MEDDEV ADVISORY

SAMPLE PREVIEW

EU MDR GSPR 10 Biocompatibility Technical Documentation Pack

Clause-accurate chemical, physical, and biological evidence mapping for MDR Annex I Section 10 and Annex II

A candid pre-purchase view of the files, controls, fictional workflow, source status, and professional-judgment boundary

MDA-TLK-EUMDR-GSPR10-01 • v3.0 • PUBLIC PRODUCT PREVIEW

PRE-PURCHASE TOUR — COMPLETE PAID FILES NOT INCLUDED

Help medical-device teams build a device-specific, source-dated, traceable GSPR 10 evidence record that connects exact legal subclauses to final-finished-device facts, controlled evidence, methods, risk and clinical files, post-market information, technical-documentation locations, actions, and qualified conclusions.

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

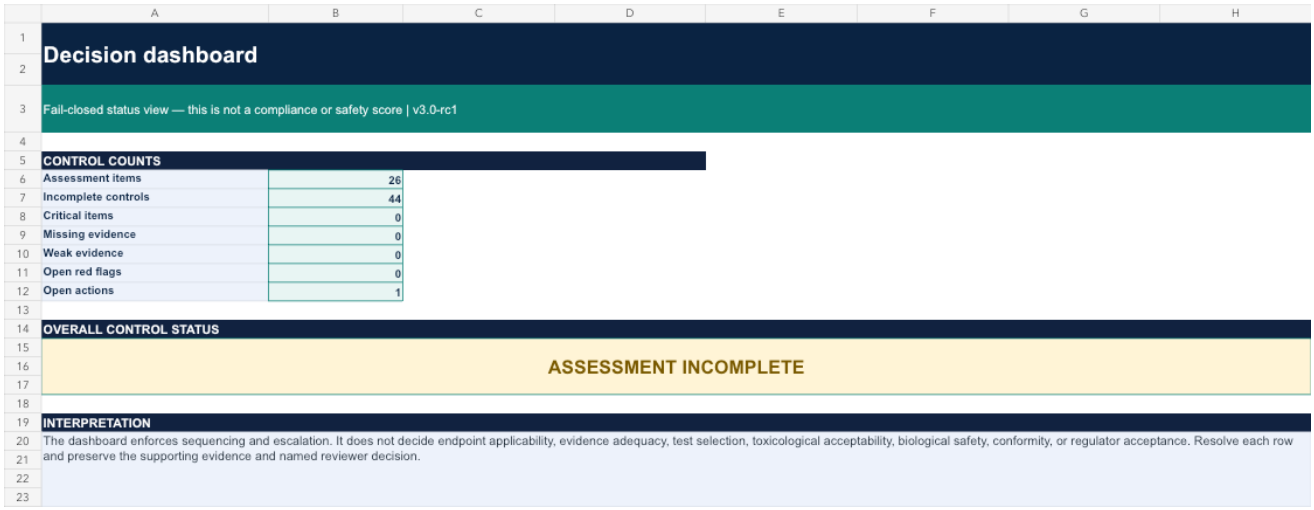
What this resource helps a team produce

- A clause-accurate map of MDR Annex I Sections 10.1 through 10.6, including every 10.1 factor and the distinct duties in 10.3, 10.4.1 through 10.4.5, 10.5, and 10.6.
- A controlled device and supplied-state baseline covering intended purpose, configurations, direct and indirect contact, materials, substances, processes, residues, particles, ingress pathways, packaging, sterilization, ageing, and use conditions.
- A component-level material and contact record tied to the exact final-finished device rather than generic material names or unbounded supplier declarations.
- A fail-closed CMR and endocrine-disruptor gate that separates device/part scope, concentration evidence, current classification status, exposure, alternatives, vulnerable groups, guideline review, labeling, and IFU actions.
- A controlled evidence index and method-status register that separates ISO publication, EN adoption, EU harmonisation, Official Journal transition, device applicability, and evidence location.
- A bridge from GSPR 10 questions to biological evaluation, chemical characterization, toxicological assessment, risk management, clinical evaluation, PMS/PMCF, labeling, and Annex II technical-documentation locators.
- A reviewer-ready list of red flags, owned actions, decisions, limitations, approvals, and reopening triggers without readiness scores or automated conformity claims.
- A complete fictional worked trace showing how a professionally correct result can remain incomplete when decisive evidence or approvals are missing.

