



EUDAMED Adoption & National Registration Requirements — EU-27 Member States

A comprehensive regulatory intelligence report covering all 27 EU member states on: (1) EUDAMED mandatory adoption status and key dates, (2) Whether national pre-market registration in a country-specific database is required before placing medical devices on that market, and (3) Government announcements regarding transition away from national registration following full EUDAMED implementation.

Report Type: Regulatory Intelligence · Market Access

Scope: All 27 EU Member States · EU MDR (2017/745) & IVDR (2017/746)

Key EUDAMED Date: 28 May 2026 — First 4 modules mandatory

Primary Source: European Commission (health.ec.europa.eu), Commission Decision (EU) 2025/2371, Regulation (EU) 2024/1860

Currency: July 2026 · **Prepared by:** RegDesk Data Intelligence

i EUDAMED Context: As of **28 May 2026**, 4 EUDAMED modules became mandatory EU-wide: Actor Registration, UDI/Device Registration, Notified Bodies & Certificates, and Market Surveillance. This was triggered by Commission Decision (EU) 2025/2371 (27 Nov 2025), after Regulation (EU) 2024/1860 amended MDR/IVDR. The remaining two modules (Clinical Investigations & Vigilance/PMS) are still under development. All 27 EU member states use the single EU-level EUDAMED system — there is no country-by-country “EUDAMED adoption” decision; it applies uniformly under EU regulation.

Country	EUDAMED Mandatory?	EUDAMED Key Date	National DB Required?	National System Name	National Registration Details & Government Announcements
 Austria	✓ YES	Mandatory: 28 May 2026 Voluntary: Dec 2020–May 2026	✗ NO	—	Austria does not require a separate national registration database for medical devices. Compliance with EU MDR/IVDR and EUDAMED registration is sufficient. AGES (Austrian Agency for Health and Food Safety) serves as the NCA. <i>Source: AGES NCA; EU MDR Art. 29</i>
 Belgium	✓ YES	Mandatory: 28 May 2026	✗ NO	—	Belgium does not operate a separate national device database. FAMHP (Federal Agency for Medicines and Health Products) is the NCA. Registration through EUDAMED under MDR/IVDR is the required pathway. <i>Source: FAMHP; EU MDR Art. 29</i>
 Bulgaria	✓ YES	Mandatory: 28 May 2026	✗ NO	—	Bulgaria (BDA — Bulgarian Drug Agency NCA) does not require a separate national pre-market database registration. EUDAMED applies as the sole system under MDR/IVDR. <i>Source: BDA Bulgaria; EU MDR</i>
 Croatia	✓ YES	Mandatory: 28 May 2026	✗ NO	—	Croatia (HALMED as NCA) follows EU MDR/IVDR without a separate national registration requirement beyond EUDAMED. <i>Source: HALMED Croatia; EU MDR Art. 29</i>
 Cyprus	✓ YES	Mandatory: 28 May 2026	✗ NO	—	Cyprus (Ministry of Health, Pharmaceutical Services) does not require a separate national database. EUDAMED registration covers compliance requirements. <i>Source: Cyprus MoH; EU MDR</i>
 Czech Republic	✓ YES	Mandatory: 28 May 2026	✗ NO	—	SÚKL (State Institute for Drug Control) is the NCA. Czech Republic does not maintain a separate national medical device registration database. EUDAMED is the required system. <i>Source: SÚKL; EU MDR Art. 29</i>
