EUDAMED: an overview of how it is being developed and deployed by the European Commission

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Glossary

Acronym	Lay Explanation
ACT	Actor registration module of EUDAMED
CA	Competent authority
CCA	Coordinating competent authority
CEAR	Clinical evaluation assessment report (MDR)
CECP	Clinical evaluation consultation procedure (MDR)
CIP	Clinical investigation plan (MDR)
CI/PS	Clinical investigations/performance study (also refers to the module of EUDAMED)
CMS	Coordinating Member State
CPSP	Clinical performance study plan (IVDR)
CRF	Notified Body and Certificates module of EUDAMED
CTIS	Clinical trial information system
DA	Designating authority
DD	Device deficiency
DoA	Date of Application – MDR or IVDR
DTX	Data exchange
EC	European Commission
EEA	European Economic Area
EO	Economic Operator
EU	European Union
EUDAMED	European Database on Medical Devices
FDA	US Food and Drug Administration
FSCA	Field safety corrective action
FSN	Field safety notice
IE	Issuing entity
IMDRF	International medical device regulators forum
IVD	In vitro diagnostic medical device
IVDR	In vitro diagnostic medical devices regulation (EU) 2017/746
LAA	Local Actor Administrator
LUA	Local User Administrator
M2M	Machine to machine data exchange services
MDCG	Medical device coordination group
MDR	Medical device regulation (EU) 2017/745
MIR	Manufacturer’s incident report
MRA	Mutual Recognition Agreement
MSU	Market surveillance module of EUDAMED
NB	Notified body
OJEU	Official Journal of the EU
PEAR	Performance evaluation assessment report (IVDR)
PECP	Performance evaluation consultation procedure (IVDR)
PMCF	Post-market clinical follow-up (MDR)
PMPF	Post-market performance follow-up (IVDR)
PMS	Post-market surveillance
PRRC	Person responsible for regulatory compliance
PSUR	Periodic safety update report
PSR	Periodic safety report

SAE	Serious adverse event
SIN	Single identification number for CI/PS
S/PP	Article 22 (MDR) System or procedure pack
SPPP	System and Procedure Pack Producer – Article 22 (MDR)
SRN	Single registration number
SS(C)P	Summary of safety and clinical performance (MDR), summary of safety and performance (IVDR)
UDI	Unique device identifier
UDID	UDI and device registration module of EUDAMED
UDI-DI	Unique device identifier – device identifier
UDI-PI	Unique device identifier – production identifier
VGL	Vigilance and post-market surveillance module of EUDAMED
XML	Extensible markup language
XSD	XML schema definition

Introduction

The European database on medical devices (EUDAMED) is an Information Technology system being built and implemented by the European Commission (EC) to fulfill many of the obligations of the Medical Device Regulation (MDR — EU 2017/745) and the In Vitro Diagnostic Medical Devices Regulation (IVDR – EU 2017/746), referred to in this white paper as the “Regulations”. It is a cornerstone of both Regulations and is intended to provide a living picture of the lifecycle of medical devices and in vitro diagnostic medical devices (IVDs) on the Union market. It integrates six separate and distinct electronic systems (referred to in this white paper as “modules”) that collate and process information related to Actor Registration, UDI & Device Registration, Notified Bodies and Certificates, Clinical Investigation/Performance Studies, Vigilance/Post-market Surveillance and Market Surveillance. Certain information will be publicly accessible via the EUDAMED public site, which will enhance transparency of the regulatory system for the public and healthcare professionals.

This white paper introduces readers to EUDAMED and provides an overview of how it is being developed and deployed by the European Commission. We will take a closer look at the modules individually, with a focus on the modules that require manufacturer, authorized representative, system and procedure pack producer, importer, or sponsor interaction. Practical tips, watch outs and recommendations are highlighted ✓ throughout the white paper. We will conclude with some suggested next steps and considerations to help support EUDAMED compliance efforts.

