

UDI Submission Readiness Checklist

Swissdamed / EUDAMED (v1.1)

Purpose

This checklist helps RA/QA teams spot common readiness gaps before submission. It is intentionally non-technical: it does not disclose implementation details, thresholds, or internal workflows.

Data completeness

- Mandatory information present (no silent gaps).
- Consistent formats across records (dates/IDs/codes).
- Stable naming and identifiers (no accidental duplicates).

Internal consistency

- No contradictions across related fields.
- Linked entities resolve correctly (organization / device / documentation).
- No conflicting references across packaging or models.

Traceability

- Clear ownership and review points are defined.
- Key claims/entries can be justified with controlled records.
- Change history exists for critical items (who/what/when/why).

Submission readiness

- A reviewable submission package exists (structure and checks documented).
- Execution steps are clear (including rollback/retry plan).
- A short stakeholder summary is ready (what is done vs blocked).

Policy: We do not publish client bundles or enabling technical details. Demos use anonymized examples; sensitive material is shared only under NDA (limited scope).

UDI Submission Readiness Checklist

Common failure modes + engagement options ()

Common failure modes (high-level)

- Missing mandatory information -> late rework.
- Inconsistent formats -> validation failures and confusion.
- Contradictions across related entries -> blocked reviews.
- Weak ownership/review gates -> last-minute surprises.
- Unclear traceability -> audit stress.
- Packaging and handover ambiguity -> internal delays.
- No clear “done vs blocked” summary -> stakeholder friction.
- Over-sharing sensitive details -> confidentiality risk.

How we help (deliverables, not advice)

- Readiness assessment: gap list + prioritization + acceptance criteria.
- Implementation support: repeatable submission operations and documentation.
- Ongoing ops: controlled updates and change control support.

Contact: contact@fwl.ai | Demos are anonymized. Sensitive packs are shared only under NDA.