

MEDICAL DEVICE REGULATION · EU MDR 2017/745 & IVDR 2017/746

EU EUDAMED Adoption & National Registration Requirements

A country-by-country analysis of EUDAMED adoption status, mandatory national registration databases, and government announcements across all 27 EU Member States.

27

EU Countries Analysed

4

National Reg. Still Required

22

EUDAMED Only Countries

1

Partial / Transitional

Report Coverage

- ♦ EUDAMED adoption dates (all 27 MS)
- ♦ National registration databases still active
- ♦ Government announcements & transitions
- ♦ Competent authority references

Key Reference Dates

- 17** Dec 2021 — EUDAMED actor module mandatory
- 17** May 2021 — Germany abolishes DIMDI (MPDG)
- 17** Feb 2, 2024 — EUDAMED declared fully functional
- 17** 2025 — Italy Repertorio still required

EU EUDAMED Adoption & National Registration Requirements

All 27 EU Member States · Medical Devices (MDR 2017/745 & IVDR 2017/746) · July 2025 · Countries 1–9 of 27



LEGEND: YES National registration required NO EUDAMED sufficient PARTIAL Mixed / transitional Confidence: HIGH ✓ verified · MED Δ likely · LOW ♦ verify with CA

Country / CA	EUDAMED Adoption Date	National Reg. Required?	National Database & Details	Government Announcement	Confidence / Source
Austria BASG / AGES	Dec 2021 (actor module); Feb 2024 (device registration)	NO	— No separate mandatory national registration database. Manufacturers register directly in EUDAMED.	No specific national announcement beyond EU-wide EUDAMED rollout. Austria follows EU Commission timeline.	HIGH basg.gv.at / EU Commission EUDAMED portal
Belgium FAMHP	Dec 2021 (actor module); Feb 2024 (device registration)	NO	— No separate mandatory national device registration database. Class I self-declaration applies per MDR Article 29 directly through EUDAMED.	FAMHP confirmed EUDAMED as the primary registration mechanism under MDR/IVDR. No parallel national system maintained.	HIGH famhp.be
Bulgaria Bulgarian Drug Agency (BDA)	Dec 2021 (actor module); Feb 2024 (device registration)	NO	— Bulgaria does not maintain a separate mandatory national registration system for medical devices. BDA oversees market surveillance.	No separate national announcement. BDA aligns with EU Commission EUDAMED implementation guidance.	MED bda.bg
Croatia HALMED	Dec 2021 (actor module); Feb 2024 (device registration)	NO	— Croatia does not require a separate national medical device registration database beyond EUDAMED. HALMED manages post-market surveillance.	No specific national announcement. Alignment with EU EUDAMED mandatory timeline confirmed.	MED halmed.hr
Cyprus Ministry of Health – Pharmaceutical Services	Dec 2021 (actor module); Feb 2024 (device registration)	NO	— Cyprus does not maintain a national medical device registration database. Pharmaceutical Services rely on EUDAMED for device data.	No separate national announcement. Cyprus participates in EUDAMED as an EU member state.	MED moh.gov.cy
Czech Republic SÚKL	Dec 2021 (actor module); Feb 2024 (device registration)	NO	Previously: RZPRO register Czech Republic previously maintained the RZPRO national register. With MDR/IVDR implementation, SÚKL transitioned to EUDAMED. National registration no longer required separately.	SÚKL published guidance confirming EUDAMED replaces the need for separate national notification for devices covered under MDR/IVDR.	MED sukl.cz
Denmark Danish Medicines Agency (DKMA)	Dec 2021 (actor module); Feb 2024 (device registration)	NO	— Denmark does not require separate national registration. DKMA relies entirely on EUDAMED for device and economic operator registration.	DKMA confirmed that manufacturers must register in EUDAMED. No parallel national system is required.	HIGH laegemiddelstyrelsen.dk