EUDAMED Overview

The MDR and IVDR represent the biggest change to the EU regulatory landscape in more than 20 years. The new legislation was created to resolve problems with diverging interpretation between EU Member States of the rules under the Directives, as well as to improve weaknesses in the legal system that were brought to light by some highly publicized incidents e.g. PIP breast implants[1] and metal on metal hips[2]. These incidents caused a loss of confidence in the regulatory system. Furthermore, it was thought that the EU legislation related to medical devices and IVDs needed to be brought up to date with technical advances, changes in medical science as well as progress in law making[3].

To address the concerns, pave the way for a more patient-friendly environment and create a robust regulatory framework, the EU adopted the Regulations. Unlike directives, regulations do not need to be transposed into national law, which helps to reduce discrepancies in interpretation across the Union.

1 See PIP breast implant scandal: A story that triggered change, https://www.massdevice.com/pip-breast-implant-scandal-story-triggered-change/ [accessed 24 March 2023].
2 See MHRA Updates Alert on Metal-on-Metal Hip Implants, https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2017/6/mhra-updates-alert-on-metal-on-metal-hip-implants [accessed 24 March 2023].
3 See Factsheet for Manufacturers of medical devices, https://health.ec.europa.eu/publications/factsheet-manufacturers-medical-devices_en [accessed 24 March 2023].

The IVDR and MDR *Whereas*[4] recitals include the following:

"Transparency and adequate access to information, appropriately presented for the intended user, are essential in the public interest, to protect public health, to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system."

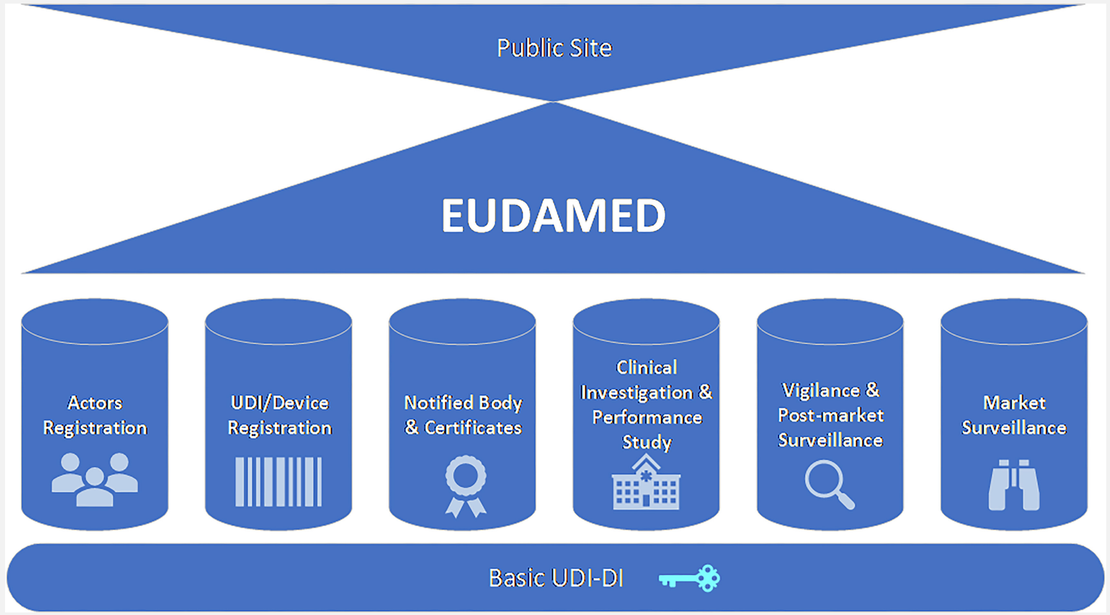
It is EUDAMED that will fulfil many of these obligations and the main objectives of EUDAMED are as follows:

- increased transparency and public access to information
- enhance traceability of medical devices
- enable actors (see Figure 4) to comply with the regulations
- avoid multiple reporting requirements i.e., to multiple individual Member States
- facilitate the flow of information between economic operators, sponsors or notified bodies and Member States, as well as between Member States themselves and with the European Commission
- enhance coordination between Member States.

