MEDDEV ADVISORY

SAMPLE PREVIEW

Wearable Electrode Biocompatibility & Skin-Contact Evidence Pack

Component-level contact mapping, cumulative wear control, Attachment G screening, and skin-interface evidence traceability

An honest view of the component-level workflow, real workbook, source transparency, and professional-judgment boundary

MDA-TLK-WEAR-ELECTRODE-10993-01 • v3.0 • PUBLIC PRODUCT PREVIEW

PRE-PURCHASE TOUR — COMPLETE PAID FILES NOT INCLUDED

Help medical-device teams build a defensible, component-level biological-evaluation record for wearable electrodes and skin-contact sensor systems across adhesives, conductive media, films, inks, housings, liners, residues, repeated application, sweat, motion, and occlusion.

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

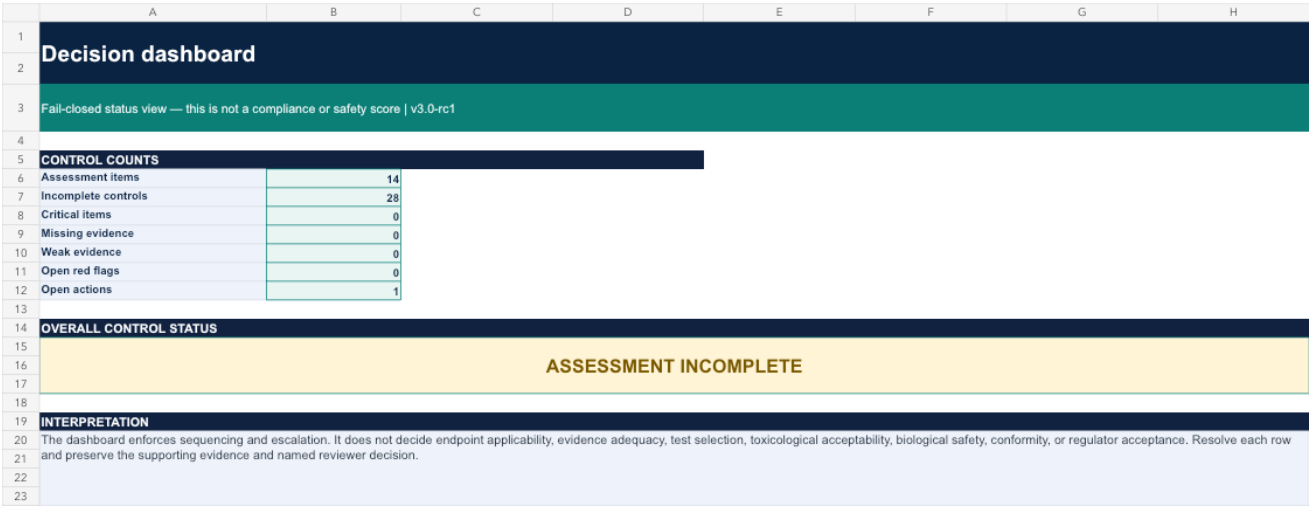
What this resource helps a team produce

- A controlled device and use profile covering intended site, skin condition, wear interval, repeated or adjacent applications, reuse, replacement, target population, and foreseeable exposure.
- A component-level contact-zone map for electrodes, conductive gels or hydrogels, adhesives, films, inks, housings, cables, liners, residues, edges, and plausible transfer or migration paths.
- A final-finished configuration baseline linking formulations, suppliers, manufacturing aids, processing, cleaning, packaging, storage, conditioning, and sterilization where applicable.
- A cumulative-contact calculation that preserves the actual labelled regimen instead of treating each patch or electrode application as an isolated event.
- An FDA Attachment G eligibility screen applied component by component, with explicit exclusion triggers, evidence locators, and qualified-decision ownership.
- An endpoint and evidence map that keeps cytotoxicity, skin sensitization, irritation, chemical characterization, toxicological assessment, clinical evidence, and post-market signals distinct and traceable.
- A real-use challenge record for sweat, heat, occlusion, motion, pressure, conductive media, removal trauma, reapplication, cleaning, and compromised-skin exclusions or warnings.
- A reviewer-ready biological-evaluation handoff showing gaps, changes, conflicts, residual uncertainty, named decisions, source status, and the exact controlled delivery set.

