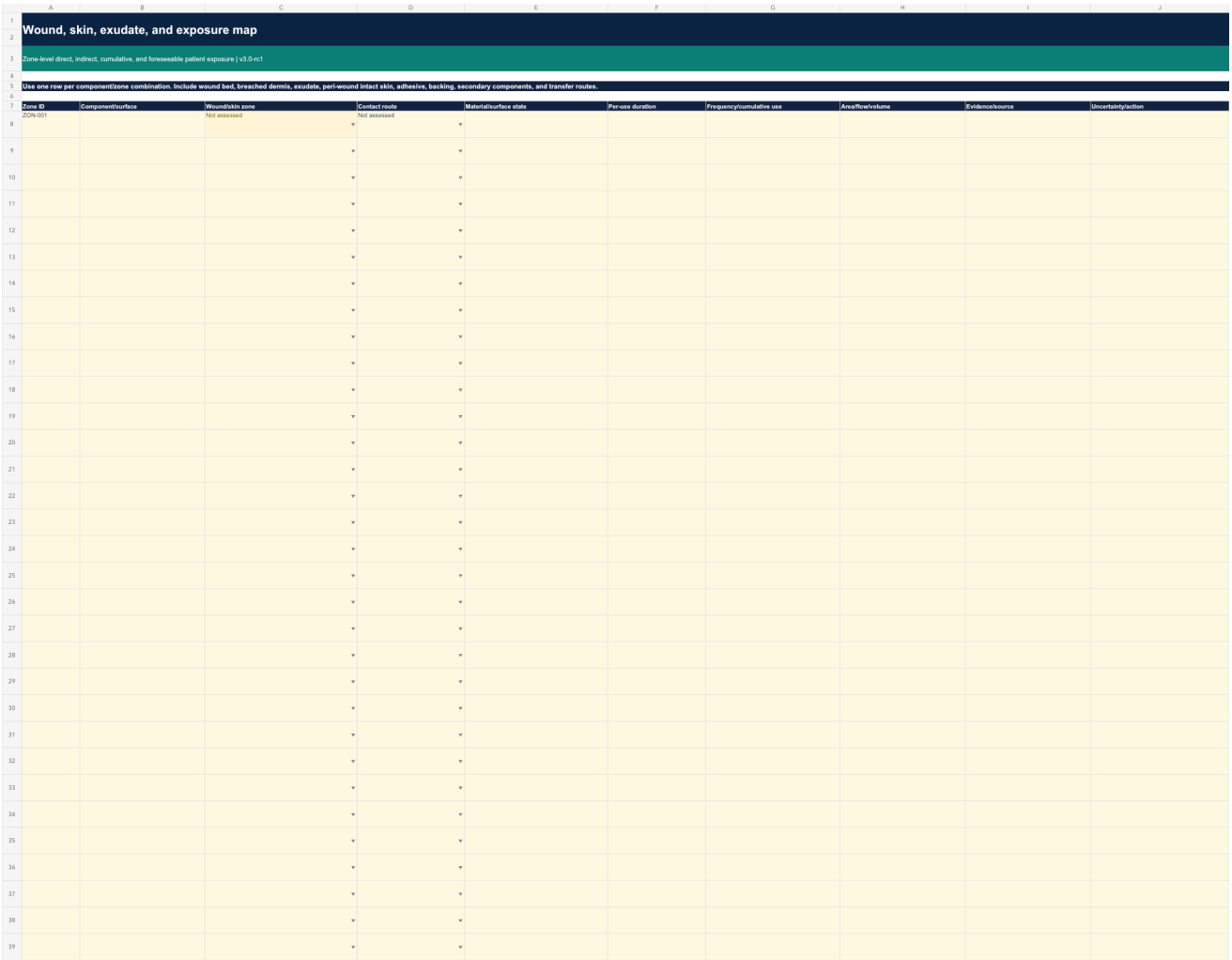
Scope and specialist-route gate

Mandatory in-scope, exclusion, jurisdiction, and route controls | v3.0-rc1

Assess every gate before downstream work. Any unclear principal mode of action or out-of-scope feature remains STOP pending a controlled specialist decision.