4 See Whereas 40 (IVDR) and Whereas 43 (MDR).

EUDAMED is integral to the implementation of the new regulatory framework and the modules span the complete lifecycle of devices. The six modules are the pillars upon which the EUDAMED house is built (see Figure 1) and this multipurpose platform is interoperable allowing both collaboration between actors and dissemination of information. As each individual module of

Figure 1: EUDAMED



EUDAMED is being developed it will have two interfaces — one that is restricted to the EUDAMED actors specifically related to that module and one that is accessible to the public.

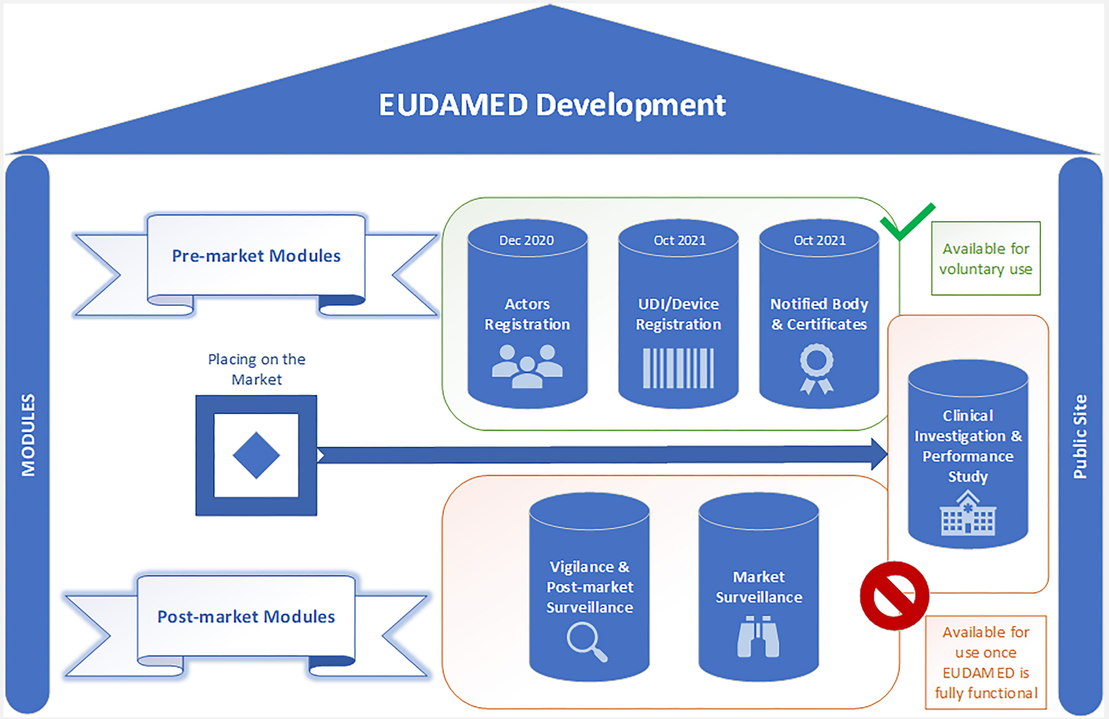
Then tying it all together we have the Basic UDI-DI, which is the main key to the EUDAMED database[5]. We will discuss each module in detail later.

EUDAMED Development & Deployment

The EC is developing EUDAMED in two separate and distinct module sets. The first module set (Figure 2, green box) are the pre-market modules, Actor Registration, UDI/Device registration and Notified Body/ Certificates. These modules are already operational and available for voluntary use. The second module set (Figure 2, orange box) is currently in development and includes the post-market modules, Vigilance/Post-market Surveillance and Market Surveillance. The Clinical Investigation/Performance Study module is also included in the second module set and straddle's the pre- and post-market space.

The second module set will not be available for use until all six modules of EUDAMED have been independently audited and the EC publishes a notice in the Official Journal of the EU (OJEU) that EUDAMED is fully functional. The EUDAMED Deployment (Table 1) outlines which modules are currently available for voluntary use, how long after EUDAMED is declared fully functional you must mandatorily start to use each module and an estimated timeframe for the end of the transitional period for each EUDAMED module.

