



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. Understand EUDAMED Requirements

Scope:

Identify which devices in your portfolio are subject to registration requirements based on their risk classification according to the applicable legislation (e.g., MDR, IVDR).

Data Points:

Understand the mandatory data elements required for each Basic UDI-DI and UDI-PI according to the applicable regulatory requirements.

Deadlines:

Track key compliance dates for EUDAMED registration (e.g., 2026 deadlines).

2. Audit Your Current UDI Processes

Data Integrity:

Ensure all device data is accurate, complete, and consistent across systems.

System Review:

Evaluate existing tools (e.g., spreadsheets, ERP, PLM) for managing UDI data.

Compliance Gaps:

Identify areas where your current processes fall short of EUDAMED requirements.

3. Centralize and Govern Your UDI Data

Single Source of Truth:

Consolidate UDI data into a centralized system to eliminate silos and version chaos.

Role-Based Access:

Implement governance workflows to ensure secure and compliant data handling.

Bulk Operations:

Prepare for large-scale data updates and submissions efficiently.

4. Validate Data Against EUDAMED Rules

Pre-Submission Checks:

Apply market-specific validation rules to ensure data accuracy.

Error Resolution:

Address inconsistencies and missing fields before submission.

5. Automate Submission Workflows

Seamless Integration:

Leverage tools that integrate with EUDAMED for direct submissions.

Real-Time Tracking:

Monitor submission statuses and resolve bottlenecks promptly.

Audit-Ready Logs:

Maintain detailed records of validations and submissions for inspections.

6. Prepare for Audits and Inspections

Documentation:

Ensure all compliance records are organized and easily accessible.

Training:

Educate cross-functional teams on EUDAMED requirements and workflows.

Continuous Monitoring:

Implement systems to track compliance and flag risks proactively.

Next Step:

Scan the QR code to schedule a consultation with our UDI Subject Matter Experts.