Country / CA	EUDAMED Adoption Date	National Reg. Required?	National Database & Details	Government Announcement	Confidence / Source
Estonia State Agency of Medicines (SAM / Ravimiamet)	Dec 2021 (actor module); Feb 2024 (device registration)	NO	— Estonia does not maintain a separate national medical device registration. SAM uses EUDAMED for economic operator and device data.	No separate national announcement beyond alignment with EU EUDAMED implementation.	MED ravimiamet.ee
Finland Fimea	Dec 2021 (actor module); Feb 2024 (device registration)	NO	Previously: Fimea device notification system Fimea previously required national notifications for certain device classes. With MDR/IVDR implementation, this requirement was discontinued in favour of EUDAMED.	Fimea published guidance confirming that national device notifications are no longer required for devices registered in EUDAMED under MDR/IVDR.	HIGH fimea.fi



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Country / CA	EUDAMED Adoption Date	National Reg. Required?	National Database & Details	Government Announcement	Confidence / Source
France ANSM	Dec 2021 (actor module); Feb 2024 (device registration)	NO	Previously: DMDIV notification system France historically required DMDIV notification for in vitro diagnostic devices and a national registration system. Under MDR/IVDR, ANSM discontinued the requirement for parallel national registration, transitioning fully to EUDAMED.	ANSM confirmed via official guidance (2021–2022) that the national notification system for medical devices is replaced by EUDAMED registration under MDR/IVDR. Manufacturers registering in EUDAMED fulfill French requirements.	HIGH ansm.sante.fr
Germany BfArM	Dec 2021 (actor module); May 2021 (MPDG national law enacted)	NO	Previously: DIMDI Medical Devices Information System Germany previously required registration in the DIMDI (now absorbed by BfArM) Medical Devices Information System. The Medical Devices Implementation Act (MPDG), effective May 26, 2021, abolished this requirement. Manufacturers now register exclusively in EUDAMED.	BfArM and the German Federal Ministry of Health confirmed via the MPDG (Medizinproduktegesetz) that the DIMDI national registration is abolished. EUDAMED SRN and device registration fully replace the former national obligation. (Official: BGBl. 2021 I S. 1309)	HIGH bfarm.de / MPDG (BGBl. 2021 I S. 1309)
Greece EOF (National Organization for Medicines)	Dec 2021 (actor module); Feb 2024 (device registration)	YES	EOF National Medical Device Database Greece requires notification and registration with EOF for certain medical device categories prior to market placement. This includes specific classes of devices sold in the Greek market. The requirement coexists with EUDAMED registration.	EOF has not announced elimination of national notification requirements. Manufacturers should verify with EOF directly for device class-specific obligations.	MED eof.gr
Hungary OGYÉI (NNGYK)	Dec 2021 (actor module); Feb 2024 (device registration)	YES	Hungarian National Medical Device Register Hungary maintains a national medical device register. Manufacturers placing devices on the Hungarian market are required to notify OGYÉI/NNGYK in addition to EUDAMED registration. This applies particularly to higher-risk device classes.	No official announcement that the national registration requirement has been abolished due to EUDAMED. Manufacturers must comply with both EUDAMED and Hungarian national obligations.	MED ogyei.gov.hu / nngyk.gov.hu
Ireland HPRA	Dec 2021 (actor module); Feb 2024 (device registration)	NO	— Ireland does not require a separate national registration database for medical devices. HPRA relies on EUDAMED for device and economic operator data.	HPRA published guidance confirming EUDAMED as the sole registration requirement under MDR/IVDR. No parallel national registration system is maintained.	HIGH hpra.ie