Gate ID	Gate question	Response	Device-specific fact	Authority/source	Route effect	State	Decision/action ID	Reviewer/date	Notes
GAT-001	Externally applied, non-resorbable wound dressing or adhesive skin-contact component?	Not assessed				Not assessed			
GAT-002	Resorbable, implantable, haemostatic, tissue-adhesive, animal/human-derived, living, internal or mucosal feature?	Not assessed				Not assessed			
GAT-003	Drug/biologic release, absorption, local dispersion, or unclear principal mode of action?	Not assessed				Not assessed			
GAT-004	FDA regulation, product code, class, exemption limits and submission route confirmed?	Not assessed				Not assessed			
GAT-005	EU MDR Rules 4, 13 and 21 considered and classification approved?	Not assessed				Not assessed			
GAT-006	India current rule, classification and licensing route confirmed?	Not assessed				Not assessed			

Scope and specialist-route gate from the actual workbook



Wound, skin, exudate, and exposure map

Zone-level direct, indirect, cumulative, and foreseeable patient exposure | v3.0-rc1

Use one row per component/zone combination. Include wound bed, breached dermis, exudate, peri-wound intact skin, adhesive, backing, secondary components, and transfer routes.

Zone ID	Component/surface	Wound/skin zone	Contact route	Material/surface state	Per-use duration	Frequency/cumulative use	Area/flow/volume	Evidence/source	Uncertainty/action
ZON-001		Not assessed	Not assessed						

Wound, skin, exudate, and cumulative-exposure map from the actual workbook

WHAT THE PREVIEW DEMONSTRATES The product controls scope, regulatory route, wound and skin exposure, finished-state materials, active-agent uncertainty, evidence, test articles, actions, sources, and qualified decisions. It does not provide a prewritten safety or submission conclusion.

Exactly what is included

File	Use it for	Complete when
Quick Start PDF	Run the route-gated workflow in the intended order and recognize mandatory stop conditions.	The team knows which records to complete, who owns each decision, and when specialist escalation is required.
Implementation Guide PDF	Understand wound-specific scope, route, contact-zone, evidence, test-article, and market-overlay controls.	The device-specific approach and its limitations can be explained without generic claims.
Editable Working Templates DOCX	Draft route, device, exposure, material, active-agent, endpoint, test-article, evidence, decision, and handoff records.	Blank response areas are replaced by controlled device content and every open item is resolved or owned.
Operational Workbook XLSX	Control records, evidence, sources, stop conditions, actions, and qualified decisions.	Every seeded route and red-flag control is assessed and every terminal state has its companion record.
Source Status and Release Notes PDF	Verify public-source status, recognition extent, transitions, jurisdiction, and recheck triggers.	The source register reflects the exact sources and dates relied upon for the current device decision.
README, responsible-use terms, manifest, and checksums	Orient the recipient and preserve package identity, integrity, and authorized-use boundaries.	Version, inventory, hashes, use boundary, support route, and release record agree.

What is deliberately not promised

- No automated product classification, combination-product jurisdiction, endpoint applicability, test selection, or biological-safety conclusion.
- No automatic FDA exemption, 510(k), De Novo, eSTAR, EU class/GSPR conformity, CDSCO class, licence, submission, or export-readiness determination.
- No toxicological-acceptability, clinical-effectiveness, infection-treatment, wound-healing, compliance, conformity, or regulator-acceptance claim.
- No reproduction of ISO standards or replacement for lawfully obtained standards, current regulator instructions, and qualified professional review.
- No assumption that legacy evidence applies after a material, supplier, active-agent, adhesive, process, sterilization, packaging, ageing, claim, use, or exposure 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.