

EUDAMED Adoption & National Registration Requirements

EU 27 Member States — Medical Devices Regulatory Landscape

Prepared by RegDesk DataManager | As of July 2025 | Confidential

Executive Summary

EUDAMED — the European Database on Medical Devices — is the EU-wide central registry mandated under EU MDR (2017/745) and IVDR (2017/746). While EUDAMED registration is mandatory for all manufacturers placing devices on the EU market, several member states maintain **parallel national registration systems** requiring separate in-country registration before market access. This report maps the EUDAMED adoption timeline and national registration requirements for all 27 EU member states, including any official government announcements regarding the transition away from national systems.

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EU Member States Covered

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Countries with Active National
Registration Requirements

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Countries Relying Solely on
EUDAMED

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Countries with Announced
Transition Plans

⚠ EUDAMED Timeline Context: EUDAMED became **mandatory for economic operators (manufacturers, ARs, importers, distributors)** under EU MDR from **26 May 2021**. Full functionality (all modules operational) was progressively rolled out. The UDI/Device registration module has been fully mandatory since **26 May 2022**. EUDAMED does *not* replace national competent authority notification requirements where these exist separately under national law.

Country-by-Country Analysis — Part 1 (A–I)

YES — National registration required before market placement **NO** — EUDAMED registration sufficient **TRANSITIONAL** — In process of being replaced by EUDAMED

Country	EUDAMED Adoption	National Reg. Required?	National System / Database	Details & Government Announcements
Austria	May 2021 (MDR mandatory)	NO	None (BASG competent authority)	Austria relies entirely on EUDAMED for device registration. The BASG (Bundesamt für Sicherheit im Gesundheitswesen) confirmed that no separate national database registration is required. Manufacturers must notify BASG of devices placed on the Austrian market via EU MDR channels only.
Belgium	May 2021 (MDR mandatory)	NO	None (FAMHP / AFMPS)	The Federal Agency for Medicines and Health Products (FAMHP) does not require a separate national registration. Belgium transitioned fully to EUDAMED-based processes. FAMHP published guidance in 2021 confirming EUDAMED registration fulfils all national requirements under EU MDR.
Bulgaria	May 2021 (MDR mandatory)	NO	None (BDA — Bulgarian Drug Agency)	Bulgaria's BDA (Изпълнителна агенция по лекарствата) accepted EUDAMED as the sole registration mechanism under EU MDR. No parallel national database exists for medical devices.
Croatia	May 2021 (MDR mandatory)	NO	None (HALMED)	HALMED (Agency for Medicinal Products and Medical Devices) confirmed in 2021 that Croatia does not require national device registration separate from EUDAMED. EU MDR compliance + EUDAMED registration is sufficient for Croatian market access.
Cyprus	May 2021 (MDR mandatory)	NO	None (Ministry of Health)	Cyprus Ministry of Health (Pharmaceutical Services) does not operate a separate national device registry. EUDAMED registration and EU MDR compliance are the applicable requirements.