SCOPE This pack structures EU MDR GSPR 10 evidence and technical-documentation preparation. It does not decide legal applicability, determine conformity or biological safety, establish toxicological acceptability, select or waive tests, establish clinical equivalence, create missing evidence, replace a biological evaluation or complete technical file, authorize CE marking or market release, or predict notified-body or authority acceptance. Device-specific decisions require competent regulatory, biological-safety, toxicology, materials, risk-management, clinical, labeling, and other specialist review as applicable.

The working sequence

Step	Action	Output
1	Freeze one exact MDR device candidate, intended purpose, variants, supplied state, markets, certificate status, source date, and decision request.	Controlled assessment charter
2	Map Sections 10.1 through 10.6 exactly; record applicability or a device-specific not-applicable rationale for each atomic control.	GSPR 10 clause map
3	Reconstruct the final-finished device, material/substance inventory, direct and indirect contacts, processing, contamination, residues, particles, ingress pathways, and use conditions.	Device, material, and exposure baseline
4	Run the 10.4 scope and concentration gate using controlled substance identity, current classification evidence, concentration, affected part, and intended use.	CMR/endocrine-disruptor gate
5	When 10.4.1 is triggered, document exposure, alternatives, functionality and benefit-risk argumentation, vulnerable groups, current guidelines, labeling, and IFU controls.	10.4 justification and information package
6	Index complete controlled evidence, methods, representative articles, findings, deviations, limitations, and exact technical-documentation locations.	Evidence and method-status register
7	Bridge every clause to risk, biological evaluation, chemistry/toxicology, clinical, PMS/PMCF, labeling, and Annex II records; reconcile contrary information.	Technical-documentation evidence bridge
8	Reverify current official sources, close or formally block actions, remove fictional records, and route the exact release candidate through qualified and independent review.	Controlled review candidate



Decision dashboard

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

CONTROL COUNTS	
Assessment items	26
Incomplete controls	44
Critical items	0
Missing evidence	0
Weak evidence	0
Open red flags	0
Open actions	1