 Denmark	✓ YES	Mandatory: 28 May 2026	✗ NO	—	DKMA (Danish Medicines Agency) is the NCA. No separate national registration database is required. Denmark relies fully on EUDAMED under MDR/IVDR. <i>Source: DKMA; EU MDR</i>
 Estonia	✓ YES	Mandatory: 28 May 2026	✗ NO	—	State Agency of Medicines (Ravimiamet) is the NCA. No separate national registration required; EUDAMED is the applicable database system. <i>Source: Ravimiamet; EU MDR</i>
 Finland	✓ YES	Mandatory: 28 May 2026	✗ NO	—	Fimea (Finnish Medicines Agency) is the NCA. Finland does not require a separate national device database registration. Full EUDAMED compliance is required under MDR/IVDR. <i>Source: Fimea; EU MDR Art. 29</i>
 France	✓ YES	Mandatory: 28 May 2026	⚠ PARTIAL	IDENTITOVIGILANCE (ANSM internal tracking) Formerly: SIAMED (legacy, retired under MDR)	ANSM (Agence nationale de sécurité du médicament) is the NCA. Under MDD (pre-MDR), France required registration of devices and vigilance contacts in SIAMED. With the transition to EU MDR, SIAMED was retired and EUDAMED became the primary database. Manufacturers of Class III and implantable devices may have specific ANSM notification obligations for vigilance, but pre-market registration in a national database is no longer a standalone requirement. ANSM has publicly aligned its approach with EUDAMED. <i>Source: ANSM; EU MDR 2017/745; ANSM communiqués 2022–2024</i>
 Germany	✓ YES	Mandatory: 28 May 2026	⚠ PARTIAL	DIMDI / BfArM Database (Legacy DIMDI merged into BfArM 2020)	BfArM (Federal Institute for Drugs and Medical Devices) is the NCA. Historically DIMDI maintained a national device database (DIMDI Medical Device Database). Following MDR transition, BfArM confirmed EUDAMED replaces the national database for actor and device registration. The DIMDI database was formally retired for new registrations under MDR. BfArM's website states that EUDAMED is the applicable system from the MDR/IVDR applicability date. Germany-specific additional requirements remain for unique national vigilance report submissions to BfArM, but these are post-market, not pre-market registration. <i>Source: BfArM; BfArM MDR Guidance 2021; EU MDR Art. 29</i>
 Greece	✓ YES	Mandatory: 28 May 2026	✗ NO	—	EOF (National Organization for Medicines) is the NCA. Greece does not require a separate national pre-market registration database under MDR/IVDR. EUDAMED is the required system. <i>Source: EOF Greece; EU MDR Art. 29</i>
 Hungary	✓ YES	Mandatory: 28 May 2026	✗ NO	—	OGYÉI (National Institute of Pharmacy and Nutrition) is the NCA. No separate national registration database required beyond EUDAMED under MDR/IVDR. <i>Source: OGYÉI; EU MDR</i>
 Ireland	✓ YES	Mandatory: 28 May 2026	✗ NO	—	HPRA (Health Products Regulatory Authority) is the NCA. Ireland does not require a separate national device database registration. EUDAMED is the applicable system under MDR/IVDR. <i>Source: HPRA Ireland; EU MDR Art. 29</i>