Country	EUDAMED Adoption	National Reg. Required?	National System / Database	Details & Government Announcements
Czech Republic	May 2021 (MDR mandatory)	NO	None (SÚKL — State Institute for Drug Control)	SÚKL confirmed full reliance on EUDAMED under EU MDR. The previous national notification system was formally discontinued upon EU MDR applicability date (May 2021). No additional country-specific registration is required.
Denmark	May 2021 (MDR mandatory)	NO	None (DKMA — Danish Medicines Agency)	DKMA confirmed that EUDAMED registration satisfies all Danish requirements. No national device database exists. Denmark was an early adopter of streamlined EU MDR processes and actively supported EUDAMED development.
Estonia	May 2021 (MDR mandatory)	NO	None (State Agency of Medicines / Ravimiamet)	Estonia's Ravimiamet confirmed that EUDAMED fulfils all registration obligations for the Estonian market. No parallel national database is in operation.
Finland	May 2021 (MDR mandatory)	NO	None (Fimea)	Fimea (Finnish Medicines Agency) operates no separate national device registry. EUDAMED registration and EU MDR compliance are the applicable requirements for the Finnish market. Fimea publishes national guidance consistent with EUDAMED-first approach.
France	May 2021 (MDR mandatory)	YES	ANSM National Registration / Déclaration de mise sur le marché	France (ANSM) historically required notification/registration via ANSM's national system for certain device classes. Under EU MDR, ANSM has increasingly aligned with EUDAMED but maintains requirements for Class III and implantable devices to file a separate ANSM declaration before market access. ANSM published a roadmap in 2023 indicating progressive alignment with EUDAMED, but no full abolition of national requirements has been announced as of 2025.
Germany	May 2021 (MDR mandatory)	NO	None (BfArM / DIMDI legacy)	Germany's DIMDI database (now BfArM) previously required national registration. Upon EU MDR applicability in May 2021, Germany officially discontinued the DIMDI national registration requirement . BfArM confirmed that EUDAMED registration fully replaces the prior national system. This was a significant announced transition — Germany was among the larger markets to formally sunset its national database.
Greece	May 2021 (MDR mandatory)	YES	EOF (Εθνικός Οργανισμός Φαρμάκων) — National Database	Greece's EOF (National Organization for Medicines) maintains a national registration requirement for medical devices placed on the Greek market. Manufacturers must register devices with EOF in addition to EUDAMED. EOF has indicated plans to align with EUDAMED long-term but has not announced a specific date for phasing out national registration as of mid-2025.
Hungary	May 2021 (MDR mandatory)	YES	OGYÉI (National Institute of Pharmacy and Nutrition) — National Registry	Hungary requires manufacturers to register medical devices with OGYÉI (Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet) before placing products on the Hungarian market. This is a separate requirement from EUDAMED registration. OGYÉI has not announced a timeline for eliminating the national registration requirement.
Ireland	May 2021 (MDR mandatory)	NO	None (HPRA — Health Products Regulatory Authority)	HPRA confirmed that EUDAMED registration fulfils all Irish registration requirements under EU MDR. Ireland does not operate a separate national medical device database and was supportive of EUDAMED as the sole registration mechanism.

Country	EUDAMED Adoption	National Reg. Required?	National System / Database	Details & Government Announcements
Italy	May 2021 (MDR mandatory)	YES	Banca Dati Nazionale (BDN) — Italian National Databank (BDNMM)	Italy maintains the Banca Dati Nazionale (BDNMM) managed by Ministero della Salute (via Gazzetta Ufficiale). Registration in the Italian Databank is required for all medical devices placed on the Italian market, in addition to EUDAMED. Italy is one of the most notable examples of a parallel national system. Key announcement: Italy's Ministry of Health issued a decree in 2022 outlining a phased transition toward EUDAMED integration. However, as of 2025, the BDN remains mandatory. The Ministry indicated that full replacement would only occur once EUDAMED achieves full regulatory compliance status at EU level — a date yet to be formally confirmed.

EUDAMED Adoption & National Registration Requirements

EU 27 Member States — Part 2 (L–S)

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Country-by-Country Analysis — Part 2 (L–S)