SCOPE This resource structures evidence and decision records. It does not determine FDA Attachment G eligibility, endpoint applicability, test selection, biological safety, toxicological acceptability, conformity, substantial equivalence, or clinical acceptability. The exact finished device, cumulative use, skin condition, product-specific requirements, current sources, and named qualified reviewers control every conclusion.

The working sequence

Step	Action	Output
1	Freeze the exact wearable system, variants, claims, intended sites, skin condition, user population, and labelled application regimen.	Controlled device/use profile
2	Calculate cumulative contact across repeated, sequential, overlapping, or adjacent applications and separate patient exposure from single-unit wear time.	Cumulative wear record
3	Map every finished-device component and plausible transfer path to direct, indirect, transient, or non-contact zones.	Component/contact-zone map
4	Control material identity, formulation, supplier, process, cleaning, packaging, ageing, storage, and finished-state differences for each contacting component.	Finished-state material baseline
5	Screen FDA Attachment G eligibility component by component, record every criterion and exclusion, and preserve the qualified decision and source locator.	Attachment G decision record
6	Map each biological endpoint to current evidence, test article, real-use relevance, limitations, and a named scientific decision.	Endpoint/evidence map
7	Challenge the evidence against sweat, heat, occlusion, motion, pressure, conductive media, repeated removal and reapplication, cleaning, ageing, and foreseeable misuse.	Real-use challenge assessment
8	Reconcile changes, complaints, clinical experience, gaps, actions, qualified reviews, and delivery-file identities before handoff.	Controlled evaluation candidate



Decision dashboard

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

CONTROL COUNTS	
Assessment items	14
Incomplete controls	28
Critical items	0
Missing evidence	0
Weak evidence	0
Open red flags	0
Open actions	1