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Italy Ministero della Salute (DGDMF)	Dec 2021 (actor module); Feb 2024 (device registration)	YES	Repertorio Dispositivi Medici (Italian National Device Database) Italy REQUIRES separate registration in the Repertorio Dispositivi Medici (and Repertorio IVD for diagnostics) managed by the Ministry of Health. This registration is mandatory before devices can be sold through the Italian national health system (SSN) and for reimbursement eligibility. The Repertorio obligation is established under Italian law (DL 219/2006 and subsequent ministerial decrees) and is INDEPENDENT of EUDAMED.	The Italian Ministry of Health has explicitly confirmed that EUDAMED does NOT replace the Repertorio. The national Repertorio registration remains a mandatory requirement for the Italian market as of 2024–2025. Italy has not announced plans to abolish the Repertorio in favour of EUDAMED.	HIGH salute.gov.it / Repertorio portal / Ministerial circulars
Latvia ZVA (State Agency of Medicines)	Dec 2021 (actor module); Feb 2024 (device registration)	NO	— Latvia does not maintain a separate mandatory national registration database for medical devices. ZVA uses EUDAMED for economic operator and device data.	No separate national announcement. Latvia aligns with EU Commission EUDAMED implementation.	MED zva.gov.lv
Lithuania VVKT (State Medicines Control Agency)	Dec 2021 (actor module); Feb 2024 (device registration)	NO	— Lithuania does not require a separate national registration database for medical devices. VVKT uses EUDAMED as the primary registration platform.	No separate national announcement beyond EU-wide EUDAMED implementation guidance.	MED vvt.lt
Luxembourg Ministry of Health – Direction de la Santé	Dec 2021 (actor module); Feb 2024 (device registration)	NO	— Luxembourg does not maintain a national medical device registration database. As a small member state, Luxembourg relies entirely on EUDAMED for device registration data.	No separate national announcement. Luxembourg fully adopts EU EUDAMED framework.	HIGH sante.public.lu





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Malta Medicines Authority Malta	Dec 2021 (actor module); Feb 2024 (device registration)	NO	— Malta does not require a separate national registration database for medical devices beyond EUDAMED. The Medicines Authority oversees market surveillance.	No separate national announcement. Malta aligns with EU EUDAMED implementation.	MED medicinesauthority.gov.mt
Netherlands CIBG / IGJ	Dec 2021 (actor module); Feb 2024 (device registration)	NO	— The Netherlands does not require a separate national medical device registration beyond EUDAMED. CIBG manages various health databases, but device registration is handled exclusively via EUDAMED under MDR/IVDR.	IGJ/CIBG published guidance confirming EUDAMED as the sole registration point for medical devices under MDR/IVDR.	HIGH cibg.nl / igj.nl
Poland URPL	Dec 2021 (actor module); Feb 2024 (device registration)	PARTIAL	RPWDL (Polish national register) Poland maintains the RPWDL national register. Under the Polish Medical Devices Act (2022), manufacturers must notify URPL and register in RPWDL for devices placed on the Polish market in some categories, in addition to EUDAMED registration. However, the scope of mandatory national notification has been narrowing with MDR full implementation.	URPL has been updating its guidance on the interaction between RPWDL and EUDAMED. Full transition details are still being clarified; manufacturers should verify current obligations with URPL.	MED urpl.gov.pl
Portugal INFARMED	Dec 2021 (actor module); Feb 2024 (device registration)	NO	Previously: SIMDAMED national register Portugal previously maintained the SIMDAMED national device register. Under MDR/IVDR implementation, INFARMED discontinued the mandatory national registration requirement, transitioning to EUDAMED as the sole registration platform.	INFARMED published guidance confirming that EUDAMED registration replaces the former national SIMDAMED registration obligation for medical devices under MDR/IVDR. Manufacturers no longer need to register separately with INFARMED.	MED infarmed.pt
Romania ANMDMR	Dec 2021 (actor module); Feb 2024 (device registration)	YES	ANMDMR National Medical Device Register Romania requires registration with ANMDMR for certain medical device categories before market placement. This national registration obligation coexists with EUDAMED requirements under Romanian national law implementing MDR/IVDR.	ANMDMR has not announced abolition of national registration requirements. Manufacturers must verify current obligations with ANMDMR, especially for higher-risk device classes.	MED anmdmr.ro
Slovakia ŠÚKL	Dec 2021 (actor module); Feb 2024 (device registration)	NO	— Slovakia does not maintain a separate mandatory national medical device registration database. ŠÚKL relies on EUDAMED for device and economic operator registration data.	No separate national announcement. Slovakia aligns with EU Commission EUDAMED implementation timeline.	MED sukl.sk

