

EUDAMED Adoption & National Registration Requirements

EU 27 Member States

Updated Report — July 2026 (Corrected Edition)

Prepared by RegDesk Data Team · Based on client feedback and verified regulatory sources

12

EUDAMED ONLY
No national reg required

12

NATIONAL REG REQUIRED
In addition to EUDAMED

3

PARTIAL / TRANSITIONAL
EUDAMED transition or dual option

27

EU MEMBER STATES
Full coverage EU27

EXECUTIVE SUMMARY

This corrected edition updates the previous EUDAMED & National Registration Requirements report based on verified client feedback and official regulatory source checks. Key corrections include:

- Newly identified national registration requirements:** Bulgaria (BDA), Croatia (HALMED), Cyprus (Ministry of Health notification), Malta (Medicines Authority), Netherlands (IGJ), and Slovakia (ŠÚKL — Section 110b, Act 362/2011).
- Finland reclassified to PARTIAL:** Notification may be made to either the CERE register or EUDAMED (Fimea guidance).
- Germany and Spain updated:** EUDAMED's first four modules became legally mandatory from May 28, 2026. Germany system is DMIDS (not legacy DIMDI/BfArM).
- Poland corrected to NO:** URPL national registration no longer required; EUDAMED is now the sole registration mechanism.
- Latvia and Luxembourg:** Remain NO, with reference databases noted (LATMED and Santé Secours respectively).

LEGEND: ✓ YES National registration required in addition to EUDAMED ✗ NO EUDAMED only ~ PARTIAL Transitional / dual option

COUNTRIES A-I (AUSTRIA TO IRELAND)

Country	EUDAMED Adoption	Nat. Reg. Required?	National System/ Database	Details & Sources
Austria	EUDAMED (MDR/IVDR)	X NO NO	EUDAMED only	Austria relies solely on EUDAMED for device registration. No additional national registration required under BASG. <i>BASG; EU MDR 2017/745</i>
Belgium	EUDAMED (MDR/IVDR)	X NO NO	EUDAMED only	Belgium (FAMHP/AFMPS) does not require national registration beyond EUDAMED. <i>FAMHP; EU MDR 2017/745</i>
Bulgaria	EUDAMED (MDR/IVDR)	✓ YES YES	BDA National Register	Bulgaria's BDA (Bulgarian Drug Agency) requires national registration in addition to EUDAMED. Manufacturers must register with BDA prior to placing devices on the Bulgarian market. <i>BDA Bulgaria; EU MDR 2017/745</i>
Croatia	EUDAMED (MDR/IVDR)	✓ YES YES	HALMED Register	HALMED (Croatian Agency for Medicinal Products and Medical Devices) requires national registration in addition to EUDAMED for devices placed on the Croatian market. <i>HALMED Croatia; EU MDR 2017/745</i>
Cyprus	EUDAMED (MDR/IVDR)	✓ YES YES / NOTIFICATION	Ministry of Health Notification	Cyprus Ministry of Health requires notification to the Agency in addition to EUDAMED registration. Manufacturers or authorized representatives must notify the competent authority. <i>Cyprus Ministry of Health; EU MDR 2017/745</i>
Czech Republic	EUDAMED (MDR/IVDR)	X NO NO	EUDAMED only	Czech Republic (SÚKL) does not require national registration beyond EUDAMED. <i>SÚKL Czech Republic; EU MDR 2017/745</i>
Denmark	EUDAMED (MDR/IVDR)	X NO NO	EUDAMED only	Denmark (Danish Medicines Agency) does not require national registration beyond EUDAMED. <i>Danish Medicines Agency; EU MDR 2017/745</i>
Estonia	EUDAMED (MDR/IVDR)	X NO NO	EUDAMED only	Estonia (State Agency of Medicines) does not require national registration beyond EUDAMED. <i>Estonian State Agency of Medicines; EU MDR 2017/745</i>
Finland	EUDAMED (MDR/IVDR)	~ PARTIAL PARTIALLY	CERE Register or EUDAMED	Fimea (Finnish Medicines Agency): notification can be made to either the CERE register or the EUDAMED register. Both options are accepted under Finnish national implementation. <i>Fimea — https://fimea.fi/en/medical-devices/registrations</i>

Table continues on next page →

COUNTRIES I–N (ITALY TO NETHERLANDS)