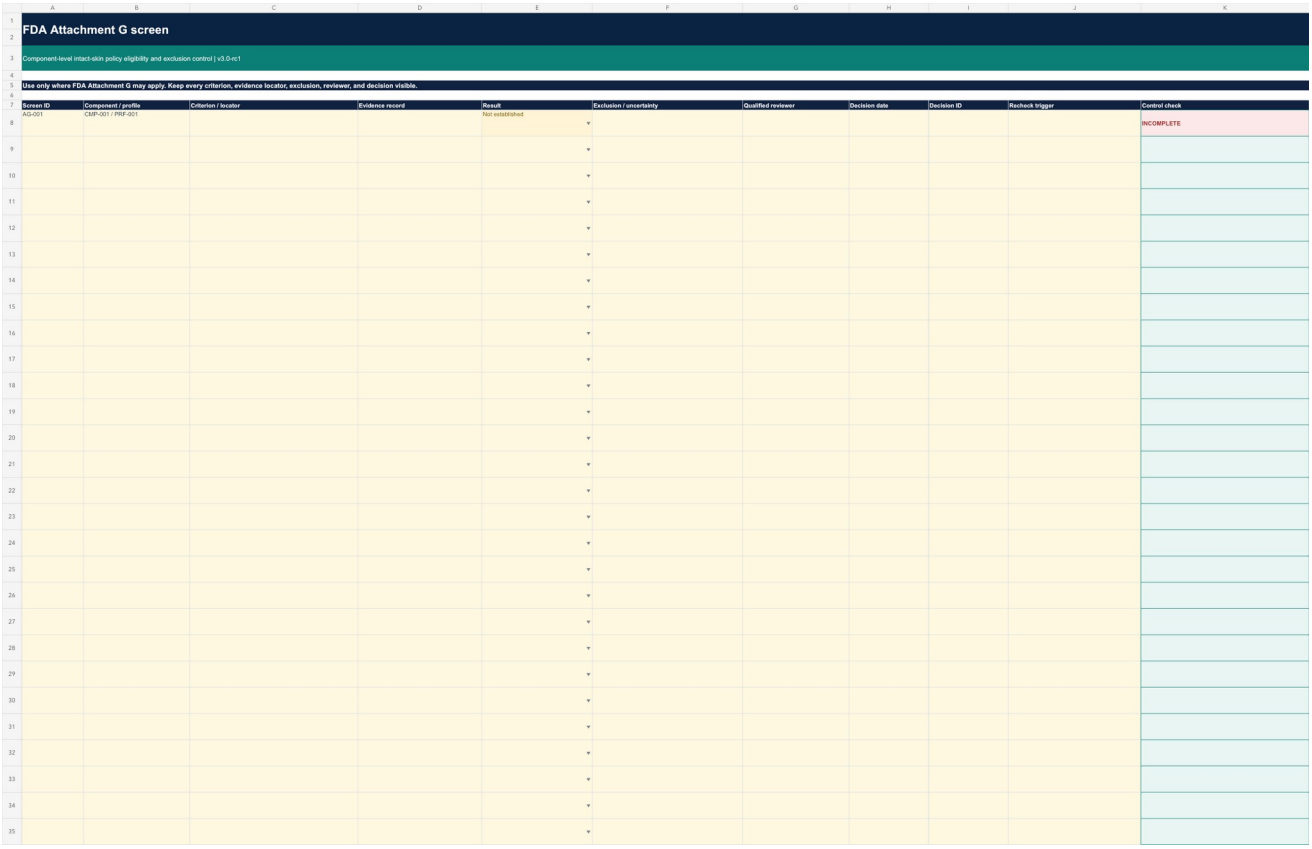
OVERALL CONTROL STATUS

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 before the wearable evidence controls are completed



FDA Attachment G screen

Component-level intact-skin policy eligibility and exclusion control | v3.0-rc1

Use only where FDA Attachment G may apply. Keep every criterion, evidence locator, exclusion, reviewer, and decision visible.

Screen ID	Component / profile	Criterion / locator	Evidence record	Result	Exclusion / uncertainty	Qualified reviewer	Decision date	Decision ID	Recheck trigger	Control check
AG-001	CMP-001 / PRF-001			Not established						INCOMPLETE

FDA Attachment G screen — component-level criteria, exclusions, evidence, and qualified decision control

WHAT THE PREVIEW DEMONSTRATES The product controls device use, cumulative wear, components, materials, Attachment G screening, endpoint evidence, test articles, real-use challenges, changes, gaps, and approvals. It does not decide biological safety or regulatory acceptability.

Exactly what is included

File	Use it for	Complete when
Quick Start PDF	Set the device, cumulative wear, component-contact, and immediate stop-condition baseline.	The team knows what touches whom, where, for how long in total, in what finished state, and which facts remain unresolved.
Implementation Guide PDF	Apply a disciplined wearable-electrode biological-evaluation and evidence-control method.	Component mapping, Attachment G boundaries, endpoints, real-use challenges, evidence limitations, and reviewer roles can be explained clearly.
Editable Working Templates DOCX	Draft device, wear, component, eligibility, evidence, endpoint, challenge, change, and approval records.	Every blank and fictional field is replaced with controlled device-specific information.
Operational Workbook XLSX	Control the full assessment, formulas, red flags, actions, evidence, and qualified decisions.	Every seeded control has complete companion evidence and no unresolved stop condition is hidden.
Source Status and Release Notes PDF	Verify current FDA, ISO, and EU source status, limitations, and recheck triggers.	The source register matches the exact public authorities and standards editions used by the team.
README, responsible-use terms, manifest, and checksums	Orient the recipient, preserve package integrity, and control authorized use.	Product identity, version, inventory, hashes, support route, and use boundary agree.

What is deliberately not promised

- No automatic FDA Attachment G eligibility, endpoint applicability, testing, biological-safety, toxicological, clinical, substantial-equivalence, or conformity conclusion.
- No assumption that a generic material name, supplier certificate, 'medical grade' claim, legacy report, market history, or lack of complaints establishes current finished-device safety.
- No universal categorization based only on one electrode or patch wear interval; cumulative repeated contact and the actual use profile require qualified interpretation.
- No reproduction of ISO standards or replacement for lawfully obtained standards, current regulator guidance, product-specific requirements, and the exact controlled device record.
- 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.