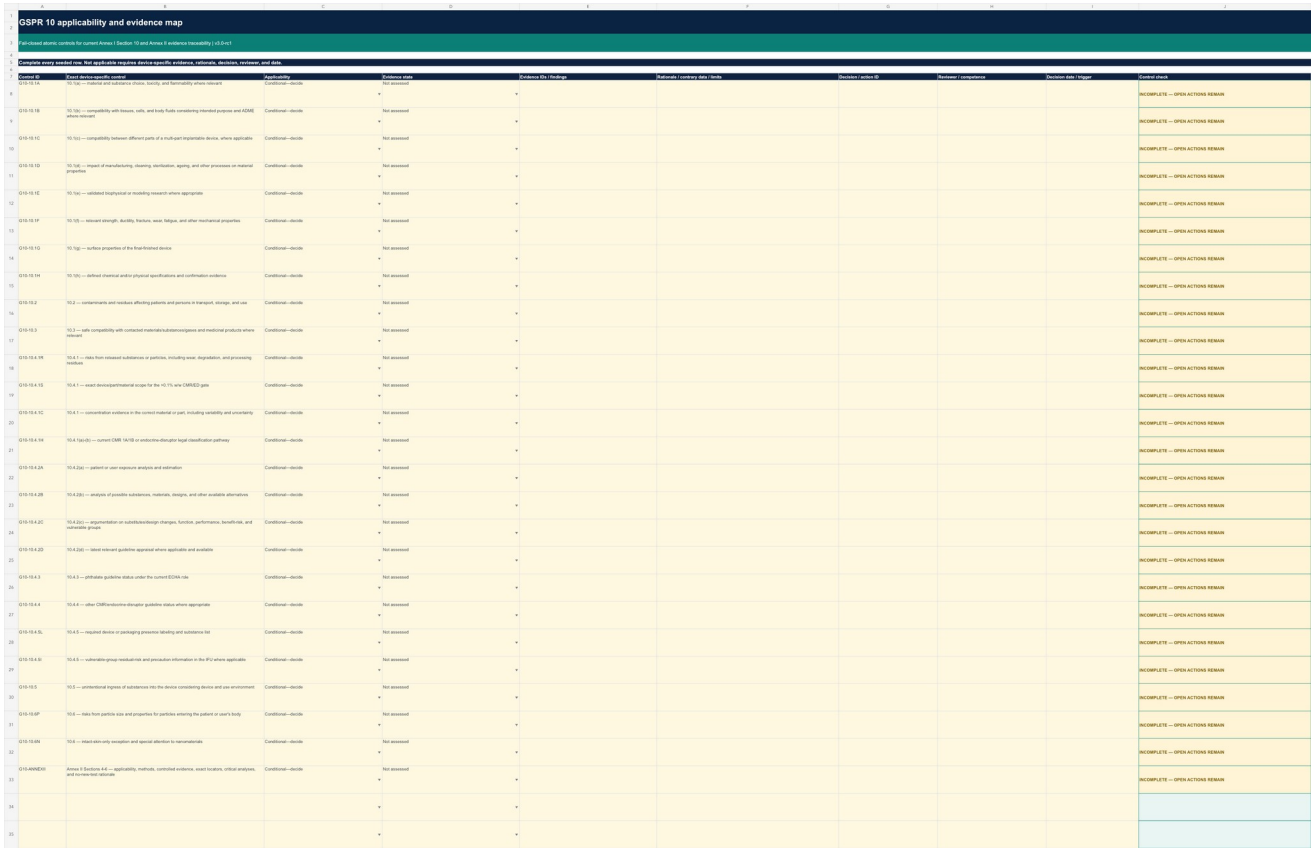
OVERALL CONTROL STATUS

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 — strict workflow completeness and escalation view from the current candidate build



GSPR 10 applicability and evidence map

Fail-closed atomic controls for current Annex I Section 10 and Annex II evidence traceability | v3.0-rc1

Complete every seeded row. Not applicable requires device-specific evidence, rationale, decision, reviewer, and date.

Control ID	Exact device-specific control	Applicability	Evidence state	Evidence IDs / findings	Rationale / contrary data / limits	Decision / action ID	Reviewer / competence	Decision date / trigger	Control check
G10-10.1A	10.1(a) — material and substance choice, toxicity, and flammability where relevant	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.1B	10.1(b) — compatibility with tissues, cells, and body fluids considering intended purpose and ADME where relevant	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.1C	10.1(c) — compatibility between different parts of a multi-part implantable device, where applicable	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.1D	10.1(d) — impact of manufacturing, cleaning, sterilization, ageing, and other processes on material properties	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.1E	10.1(e) — validated biophysical or modelling research where appropriate	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.1F	10.1(f) — relevant strength, ductility, fracture, wear, fatigue, and other mechanical properties	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.1G	10.1(g) — surface properties of the final-finished device	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.1H	10.1(h) — defined chemical and/or physical specifications and confirmation evidence	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.2	10.2 — contaminants and residues affecting patients and persons in transport, storage, and use	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.3	10.3 — safe compatibility with contacted materials/substances/gases and medicinal products where relevant	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.4.1R	10.4.1 — risks from released substances or particles, including wear, degradation, and processing residues	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.4.1S	10.4.1 — exact device/part/material scope for the >0.1% w/w CMR/ED gate	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.4.1C	10.4.1 — concentration evidence in the correct material or part, including variability and uncertainty	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.4.1H	10.4.1(a)-(b) — current CMR 1A/1B or endocrine-disruptor legal classification pathway	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.4.2A	10.4.2(a) — patient or user exposure analysis and estimation	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.4.2B	10.4.2(b) — analysis of possible substances, materials, designs, and other available alternatives	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.4.2C	10.4.2(c) — argumentation on substitute/design changes, function, performance, benefit-risk, and vulnerable groups	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.4.2D	10.4.2(d) — latest relevant guideline appraisal where applicable and available	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.4.3	10.4.3 — phthalate guideline status under the current ECHA rule	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.4.4	10.4.4 — other CMR/endocrine-disruptor guideline status where appropriate	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.4.5L	10.4.5 — required device or packaging presence labeling and substance list	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.4.5I	10.4.5 — vulnerable-group residual-risk and precaution information in the IFU where applicable	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.5	10.5 — unintentional ingress of substances into the device considering device and use environment	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.6P	10.6 — risks from particle size and properties for particles entering the patient or user's body	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-10.6N	10.6 — intact-skin-only exception and special attention to nanomaterials	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN
G10-ANNEXII	Annex II Sections 4-6 — applicability, methods, controlled evidence, exact location, critical analyses, and none-test rationale	Conditional—decide	Not assessed						INCOMPLETE — OPEN ACTIONS REMAIN

