EUDAMED Readiness Checklist

for MedTech Companies

Why EUDAMED Compliance Matters?

EUDAMED is the European Union's centralized database for medical devices, aimed at enhancing transparency, traceability, and patient safety. MedTech companies must ensure their devices meet the requirements for registration, including specific data for Basic UDI-DIs and UDI-DIs. Preparing for EUDAMED compliance is not just about meeting deadlines - it's an opportunity to streamline operations and strengthen regulatory governance.

BASIC UDI-DI AND UDI-DI REGISTRATION OF NEW DEVICES:

28.May 2026

FULL EUDAMED COMPLIANCE FOR ALL DEVICES:

28.Nov 2026

And why it matters now even more?

The European Union has set two critical deadlines: **May 28, 2026**, for Basic UDI-DI and UDI-DI registration of new Devices, and **November 28, 2026**, for existing devices. These fast-approaching dates leave little room for error, and delays could lead to rejected submissions or market access issues. Starting now ensures your organization avoids bottlenecks and stays ahead in the MedTech industry. The good news is: you are not alone. The below checklist helps you to understand the next important steps to take.

BOOK A MEETING WITH OUR UDI EXPERTS

EUDAMED Readiness Checklist

1. Scope & Classification

- Every device flagged in-scope/out-of-scope with a documented reason
- Risk classificaion confirmed per regulation (MDR/IVDR)
- Edge cases handled: legacy devices, kits/systems/procedure packs, variants
- Mandatory data elements per Basis UDI-DI and UDI-DI documented

2. People & Ownership

- A named owner exists for every EUDAMED-relevant data domain
- RACI defined across RA/QA, Master Data, IT, and Quality
- Cross-functional team trained on requirements and workflow
- One accountable owner for overall EUDAMED readiness

3. Process & Governance

- Defined change-handling process (what tirggers an update, who approves)
- Approval workflow (e.g. multi-eye) before submission
- Documented process for post-submission updates and re-validation
- Readiness reviewed on a schedule, not only before deadlines

4. Data Quality (Single Source of Truth)

- UDI data consolidated into one authoritative source
- Data reconciled across ERP, PLM, or existing spreadsheets
- Basic UDI-DI grouping logic reviewed and documented
- Units, languages and supplier fields verified forconsistenc

5. Validation before Submission

- Market-specific validation rules applied pre-submission
- Conditional/required-if rules checked (valid AND consistent)
- Error-resolution routine defined (fix before submit)
- A test/dry-run submission performed for a sample

6. Systems & Submission

- Reliable submission path (no manual copy/paste at scale)
- Bulk operations supported for large volumes
- Submission status tracking and bottleneck handling
- Integration approach decided (manual vs machine-to-machine)

7. Audit-Readiness & Evidence

- Audit-ready logs: who changed what, when, and why
- Validation and submission records retained and retrievable
- Documentation organized and accessible for inspection
- Continuous monitoring flags risks proactively

Next Step:
Scan the QR code to schedule a consultation with our UDI Subject Matter Experts