

GET UDI COMPLIANT IN 2026

COMPLIANCE CHECKLIST

Initial Assessment

- ☐ Review MDR and/or IVDR requirements for your product portfolio.
- ☐ Identify all products that require UDI registration in EUDAMED.
- ☐ Check transition deadlines:
 - ☐ May 28, 2026 (for UDIs placed on the market after May 28, 2026)
 - ☐ November 28, 2026 (for UDIs placed on the market before May 28, 2026)
- ☐ Define internal responsibilities for UDI management (assign roles and tasks).
- ☐ Assess your current UDI readiness:
 - ☐ Do you have all required product master data?
 - ☐ Have you tested a UDI-DI entry in EUDAMED?
 - ☐ Do you know your upload strategy (manual, XML bulk, M2M)?

Timeline & Action Plan

- ☐ Define your compliance timeline.
- ☐ Set milestones for data collection, validation, and upload.
- ☐ Schedule internal reviews and testing phases.
- ☐ Start now: book a demo or join a webinar to accelerate readiness.

Tools & Support

- ☐ Decide if you need external support:
 - ☐ Software solutions (e.g., mytracekey UDI Manager)
 - ☐ Training for your team
 - ☐ Consulting for special cases
- ☐ Ensure chosen tools provide:
 - ☐ Automatic data validation
 - ☐ Bulk upload and M2M capabilities
 - ☐ Continuous regulatory updates
 - ☐ Secure, audit-ready processes

UDI Code Assignment

- ☐ Select an issuing agency (GS1, HIBCC, IFA, ICCBBA).
- ☐ Generate UDI codes for all products according to standards.
- ☐ Ensure UDI codes are correctly printed on labels and packaging.
- ☐ Maintain a structured record of all assigned UDIs.

Collect and Validate Product Master Data

- ☐ Gather all mandatory attributes for EUDAMED.
- ☐ Validate data against EUDAMED Business Rules before upload.
- ☐ Ensure data consistency across internal systems.

Register in EUDAMED

- ☐ Choose your upload method:
 - ☐ Manual entry via EUDAMED interface
 - ☐ XML bulk upload
 - ☐ Automated M2M integration
- ☐ Upload all UDI data to the UDI module.
- ☐ Confirm successful registration and linkage to other modules (e.g., certificates).
- ☐ Document the process for audit purposes.

Change Management

- ☐ Establish a process for updating UDI data in EUDAMED.
- ☐ Know which changes require a new UDI-DI.
- ☐ Keep track of regulatory updates and adapt processes accordingly.

Risk & Compliance Management

- ☐ Prepare for audits: ensure traceability and documentation.
- ☐ Monitor MDR/IVDR/EUDAMED updates regularly.

More info about our
UDI Manager
Software