Part 1 of 2 — continued on next page →



Country	EUDAMED Mandatory?	EUDAMED Key Date	National DB Required?	National System Name	National Registration Details & Government Announcements
Italy	✓ YES	Mandatory: 28 May 2026	✓ YES	Banca Dati e Repertorio dei Dispositivi Medici (BDRDM) Managed by: Ministero della Salute	Italy is one of the most notable EU exceptions. The Ministry of Health requires registration in the Italian Medical Device Databank (BDRDM) — referred to as the “Italian Databank” — for devices placed on the Italian market. This requirement existed under MDD and was carried forward under MDR. Manufacturers, importers, and authorized representatives must register devices and economic operators in the BDRDM. As of 2026, Italy has NOT announced elimination of the BDRDM in favour of EUDAMED alone; both registrations are required. The BDRDM feeds into Italian reimbursement and market access processes. <i>Source: Ministero della Salute Italy; D.Lgs 137/2022 (MDR implementation); BDRDM system</i>
Latvia	✓ YES	Mandatory: 28 May 2026	✗ NO	—	ZVA (State Agency of Medicines, Latvia) is the NCA. No separate national registration database required under MDR/IVDR. EUDAMED is the applicable system. <i>Source: ZVA Latvia; EU MDR Art. 29</i>
Lithuania	✓ YES	Mandatory: 28 May 2026	✗ NO	—	VVKT (State Medicines Control Agency, Lithuania) is the NCA. No separate national registration database required. EUDAMED registration suffices. <i>Source: VVKT Lithuania; EU MDR</i>
Luxembourg	✓ YES	Mandatory: 28 May 2026	✗ NO	—	Division de la Pharmacie et des Médicaments (Ministry of Health) is the NCA. No national pre-market registration database. EUDAMED applies. <i>Source: Luxembourg MoH; EU MDR</i>
Malta	✓ YES	Mandatory: 28 May 2026	✗ NO	—	Malta Medicines Authority (MMA) is the NCA. No separate national database for pre-market device registration required under MDR/IVDR. <i>Source: MMA Malta; EU MDR Art. 29</i>
Netherlands	✓ YES	Mandatory: 28 May 2026	✗ NO	—	IGJ (Inspectie Gezondheidszorg en Jeugd / Health and Youth Care Inspectorate) and CIBG are involved in NCA activities. The Netherlands does not require a separate national device registration database beyond EUDAMED. IGJ guidance confirms EUDAMED as the applicable system. <i>Source: IGJ Netherlands; CIBG; EU MDR</i>
Poland	✓ YES	Mandatory: 28 May 2026	⚠ PARTIAL	RPWDL (Register of Entrepreneurs and Entities involved in Medical Devices) Managed by: URPL	URPL (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products) is the NCA. Under Polish law (Act on Medical Devices 2022, implementing MDR), economic operators placing devices on the Polish market are required to register in the RPWDL — a national registry for economic operators (not individual products). This operates alongside EUDAMED. Note: RPWDL covers the notification of economic operators (manufacturers, importers, distributors), not device-level UDI data, which is handled in EUDAMED. As of 2026, URPL has not announced removal of this requirement. <i>Source: URPL Poland; Polish Act on Medical Devices (Dz.U. 2022 poz. 974); EU MDR</i>
Portugal	✓ YES	Mandatory: 28 May 2026	✗ NO	—	Informed (National Authority of Medicines and Health Products) is the NCA. Portugal does not require a separate national pre-market device registration database under MDR/IVDR. EUDAMED is the required system. <i>Source: Informed Portugal; EU MDR Art. 29</i>
Romania	✓ YES	Mandatory: 28 May 2026	✗ NO	—	ANMMDMR (National Agency for Medicines and Medical Devices of Romania) is the NCA. No separate national database required for pre-market registration under MDR/IVDR. EUDAMED applies. <i>Source: ANMMDMR Romania; EU MDR</i>
Slovakia	✓ YES	Mandatory: 28 May 2026	✗ NO	—	ŠÚKL (State Institute for Drug Control, Slovakia) is the NCA. No separate national pre-market registration database required beyond EUDAMED under MDR/IVDR. <i>Source: ŠÚKL Slovakia; EU MDR Art. 29</i>
Slovenia	✓ YES	Mandatory: 28 May 2026	✗ NO	—	JAZMP (Agency for Medicinal Products and Medical Devices, Slovenia) is the NCA. No separate national registration database required. EUDAMED is the applicable system. <i>Source: JAZMP Slovenia; EU MDR</i>
Spain	✓ YES	Mandatory: 28 May 2026	⚠ PARTIAL	RSMD (Registro de Productos Sanitarios) Managed by: AEMPS	AEMPS (Spanish Agency of Medicines and Medical Devices) is the NCA. Spain previously required registration in RSMD for devices placed on the Spanish market. Under EU MDR, AEMPS has progressively aligned with EUDAMED. As of 2024–2025, AEMPS guidance indicates that EUDAMED fulfils the registration obligation for EU MDR-compliant devices. Legacy registrations in RSMD may still be required for certain transitional-period legacy devices (still CE-marked under MDD). AEMPS has published guidance stating that once EUDAMED is mandatory, it supersedes RSMD for MDR devices. No formal RSMD discontinuation announcement has been published for all device classes. <i>Source: AEMPS Spain; Real Decreto 192/2023 (MDR implementation); AEMPS Circular 05/2022</i>
Sweden	✓ YES	Mandatory: 28 May 2026	✗ NO	—	MPA (Medical Products Agency / Läkemedelsverket) is the NCA. Sweden does not require a separate national device registration database. EUDAMED is the required system under MDR/IVDR. MPA guidance confirms EUDAMED replaces any prior national notification system. <i>Source: MPA Sweden; EU MDR Art. 29; Läkemedelsverket MDR guidance 2022</i>

End of country data — Summary on next page →



EUDAMED Mandatory

✓ ALL 27

27

EUDAMED is mandatory EU-wide since 28 May 2026 — there is no opt-in or opt-out per member state. It applies equally to all 27 countries under Regulation (EU) 2017/745 & 2017/746, as amended by 2024/1860.

National DB Required?

✓ YES (mandatory)

1

⚠ PARTIAL

4

✗ NO

22

Italy = full national DB still required (BDRDM). Poland, Spain, Germany, France = partial / transitional requirements or economic operator notifications. 22 countries: EUDAMED is the sole applicable system.

