**PRD-40 — Medical Devices — UDI & EUDAMED Record and Labelling**

**Intent**

Capture and manage Unique Device Identification (UDI) data, EUDAMED core records, and compliant labelling for medical devices, with audit-ready proofs and advisory-only AI assists.

**Preconditions**

• Product category flagged as medical device (class, intended use, sterilization).

• UDI schema registry per market (EU/US/etc) and label template library.

• Attachment vault (hashing) for certificates, clinical/biocompatibility reports (PRD-11), and Lab/QA linkage (PRD-34).

• PCV/PCT in place for jurisdictional HS/ECCN (PRD-04); serial/lot tracking (PRD-17) enabled where device tracking is required.

**Steps**

• Scope & Market Selection: choose target markets (EU/US/etc). Load applicable UDI fields (device ID, PI elements, packaging levels).

• Data Capture: record device identifier(s), packaging hierarchy, device class, sterilization status, MR conditionality, clinical/biocompatibility refs, Basic UDI-DI (EU).

• AI Assist (advisory): parse IFU/datasheets to suggest UDI attributes with page citations; reviewer accepts/edits. No auto-write.

• EUDAMED Core: create EUDAMED-ready record fields (manufacturer, authorized rep, device risk class, Basic UDI-DI, intended purpose). Link evidence attachments; store a Core Record Receipt (hash + time + signer).

• Label Build: generate market-specific labels (human-readable + AIDC/2D barcode) with LOT/EXP/UDI composition; preview per packaging level.

• Registration & Export: export EUDAMED/GUDID payloads (where applicable), sign and archive submission receipts; track status and renewal dates.

• Gate Hooks: order/ship requires a valid UDI label set + registration status for target market; otherwise HOLD with precise WHY/FIX steps.

• Change Hooks: any governed attribute change (sterilization, class, IFU) triggers label rebuild and, if needed, EUDAMED update task; emit ImpactDelta.

**Edge cases**

• Multi-market differences (EU Basic UDI-DI vs US DI) → maintain separate views tied to the same product version.

• Relabeling for kit bundles → compute UDI per packaging level; block shipment if parent label lacks a child reference.

• Missing clinical evidence → allow draft but block publish/registration; open targeted request with evidence checklist.

**Done when**

• Each device has valid market UDI data, labels render correctly for all packaging levels, registration exports carry signed receipts, and shipments enforce UDI presence with clear WHY/FIX messages.