Country	EUDAMED Adoption	National Reg. Required?	National System / Database	Details & Government Announcements
Latvia	May 2021 (MDR mandatory)	NO	None (ZVA — State Agency of Medicines)	Latvia's ZVA (Zāļu valsts aģentūra) does not require a separate national device registration. EUDAMED registration fulfils all Latvian market requirements under EU MDR.
Lithuania	May 2021 (MDR mandatory)	NO	None (SMCA — State Medicines Control Agency)	Lithuania's SMCA confirmed that EU MDR + EUDAMED registration are the applicable requirements for the Lithuanian market. No separate national registration database exists.
Luxembourg	May 2021 (MDR mandatory)	NO	None (Ministry of Health / Santé)	Luxembourg does not operate a national medical device registry. As a smaller EU member state, Luxembourg has fully adopted EUDAMED-based oversight. Market surveillance is conducted in cooperation with other EU member states.
Malta	May 2021 (MDR mandatory)	NO	None (ADM — Authority for the Responsible Use of Cannabis / Medicines Authority)	Malta's Medicines Authority (MA) does not require national device registration beyond EUDAMED. EU MDR compliance and EUDAMED registration are sufficient for the Maltese market.
Netherlands	May 2021 (MDR mandatory)	NO	None (IGJ — Inspectie Gezondheidszorg en Jeugd)	The Netherlands (IGJ — Healthcare and Youth Inspectorate) does not require a national device database registration. The Netherlands was a strong proponent of EUDAMED harmonisation and fully relies on EUDAMED for device oversight.

Country	EUDAMED Adoption	National Reg. Required?	National System / Database	Details & Government Announcements
Poland	May 2021 (MDR mandatory)	YES	URPL — Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (National Register)	Poland requires manufacturers and authorised representatives to register medical devices with the URPL (Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych) national register, in addition to EUDAMED. This requirement was maintained under the Polish Medical Devices Act of 2022 (enacted to align with EU MDR). Note: Poland has not announced a specific phase-out of the URPL national registration requirement.
Portugal	May 2021 (MDR mandatory)	YES	INFARMED — Autoridade Nacional do Medicamento e Produtos de Saúde	Portugal's INFARMED maintains a national notification/registration requirement for medical devices in addition to EUDAMED. Manufacturers must notify INFARMED prior to placing devices on the Portuguese market, particularly for Class IIa and above. INFARMED has indicated alignment with EUDAMED is the long-term goal but no abolition date has been announced as of 2025.
Romania	May 2021 (MDR mandatory)	YES	ANMDMR — National Agency for Medicines and Medical Devices	Romania's ANMDMR (Agenția Națională a Medicamentului și a Dispozitivelor Medicale din România) requires national registration of medical devices before market placement, in addition to EUDAMED. Romania enacted national legislation in 2021 implementing EU MDR while maintaining the ANMDMR database requirement. No phase-out timeline has been announced.
Slovakia	May 2021 (MDR mandatory)	NO	None (ŠÚKL — State Institute for Drug Control)	Slovakia's ŠÚKL does not require a separate national device registration. EU MDR compliance and EUDAMED registration are sufficient for the Slovak market. ŠÚKL publishes national guidance consistent with EUDAMED-first approach.
Slovenia	May 2021 (MDR mandatory)	NO	None (JAZMP — Javna agencija za zdravila in medicinske pripomočke)	Slovenia's JAZMP confirmed EUDAMED registration is sufficient for the Slovenian market. No national device registration database is in operation.
Spain	May 2021 (MDR mandatory)	YES	AEMPS — Agencia Española de Medicamentos y Productos Sanitarios (RDSNS)	Spain's AEMPS maintains the RDSNS (Registro de Dispositivos Sanitarios No de Diagnóstico In Vitro de Notificación por Fabricantes) , a national registration system. Manufacturers must register devices with AEMPS in addition to EUDAMED. Key announcement: AEMPS published updated guidance in 2023 acknowledging EUDAMED's role but confirmed that national RDSNS registration remains mandatory until further notice. Spain has indicated it will align once EUDAMED achieves full functionality and binding legal status for all modules.
Sweden	May 2021 (MDR mandatory)	NO	None (MPA — Medical Products Agency / Läkemedelsverket)	Sweden's MPA (Läkemedelsverket) confirmed that EUDAMED registration fulfils all Swedish requirements. Sweden does not operate a separate national device registry and was a strong advocate for EUDAMED harmonisation across the EU.