Figure 2: EUDAMED Development



5 See MDCG 2018-1 Rev.4 Guidance on Basic UDI-DI (April 2021) and changes to UDI-DI.

Table 1: EUDAMED Deployment

EUDAMED Module	Voluntary Use	Mandatory use starts after EUDAMED declared fully functional	Transitional timeframe ends & mandatory use begins
EUDAMED Fully Functional: Q2 2024			
Actor Registration	December 2020	+ 6 months	From Q4 2024
UDI & Device Registration	October 2021	+ 24 months	From Q2 2026
Notified Body & Certificates	October 2021	+ 24 months	From Q2 2026
Vigilance & Post-market Surveillance	Not applicable	+ 6 months	From Q4 2024
Clinical Investigation & Performance Study	Not applicable	+ 6 months	From Q4 2024
Market Surveillance	Not applicable	+ 6 months	From Q4 2024

Note:. The EUDAMED full functionality date of Q2 2024 and dates included for the end of the transitional timeframe & mandatory use beginning, are taken from the last available public EUDAMED timeline published on the EC website (which is no longer available). It is recommended to monitor the EC website for further updates to the EUDAMED timeline.

Countries Available in EUDAMED

Due to recent events in the European regulatory environment, it is important to clarify which countries EUDAMED applies to:

- the 27 EU Member states
- the 3 EEA countries — Iceland, Liechtenstein, and Norway
- Turkey: is in a customs union with the EU and has aligned its legislation with the EU Regulations, EUDAMED is also applicable to Turkey[6]
- Northern Ireland: The United Kingdom has withdrawn from the EU since 1 February 2020, commonly referred to as BREXIT. However, due to the protocol on Ireland/ Northern Ireland, the UK competent authority is in EUDAMED with respect to Northern Ireland only[7]
- Note: As the MRA between Switzerland and the EU was not updated to include the MDR/IVDR by the respective DOAs of the Regulations — Switzerland is not included[8].

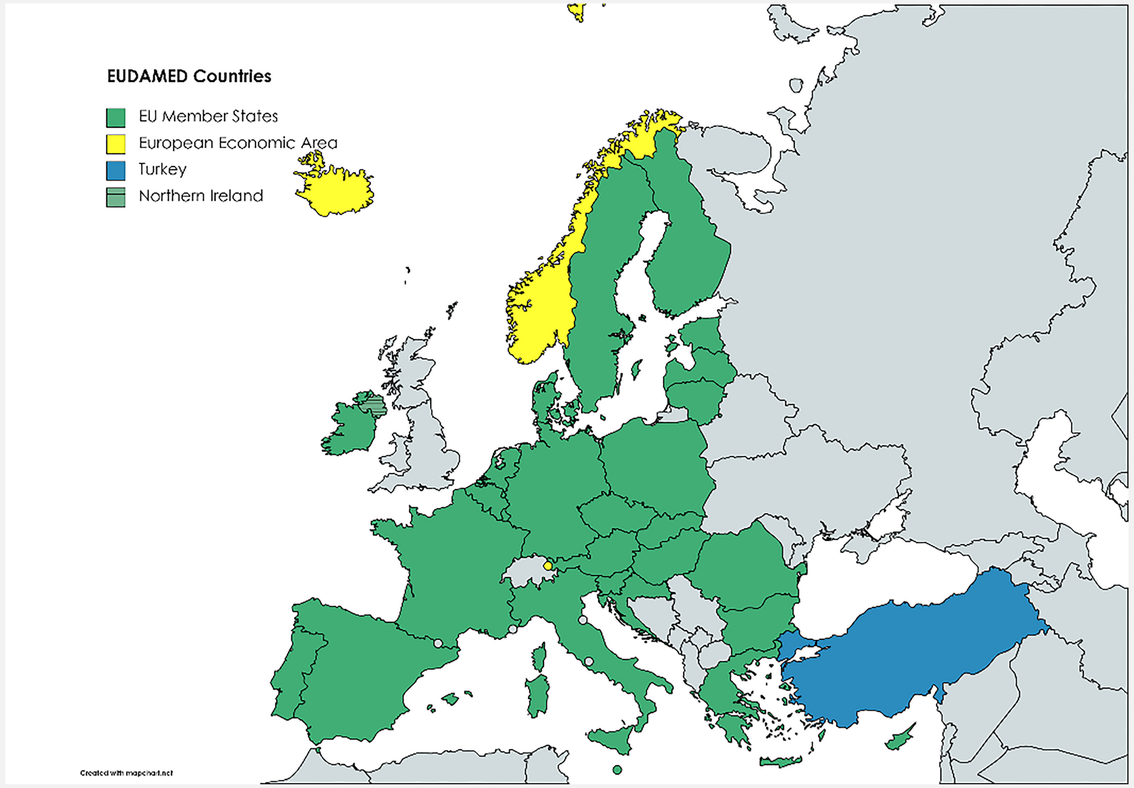
The EUDAMED user interface is available in all official languages of the Union.