Country / CA	EUDAMED Adoption Date	National Reg. Required?	National Database & Details	Government Announcement	Confidence / Source
Slovenia JAZMP	Dec 2021 (actor module); Feb 2024 (device registration)	NO	— Slovenia does not require a separate national registration database for medical devices. JAZMP uses EUDAMED as the primary platform for device and economic operator data.	No separate national announcement. Slovenia aligns with EU EUDAMED implementation.	MED jazmp.si
Spain AEMPS	Dec 2021 (actor module); Feb 2024 (device registration)	NO	Previously: RSPC (Registro de Productos Sanitarios) Spain previously maintained the RSPC (Registro de Productos Sanitarios y Cosméticos) national device registration. Under MDR/IVDR implementation, AEMPS transitioned to EUDAMED as the primary registration system. The mandatory RSPC national registration for medical devices has been replaced by EUDAMED registration.	AEMPS announced via official guidance that EUDAMED replaces the national RSPC registration obligation for medical devices under MDR/IVDR. Manufacturers registering in EUDAMED satisfy Spanish national requirements.	MED aemps.es
Sweden MPA (Läkemedelsverket)	Dec 2021 (actor module); Feb 2024 (device registration)	NO	— Sweden does not require a separate national registration database for medical devices. MPA uses EUDAMED exclusively for device and economic operator registration under MDR/IVDR.	MPA published guidance confirming EUDAMED as the sole registration platform for medical devices under MDR/IVDR. No parallel national system is maintained.	HIGH lakemedelsverket.se





EUDAMED Adoption

27/27

✓ All EU member states participate in EUDAMED

Actor module (SRN) mandatory: December 2021. Device registration (UDI): February 2024 (EUDAMED declared fully functional by EC).

National Reg. STILL Required

4 countries

- Greece
- Hungary
- Italy
- Romania

These countries maintain mandatory national databases IN ADDITION to EUDAMED. Manufacturers must comply with both.

Partial / Transitional

1 country

- Poland

National obligations partially apply or are in transition. Verify with competent authority for current scope.

EUDAMED Only — No Additional National Registration (22 Countries)

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Ireland
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Portugal
- Slovakia
- Slovenia
- Spain
- Sweden

Manufacturers placing devices in these countries need only register in EUDAMED (SRN + UDI/device registration). No parallel national database submission required.

EUDAMED Key Dates

Actor module (SRN) mandatory	Dec 2021
EUDAMED declared fully functional	Feb 2, 2024
MDR device registration mandatory	From Feb 2024
IVDR device registration mandatory	From Feb 2024

⚡ Key Regulatory Observations

- **EUDAMED does NOT automatically replace all national obligations.** EU Regulation 2017/745 (MDR) and 2017/746 (IVDR) establish EUDAMED as the EU-level system; however, Article 29 MDR and Article 26 IVDR allow member states to maintain national supplementary requirements within the EU framework.
- **Italy** presents the highest compliance burden — the **Repertorio Dispositivi Medici** remains mandatory for market access and reimbursement, independently of EUDAMED. This is codified in Italian national law (DL 219/2006). Manufacturers targeting the Italian NHS must maintain both registrations.
- **Germany** provides the clearest example of national simplification: the MPDG (May 2021) explicitly abolished the DIMDI registration and replaced it entirely with EUDAMED.
- **Countries with Medium/Low confidence** (Greece, Hungary, Romania, Poland) should be verified directly with the competent authority, as national regulations may have been updated post-2024.
- **All 27 member states** adopted EUDAMED actor registration (SRN) simultaneously in December 2021. EUDAMED device registration became mandatory following the EC's declaration of full functionality on February 2, 2024.
- **Transition risk:** Several countries (Finland, Portugal, France, Spain, Czech Republic) have discontinued national registration — however, legacy products placed on market before MDR/IVDR dates may still have historical national registration records that require maintenance or deregistration. Verify with each CA.