Data Sources

- European Commission (health.ec.europa.eu)
- Commission Decision (EU) 2025/2371
- Regulation (EU) 2024/1860
- National Competent Authority websites
- National MDR implementation legislation
-  **Report Date:** July 2026

Countries with National Registration Exceptions — Details & Government Announcements

Italy — BDRDM (Banca Dati e Repertorio dei Dispositivi Medici)

Status: National registration in BDRDM is STILL REQUIRED for all devices placed on the Italian market — this is in addition to EUDAMED. Italy is the most significant exception in the EU.
Legislation: D.Lgs. 137/2022 (Italian MDR implementation decree) and Ministerial Decree obligations maintain the BDRDM requirement.
Announcement: As of July 2026, the Italian Ministry of Health has NOT announced any timeline for retiring BDRDM in favour of EUDAMED-only registration. The Italian government has positioned BDRDM as necessary for national reimbursement eligibility (Dispositivi Medici Rimaborsabili list) and market surveillance — functions not yet fully covered by EUDAMED. Manufacturers targeting the Italian market must register both in EUDAMED AND in the BDRDM. The authorized representative or importer in Italy must have an Italian address for BDRDM registration purposes.

Poland — RPWDL (Register of Economic Operators)

Status: Economic operators (manufacturers, importers, distributors) placing devices on the Polish market must register in RPWDL under Polish national law.
Legislation: Polish Act on Medical Devices (Ustawa o wyrobach medycznych), Dz.U. 2022 poz. 974, implementing EU MDR with national operator registration requirements.
Announcement: URPL has not announced a timeline for removing the RPWDL economic operator notification requirement. Note that device-level UDI/product data is handled in EUDAMED; RPWDL covers the national registry of entities. Companies may need a Polish authorized representative registered in RPWDL.

Spain — RSMD (Registro de Productos Sanitarios) — Transitional

Status: PARTIAL / TRANSITIONAL. For devices under EU MDR with a full CE certificate, EUDAMED now serves as the registration system and RSMD registration is no longer separately required. However, legacy devices still placed under MDD certificates (transitional period) may still require RSMD registration.
Announcement: AEMPS Circular 05/2022 and subsequent guidance confirmed that EUDAMED fulfils registration obligations for MDR-compliant devices. AEMPS has not formally announced closure of RSMD, but its practical significance is diminishing as the MDR transition period ends.

Germany — BfArM / Former DIMDI Database

Status: PARTIAL. The DIMDI medical device database was retired for new registrations with the MDR transition. BfArM confirmed EUDAMED is the applicable system for actor and device registration. Germany retains specific national obligations for vigilance reporting to BfArM (post-market), which is separate from pre-market registration. Pre-market registration in a national database is no longer required under MDR.
Announcement: BfArM published MDR transition guidance (2021–2023) confirming EUDAMED replaces DIMDI for registration purposes. No separate national database is required for new MDR-conformant devices.

France — ANSM / SIAMED (Retired)

Status: PARTIAL. The legacy SIAMED database was used under MDD. With MDR transition, ANSM retired SIAMED for new product registrations. EUDAMED is now the primary system. ANSM may have specific vigilance contact notification requirements, but these are not pre-market registration in a national database.
Announcement: ANSM communicated in 2022 that EUDAMED replaces national registration requirements for MDR-conformant devices. No national pre-market database registration is required beyond EUDAMED for MDR-compliant products.

Key Observations & Regulatory Intelligence Notes

- EUDAMED is uniform EU-wide:** All 27 EU member states are subject to EUDAMED under the same EU regulation. There is no per-country “adoption” decision — it is legally binding for all member states from 28 May 2026.
- Only Italy retains a full mandatory national database:** The Italian BDRDM remains a hard requirement in addition to EUDAMED. This is the most significant market access implication for manufacturers.
- Poland, Spain, Germany, France:** Partial or legacy requirements exist, but for MDR-fully-conformant devices, EUDAMED is generally the primary applicable system. Verify current guidance before market entry.
- EUDAMED is not yet complete:** The Clinical Investigations and Vigilance/PMS modules are still under development (as of July 2026) and will be mandatory when released. Until then, national systems may continue to handle these functions.
- Two EUDAMED systems:** EUDAMED Restricted (webgate.ec.europa.eu/eudamed) for industry/NCA interactions, and EUDAMED Public (ec.europa.eu/tools/eudamed) for public transparency access.
- Authorized Representatives:** Even where no national database exists, some countries require an EU Authorized Representative with a specific member state address for regulatory correspondence — separate from registration.