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STANDARDS & GUIDANCE BRIEF · EUROPEAN UNION · EU DATABASE AND COMMISSION DECISION

EUDAMED

European database on medical devices — mandatory modules (Commission Decision (EU) 2025/2371)

DOCUMENT	QES-WP-113, Rev B	DATE	November 7, 2026
ISSUED BY	European Commission	PREPARED BY	Conner Davidson
EDITION	Gradual roll-out under Regulation (EU) 2024/1860; four modules declared functional by Commission Decision (EU) 2025/2371 (published November 27, 2025)	STATUS CHECKED	October 24, 2026
INDUSTRIES	Medical Devices	ONLINE	qesisbest.com/standard-eudamed.html

IN FORCE Mandatory since May 28, 2026 for four modules: actor registration, UDI and device registration, notified bodies and certificates, and market surveillance. Devices placed on the market before May 28, 2026 and still made available must be registered by November 28, 2026; notified bodies have until May 28, 2027 for legacy certificate data. **Next:** November 28, 2026: legacy device registration deadline. The vigilance and clinical investigation modules follow later.

What It Covers

The EU's central database for medical devices and in vitro diagnostics: who the economic operators are, which devices they place on the market, which certificates cover them, and, as later modules arrive, vigilance and clinical investigations.

Who It Applies To

Manufacturers, authorized representatives and importers placing devices on the EU market, and notified bodies.

Key Requirements

- Actor registration and a Single Registration Number (SRN) for each economic operator.
- Basic UDI-DI and UDI-DI data for each device registered before it is placed on the market.
- Certificates entered by notified bodies.
- Data kept current: changes to a device or its labeling reflected in the database.

What an Auditor Asks to See

- Your SRN and the registration status of every device you sell in the EU.
- The process for keeping EUDAMED data aligned with labeling and the technical documentation.

Where Systems Fall Short

- Legacy devices still on the market and not yet registered.
- UDI data in EUDAMED that no longer matches the label.

How QES helps. A device-by-device registration check against the November 28, 2026 deadline. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. DNV — EUDAMED mandatory use: what manufacturers need to know — www.dnv.com/article/eudamed-mandatory-use-what-manufacturers-need-to-know; EUR-Lex — Regulation (EU) 2017/745 on medical devices — eur-lex.europa.eu/eli/reg/2017/745/oj.

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