6 See EU-Turkey Customs Union Agreement in the field of medical devices, https://health.ec.europa.eu/latest-updates/notice-stakeholders-eu-turkiye-customs-union-agreement-field-medical-devices-2022-04-13_en [accessed 24 March 2023].

7 See Protocol on Ireland and Northern Ireland, https://commission.europa.eu/strategy-and-policy/relations-non-eu-countries/relations-united-kingdom/eu-uk-withdrawal-agreement/protocol-ireland-and-northern-ireland_en [accessed 24 March 2023].

8 See Notice to stakeholders: Status of the EU-Switzerland Mutual Recognition Agreement (MRA) for Medical Devices, https://health.ec.europa.eu/latest-updates/notice-stakeholders-status-eu-switzerland-mutual-recognition-agreement-mra-medical-devices-2021-05-26_en [accessed 24 March 2023].

Figure 3: EUDAMED country overview

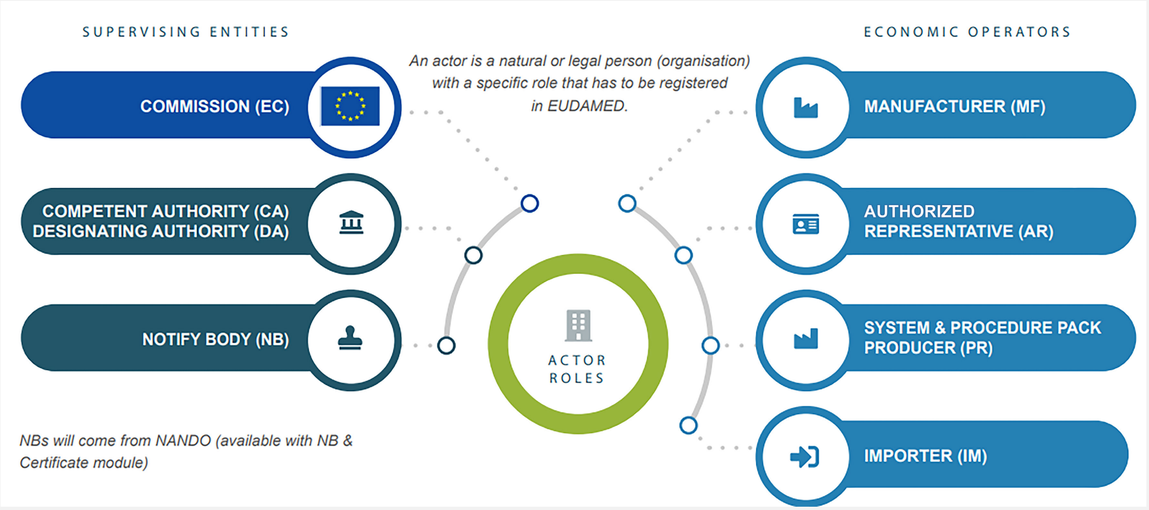


Actors Roles

Each actor has a specific role that requires registration in EUDAMED. Although we will focus our discussions regarding the actor module of EUDAMED on the EO roles that are part of or linked to a manufacturer's organization, it is important to have an overview of all the various actors in EUDAMED. The actor roles in EUDAMED break down as follows:

Please note that Distributors are not registered in EUDAMED. You need to refer to each country's national legislation to understand if there are local distributor registration requirements — we will not cover national distributor registration obligations in this paper.