Atomic GSPR 10 map — current clause-specific applicability, evidence, rationale, decision, reviewer, date, and trigger controls

WHAT THE PREVIEW DEMONSTRATES The product controls current GSPR 10 requirements, final-device facts, 10.4 trigger and justification, evidence and standards status, lifecycle links, precise Annex II locations, actions, and qualified decisions. It does not supply a prewritten conformity, safety, toxicology, testing, labeling, CE-marking, or notified-body conclusion.

Exactly what is included

File	Use it for	Complete when
Quick Start PDF	Freeze the candidate, follow the safe sequence, identify source rechecks, and recognize legal/scientific stop conditions before drafting conclusions.	The team knows the exact device, intended purpose, variants, supplied state, MDR baseline, roles, source date, review order, and reserved decisions.
Implementation Guide PDF	Understand every current GSPR 10 clause, the CMR/ED gate, evidence appraisal, standards distinctions, lifecycle links, and Annex II navigation.	The team can explain each requirement, device fact, method, evidence item, limitation, action, and approval without relying on a score or generic biocompatibility claim.
Editable Working Templates DOCX	Draft the charter, clause map, material/contact baseline, process/compatibility records, CMR/ED gate, justification, evidence bridges, locators, and release memo.	Every entry is device specific; all uncertainty, contrary data, and missing evidence has an owner, action, due date, and decision path.
Operational Workbook XLSX	Control the atomic GSPR map, device facts, evidence, standards status, red flags, actions, decisions, precise locators, and fictional training trace.	No invalid or incomplete control remains; open/blocked actions are resolved; every terminal row has evidence, rationale, decision, reviewer/competence, date, and trigger.
Source Status and Release Notes PDF	Verify current MDR, 2025 amendment, 2026 harmonisation acts/corrigendum, ECHA/SCHEER status, dynamic classifications, and ISO/EN/OJ distinctions.	The register matches the exact official sources and controlled standards used for the candidate decision on the recorded date.
Customer README, responsible-use terms, and official source register	Orient recipients, preserve identity and version, control authorized use, and make update obligations explicit.	Product/workbook IDs, version, files, source date, support route, and professional boundaries agree across the package.

What is deliberately not promised

- No automated legal applicability, conformity, biological-safety, toxicological-acceptability, test-selection, no-new-test, or representative-article decision.
- No automated CMR/endocrine-disruptor identity, classification, threshold, exposure, alternatives, vulnerable-group, labeling, or IFU conclusion.
- No notified-body, competent-authority, certificate, submission, CE-marking, implementation, or market-release decision.
- No universal coverage of IVDs, combination products, medicinal substances, tissues/cells, animal derivatives, degradable/resorbable devices, nanomaterials, reusable processing, implants, or other specialist technologies without additional expertise.
- No reproduction of ISO standards or replacement for lawfully obtained controlled standards, current legal text, applicable CS, device-specific guidance, or qualified review.
- No guarantee that historical, similar-device, equivalent-device, supplier, literature, clinical, or post-market evidence applies to the exact final-finished candidate.

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