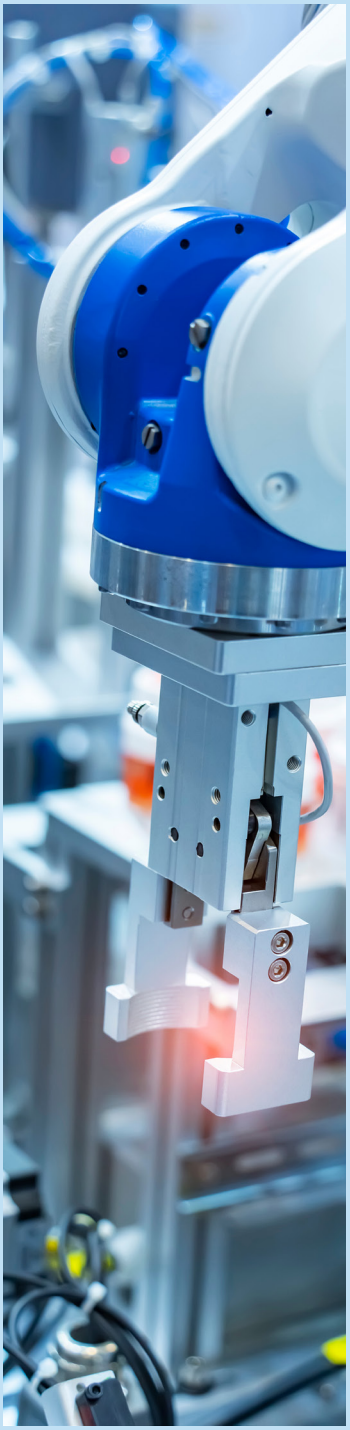
VIEW POINT



EUDAMED UDI/DEVICE REGISTRATION – DRIVING TRANSPARENCY & TRACEABILITY IN EU MARKET

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Introduction: Why UDI/Device Registration Is More Than Just Compliance

Under the EU MDR and IVDR, traceability isn't optional-it's foundational. EUDAMED's Module 2 (UDI/Device Registration) plays a pivotal role by linking device identifiers with regulatory documentation, enabling full lifecycle visibility. This isn't just about meeting requirements-it's about building trust, ensuring patient safety, and unlocking operational clarity across the EU market.

UDI/Device Registration- A Strategic Lens on Traceability

UDI (Unique Device Identification) is more than a coding system—it's the backbone of device traceability under EU MDR and IVDR. EUDAMED's UDI/Device Registration module links product identifiers with regulatory documentation, enabling seamless tracking across the device lifecycle.

Key Identifiers at a Glance

Identifier Type	Definition	Purpose	Where It Appears	Changes When
Basic UDI-DI	Group identifier for devices with same purpose, class, and design	Regulatory documentation and database key	Certificates, declarations, technical docs (not on label)	Device group characteristics change
UDI-DI	Unique identifier for a specific device version or model	Product traceability and regulatory submissions	Device label, packaging, regulatory databases	Device version/model changes
Package UDI-DI	Identifier for a specific packaging configuration	Identifies packaging levels for logistics and inventory	Packaging labels (e.g., box of 10 units)	Packaging configuration changes

Each identifier supports regulatory, commercial, and logistical stakeholders by reducing errors, preventing duplication, and safeguarding against counterfeit device.

UDI Registration: Step-by-Step Guide to EUDAMED Device Registration

Each step, from manufacturer initiation to final confirmation, ensures that devices are accurately identified, validated, and visible across the EU ecosystem.

MANUFACTURER INITIATION

- Start registration process.
- Enter Basic UDI-DI attributes and certificates.
- Upload labeling and technical docs.
- Assign CND codes.

SUBMISSION

- Add packaging/container details.
- Provide multilingual product information.

CONFIRMATION

- Device is registered and becomes publicly available in EUDAMED.

NOTIFIED BODY (FOR HIGH-RISK DEVICES)

- Validation and confirmation of device data.
- Upload of signed certificates (if applicable).

FINAL CONFIRMATION

- Device is fully registered, traceable, and publicly visible.

Key Stakeholders & User Roles: Who Powers EUDAMED Compliance

Successful device registration in EUDAMED depends on coordinated action across a network of stakeholders. Each role carries distinct responsibilities that, when aligned, ensure traceability, regulatory integrity, and market readiness.

Manufacturers

Own the registration process—enter device data, maintain UDI integrity, and ensure documentation is complete and current.

Authorized Representatives (AR)

Represent non-EU manufacturers, acting as the official liaison for regulatory submissions and communications

Importers

Verify that devices entering the EU are properly registered and compliant with MDR/IVDR requirements

System/Procedure Pack Producers

Manage registration of packs that combine multiple devices, ensuring traceability at the configuration level.

Notified Bodies

Validate data and documentation for high-risk devices, including certificate uploads and conformity assessments.

Business & Compliance Impact: Why Device Registration Matters?

UDI registration in EUDAMED is more than a regulatory requirement

It's a strategic enabler that drives clarity, trust, and efficiency across the healthcare ecosystem. Here's how it delivers value to key stakeholders: For Regulators – Enables stronger market surveillance and compliance checks.

For Manufacturers
Streamlines submissions, reduces redundant reporting, and secures EU market access.

For Patients & HCPs
Ensures confidence in device safety, traceability, and authenticity.

For Supply Chain
Improves inventory management and reduces recall risks.

Challenges & Considerations: What Can Slow You Down—and How to Stay Ahead

While UDI registration unlocks compliance and market access, it also introduces operational complexity. Success depends on anticipating key challenges and aligning systems, teams, and timelines

Data Complexity:
Managing hierarchical UDI data across diverse product families and packaging levels increases the risk of inconsistencies and errors.

System Integration:
Aligning EUDAMED with internal ERP, LIMS, and PLM systems demands seamless data flow and robust mapping to avoid compliance gaps.

Regulatory Readiness:
Meeting MDR/IVDR deadlines and NB validation timelines.

Change Management:
Training cross-functional teams on UDI impact.

Future Road & Opportunities: Beyond Compliance, Toward Innovation

UDI registration is just the beginning. As digital health evolves, EUDAMED opens doors to broader transformation across regulatory, operational, and clinical domains:

Digital Twins & Traceability

Extending UDI integration with AI/IoT for proactive surveillance.

Regulatory AI & Analytics

Using UDI data for predictive compliance and market intelligence.

Global Convergence

Alignment of EU UDI with FDA and IMDRF will simplify multi-market strategies.

End-to-End Automation

Embedding UDI in supply chain and hospital procurement systems.

To conclude, EUDAMED's UDI/Device Registration module is not just a regulatory requirement but a strategic enabler for safety, transparency, and competitiveness in the EU market. By embracing UDI early, manufacturers can unlock process efficiencies, strengthen compliance posture, and build greater trust with regulators, healthcare professionals, and patients alike.

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Sapna is a seasoned life sciences consultant with over nine years of experience in R&D, Project and Quality Management, Data Analysis, and Computer System Validation (CSV). She has successfully led projects in safety and quality, driving continuous process improvements to enhance client performance. Passionate about innovation, she is eager to explore AI technologies and their responsible application in the life sciences industry.

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