Figure 4: Actor roles in EUDAMED



*Source: EC Infographic: Actor roles and Actor ID/SRN

EUDAMED Modules

Actor Registration Module (ACT)

Identification of Economic Operators (EOs) in the supply chain and traceability of devices go hand in hand. Prior to a device being placed on the market, EOs are required to register in EUDAMED[9] . Depending on the size and structure of your organization, you could have one or multiple EOs to register in EUDAMED i.e. manufacturer, System/ Procedure Pack Producer (SPPP), authorized representative and/or importer. If an organization has multiple actors to register, separate registrations are required for each individual actor role in EUDAMED. The EC have made considerable information available to help actors navigate EUDAMED registration, including a guide to using the EUDAMED actor registration module, technical documents, infographics, FAQs and video demos which are accessible via the EC website, actor registration page.[10]

All EOs must complete the EUDAMED registration application and upload a signed declaration on information security. Third country manufacturers located outside of the Union also need to upload a mandate summary document as they need to have an active authorized representative.

Some practical considerations and tips are listed below:

- ✓ The manufacturers name that you are registering in EUDAMED has to match the name on the device label and regulatory documents i.e., technical documentation, Declarations of Conformity and certificates (as applicable).
- ✓ It is possible to register the same organization name and address in EUDAMED multiple times, so long as they are associated with different actor roles. EUDAMED will check for possible duplicates when you are registering. The duplicate check is a warning flag only and does not prevent the submission of an actor registration request. In case of duplicate warning, it is valuable to add a justification for the CA.
- ✓ If you are a manufacturer based in a third country (outside of the Union), your authorized representative needs to register in EUDAMED first. The authorized representative's single registration number (SRN) is required in third country manufacturer registration applications, and the authorized representative verifies the third country manufacturers registration application before it is submitted to the relevant CA for validation.
- ✓ If you are a third country manufacturer, check with the CA in the Member State where your authorized representative is located to ascertain if any additional details need to be added to the mandate summary template i.e., "applicable legislation", as expectations can vary between CAs.
- ✓ Some CAs require non-mandatory fields to be completed in your EUDAMED registration. Check with the applicable CA if they have any required data fields e.g., national trade registry number and who should sign the EUDAMED declaration on information security, as expectations can vary between CAs.
- ✓ Custom-made device manufacturers are only required to register in EUDAMED if they have Class III custom made implantable devices that require a Notified Body (NB) certificate, or in case they need to submit vigilance reports for serious incidents, FSCAs, FSNs or trend reports for custom made devices of any risk class.[11]
- ✓ EO contact details are publicly available in EUDAMED. It is recommended to use business/professional contact details.
- ✓ Manufacturers and authorized representatives each have to register a minimum of one person responsible for regulatory compliance (PRRC) in EUDAMED, there is no upward limit. As PRRC contact details are publicly available in EUDAMED, it is recommended to use business/ professional contact details or a business functional mailbox. Using a functional mailbox limits unwanted spam mail to an individual's inbox and adds value by ensuring that email communications can be always monitored e.g. holiday cover.
- ✓ The PRRC for the authorized representative is required to be located in the Union and the address needs to be provided during the authorized representative actor registration.[12]

9 See Article 30 MDR and Article 28 IVDR.
10 See EC website actor registration page, https://health.ec.europa.eu/medical-devices-eudamed/actor-registration-module_en [accessed 24 March 2023].
11 See Question 3 MDCG 2021-13 rev.1, https://health.ec.europa.eu/system/files/2021-07/md_mdcg_2021-13_q-a-actor_registr_eudamed_en_0.pdf [accessed 24 March 2023].
12 See Article 3, Section 4 of the COMMISSION IMPLEMENTING REGULATION (EU) 2021/2078 of 26 November 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the European Database on Medical Devices (Eudamed).