Country	EUDAMED Adoption	Nat. Reg. Required?	National System/ Database	Details & Sources
France	EUDAMED (MDR/IVDR)	✓ YES YES	ANSM National Database	France (ANSM) maintains a national registration requirement alongside EUDAMED. Manufacturers must register with ANSM's national system. <i>ANSM France; EU MDR 2017/745</i>
Germany	EUDAMED — Mandatory from May 28, 2026	~ PARTIAL NO*	DMIDS (BfArM)	EUDAMED's first four modules became legally mandatory as of May 28, 2026. System name is DMIDS (not legacy DIMDI/BfArM). New products must be reported in DMIDS by May 27, 2026; from May 28, 2026, registration in EUDAMED is mandatory. (*No separate national reg beyond DMIDS/EUDAMED.) <i>BfArM — https://www.bfarm.de/EN/Medical-devices/Overview/Europe-and-EUDAMED/_node.html</i>
Greece	EUDAMED (MDR/IVDR)	✓ YES YES	EOF National Register	Greece (EOF — National Organisation for Medicines) requires national registration in addition to EUDAMED. <i>EOF Greece; EU MDR 2017/745</i>
Hungary	EUDAMED (MDR/IVDR)	✓ YES YES	OGYÉI National Register	Hungary (OGYÉI) requires national registration in addition to EUDAMED for medical devices placed on the Hungarian market. <i>OGYÉI Hungary; EU MDR 2017/745</i>
Ireland	EUDAMED (MDR/IVDR)	✗ NO NO	EUDAMED only	Ireland (HPRA) does not require national registration beyond EUDAMED. <i>HPRA Ireland; EU MDR 2017/745</i>
Italy	EUDAMED (MDR/IVDR)	✓ YES YES	BDN (Banca Dati Nazionale)	Italy requires registration in the BDN (Banca Dati Nazionale dei Dispositivi Medici) managed by the Ministry of Health, in addition to EUDAMED. <i>Italian Ministry of Health; BDN; EU MDR 2017/745</i>
Latvia	EUDAMED (MDR/IVDR)	✗ NO NO	LATMED Database (reference)	Latvia (ZVA) does not require mandatory national registration beyond EUDAMED. However, ZVA maintains the LATMED database as a reference tool for market surveillance. <i>ZVA Latvia — https://www.zva.gov.lv/en/industry/medical-device-manufacturers-authorized-representatives/latmed</i>
Lithuania	EUDAMED (MDR/IVDR)	✗ NO NO	EUDAMED only	Lithuania (VVKT) does not require national registration beyond EUDAMED. <i>VVKT Lithuania; EU MDR 2017/745</i>
Luxembourg	EUDAMED (MDR/IVDR)	✗ NO NO	EUDAMED only	Luxembourg (Ministry of Health / Santé Secours) does not require national registration beyond EUDAMED. <i>Luxembourg Ministry of Health — https://santeseu.public.lu/en/espace-professionnel/departement-sante/pharmacies-et-medicaments/dispositifs-medicaux.html</i>

Table continues on next page →

COUNTRIES P-S (POLAND TO SWEDEN)

Country	EUDAMED Adoption	Nat. Reg. Required?	National System/ Database	Details & Sources
Malta	EUDAMED (MDR/IVDR)	✓ YES YES	Malta Medicines Authority	Malta maintains a mandatory parallel national notification system alongside EUDAMED. Manufacturers must notify the Malta Medicines Authority in addition to EUDAMED registration. <i>Malta Medicines Authority — https://medicinesauthority.gov.mt/medicaldevices</i>
Netherlands	EUDAMED (MDR/IVDR)	✓ YES YES	IGJ National Registration	Netherlands (IGJ — Inspectie Gezondheidszorg en Jeugd) requires national registration for medical devices in addition to EUDAMED. <i>IGJ Netherlands — https://english.igj.nl/medical-technology/market-authorisation/registration-and-deregistration</i>
Poland	EUDAMED (MDR/IVDR)	✗ NO NO	EUDAMED only (URPL no longer required)	Before placing on market, device must be registered in the EUDAMED database. URPL national registration is no longer required since the MDR transition. EUDAMED is the sole registration mechanism. <i>URPL Poland — https://www.gov.pl/web/urpl/rejestracja-wyrobow-medycznych</i>
Portugal	EUDAMED (MDR/IVDR)	✓ YES YES	INFARMED National Register	Portugal (INFARMED) requires national registration alongside EUDAMED for medical devices placed on the Portuguese market. <i>INFARMED Portugal; EU MDR 2017/745</i>
Romania	EUDAMED (MDR/IVDR)	✓ YES YES	ANMDMR National Register	Romania (ANMDMR) requires national registration in addition to EUDAMED for medical devices placed on the Romanian market. <i>ANMDMR Romania; EU MDR 2017/745</i>
Slovakia	EUDAMED (MDR/IVDR)	✓ YES YES	ŠÚKL National Notification	National notification obligation under Section 110b of Act No. 362/2011 remains in effect in Slovakia. Manufacturers must notify ŠÚKL in addition to EUDAMED from May 28, 2026. <i>ŠÚKL Slovakia — https://www.sukl.sk/pre-odbornikov-a-firmy/zdravotnicke-pomocky/postupy-od-28.maja-2026-povinne-pouzivanie-eudamed</i>
Slovenia	EUDAMED (MDR/IVDR)	✗ NO NO	EUDAMED only	Slovenia (JAZMP) does not require national registration beyond EUDAMED. <i>JAZMP Slovenia; EU MDR 2017/745</i>
Spain	EUDAMED — Mandatory from May 28, 2026	~ PARTIAL NO*	AEMPS / EUDAMED	EUDAMED's first four modules are mandatory from May 28, 2026 for Spain (AEMPS). (*No separate national database beyond EUDAMED/AEMPS after MDR full implementation.) <i>AEMPS Spain — https://www.aemps.gob.es/informa/la-aemps-informa-de-que-los-primeros-cuatro-modulos-de-eudamed-seran-obligatorios-desde-el-28-de-mayo-de-2026/</i>
Sweden	EUDAMED (MDR/IVDR)	✗ NO NO	EUDAMED only	Sweden (Medical Products Agency / MPA) does not require national registration beyond EUDAMED. <i>Swedish Medical Products Agency; EU MDR 2017/745</i>

⚠ Important Notes

EUDAMED mandatory date: As of **May 28, 2026**, EUDAMED's first four modules (UDI/Device registration, Economic Operator, Notified Body, and Certificate modules) are legally mandatory across the EU. | **Germany (DMIDS):** New products must be reported in DMIDS by May 27, 2026; from May 28, 2026, registration in EUDAMED is mandatory. | **Finland dual-option:** Notification may be submitted to either CERE register or EUDAMED (Fimea guidance). | **Always verify** with the national competent authority prior to market entry, as requirements may evolve.