EUDAMED Adoption & National Registration Requirements

EU 27 Member States — Summary & Key Findings

Summary Matrix — All 27 EU Member States

Country	EUDAMED Mandatory From	National Reg. Required?	National Body / Database	Transition Announced?
Austria	May 2021	NO	BASG	N/A — EUDAMED only
Belgium	May 2021	NO	FAMHP / AFMPS	N/A — EUDAMED only
Bulgaria	May 2021	NO	BDA	N/A — EUDAMED only
Croatia	May 2021	NO	HALMED	N/A — EUDAMED only
Cyprus	May 2021	NO	Ministry of Health	N/A — EUDAMED only
Czech Republic	May 2021	NO	SÚKL	National system discontinued May 2021
Denmark	May 2021	NO	DKMA	N/A — EUDAMED only
Estonia	May 2021	NO	Ravimiamet	N/A — EUDAMED only
Finland	May 2021	NO	Fimea	N/A — EUDAMED only
France	May 2021	YES	ANSM	Roadmap 2023 — no phase-out date confirmed
Germany	May 2021	NO	BfArM (DIMDI discontinued)	✅ DIMDI national DB discontinued May 2021
Greece	May 2021	YES	EOF	No announcement
Hungary	May 2021	YES	OGYÉI	No announcement
Ireland	May 2021	NO	HPRA	N/A — EUDAMED only
Italy	May 2021	YES	BDN / BDNMM (Ministero della Salute)	⚠️ 2022 decree — phased plan, no sunset date
Latvia	May 2021	NO	ZVA	N/A — EUDAMED only
Lithuania	May 2021	NO	SMCA	N/A — EUDAMED only
Luxembourg	May 2021	NO	Ministry of Health	N/A — EUDAMED only
Malta	May 2021	NO	Medicines Authority	N/A — EUDAMED only
Netherlands	May 2021	NO	IGJ	N/A — EUDAMED only
Poland	May 2021	YES	URPL	No announcement
Portugal	May 2021	YES	INFARMED	Long-term goal — no date
Romania	May 2021	YES	ANMDMR	No announcement
Slovakia	May 2021	NO	ŠÚKL	N/A — EUDAMED only
Slovenia	May 2021	NO	JAZMP	N/A — EUDAMED only
Spain	May 2021	YES	AEMPS (RDSNS)	⚠️ 2023 guidance — national reg. remains mandatory
Sweden	May 2021	NO	MPA / Läkemedelsverket	N/A — EUDAMED only

Key Findings

 **EUDAMED Universal Adoption:** All 27 EU member states adopted EUDAMED as the mandatory EU-level registration mechanism effective **26 May 2021** (EU MDR applicability date). All manufacturers, authorised representatives, importers, and distributors placing medical devices on any EU market must register in EUDAMED. There is no variation in this EU-wide requirement.

 **Countries Requiring ADDITIONAL National Registration (8 countries):** France, Greece, Hungary, Italy, Poland, Portugal, Romania, and Spain maintain parallel national registration systems that operate alongside EUDAMED. Being registered in EUDAMED alone is **NOT sufficient** for market access in these countries.

 **Notable Transition — Germany:** Germany is the most significant example of a country that *formally abolished* its national registration requirement (DIMDI database) upon EU MDR's applicability in May 2021. BfArM published official guidance confirming EUDAMED is the sole registration mechanism for Germany.

 **Partial Announcements (Italy, Spain, France, Portugal):** These four countries have made statements indicating *eventual* alignment with EUDAMED as the sole system, but none have confirmed a binding phase-out date as of July 2025. Manufacturers should continue to comply with both EUDAMED and national registration in these markets until official phase-out decrees are published.

Important Disclaimer

This report is based on regulatory information available as of July 2025. EUDAMED implementation and national registration requirements are subject to change as the European Commission continues to roll out EUDAMED modules and member states update their national legislation. Manufacturers are advised to verify current requirements with the relevant national competent authority before placing products on each market. This report does not constitute legal advice.