- ✓ SPPPs located in third countries should choose the CA of the Member State where the first system or procedure pack of that producer is to be placed on the market.
- ✓ Sponsors registration will only be available in the ACT module once EUDAMED has been declared fully functional and the clinical investigation/performance study module is available.
- ✓ Data management: EOs need to update EUDAMED within one week of any change to the data required for the EUDAMED registration. No later than one year after submission and every second year after that, EOs need to confirm the accuracy of their data in EUDAMED[13]. This is expected be captured in related SOP or WI as applicable.
- ✓ Importers are required to check that the manufacturer or authorized representative have registered in EUDAMED, within two weeks of placing an associated device on the market and associate their details to the manufacturer.[14] The capability for importers to associate their details to specific devices will not be available for EUDAMED minimum viable product (MVP) — the specification that will be audited before EUDAMED is declared fully functional in the OJEU.

13 See Article 28 IVDR, Article 31 MDR.
14 See Article 27 IVDR and Article 30 MDR.

Single Registration Number (SRN) and Actor ID

To identify EOs and sponsors registered in EUDAMED uniquely, they are issued with an Actor ID. The Actor ID is automatically generated by EUDAMED once the relevant CA validates the registration request. If the EO that has registered is a manufacturer, authorized representative or importer, the Actor ID is also considered an SRN.[15]

Actor IDs and SRNs are configured as follows: Country Code (ISO 2 code) + Actor role (2-character abbreviation) + 9 digits. Figure 5 shows an example of a manufacturer based in Belgium.

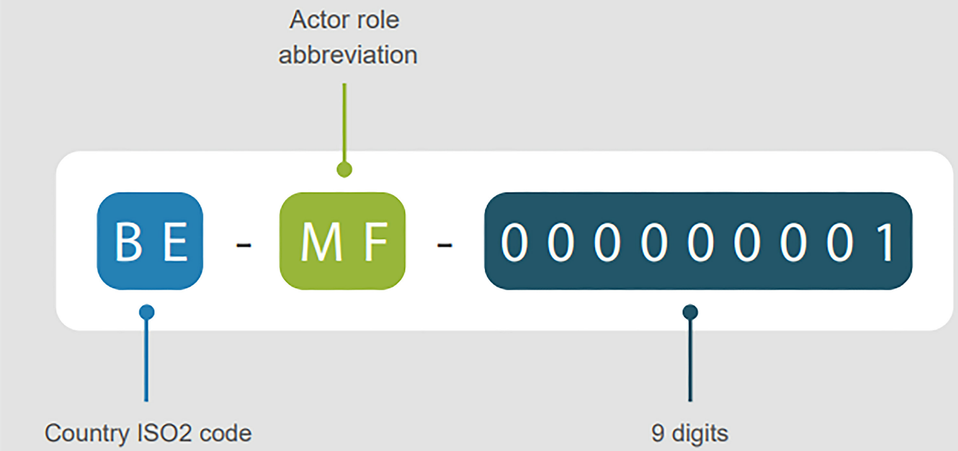
The Actor ID/SRN can be considered a EUDAMED key, linking data and documents related to EOs across the various modules. Although EUDAMED actor registration is currently voluntary, there are several advantages to obtaining an Actor ID/SRN now:

- ✓ Member state CAs may accept EUDAMED EO registration in lieu of local registration directly with the CA.
- ✓ Manufacturers can utilise the SRN in required regulatory documentation.

15 See Article 28 IVDR, Article 31 MDR and MDCG 2021-12 rev.7 Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR.

- ✓ It mitigates the need to reissue or update regulatory documents later to include the Actor ID/SRN once EUDAMED is fully functional and actor registration is mandatory.
- ✓ A non-exhaustive list of documents that need to have an Actor ID/SRN include: technical documentation, declaration of conformity, certificates issued by a notified body, certificates of free sale, summary of safety and (clinical) performance, clinical evaluation assessment report (MDR), performance evaluation report (IVDR), field safety notice, field safety corrective action, manufacturer incident report, periodic safety report, periodic safety update report, trend report, clinical investigation application and reports, serious adverse event report, post-market clinical follow up (MDR) and post-market performance follow up (IVDR).

