

UDI Ops - Swisssdamed / EUDAMED

Overview (v1.1)

We build audit-ready UDI submission operations: clear readiness gates, traceability, and repeatable execution. This one-pager is intentionally non-technical and does not disclose enabling implementation details.

Phase 1 - Assess

- Readiness scan
- Gap list + priorities
- Acceptance criteria

Phase 2 - Implement

- Repeatable workflow
- Review gates + handover
- Operator guide

Phase 3 - Operate

- Dry-run + fixes
- Change control
- Ongoing support (optional)

Engagement options

- Rapid readiness check (1-2 weeks): gaps + plan.
- Implementation sprint (2-6 weeks): workflow + guides.
- Ongoing ops: periodic support and controlled updates.

Policy: No sensitive client bundles are published. Public demos are anonymized; detailed packs available under NDA (limited scope).

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