Figure 5: Actor ID/SRN Example

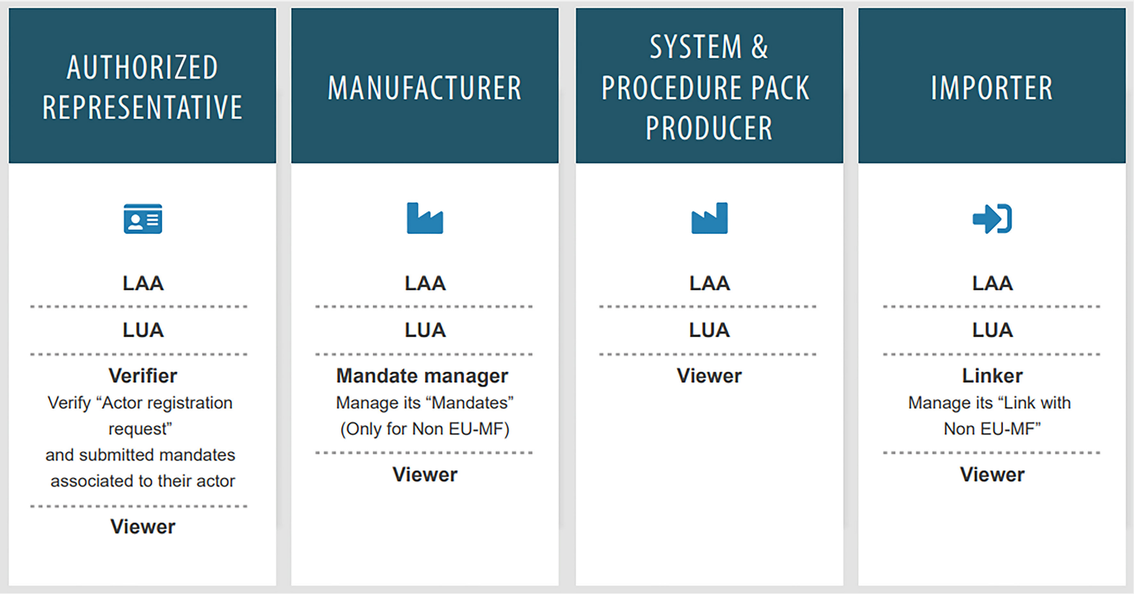


Source: EC Infographic – Actor Roles

EUDAMED Profiles' Hierarchy

The person who registers an individual EO in EUDAMED automatically becomes the Local Actor Administrator (LAA) once the CA has validated the actor registration. The LAA manages the EOs data and notification email addresses in EUDAMED and is the only profile able to make changes to registration details once an EO has been validated by a CA. If an EO wishes to communicate with EUDAMED via Machine to Machine (M2M) data exchange services in other EUDAMED modules, it is the LAA who has to submit this request. The LAA is the highest profile in the EUDAMED profile hierarchy and contains all grants & rights of the profiles beneath it in the hierarchy e.g., an LAA is automatically assigned the rights of the Local User Administrator (LUA). The LUA manages all user access requests for the same actor, by accepting or rejecting them. Each user access profile type is specific to the EO type and/or profile type requested as applicable (see Figure 6).

Figure 6: EUDAMED Profile Hierarchy



Source: EC Infographic – User Access Requests

- ✓ One LAA has to be associated with an EO in EUDAMED at all times, unless the EO has ceased to exist.
- ✓ It is highly recommended to have a minimum of two LAAs in EUDAMED per EO to ensure continued access to the EO. An additional consideration is that if an LAA requests access to an additional module of EUDAMED i.e., Vigilance & Post-market Surveillance (once EUDAMED is fully functional and the module is available), a second LAA/LUA is needed to validate that access request & enable access to the module for the first LAA and vice versa.
- ✓ It is possible to centralize LAA/LUA tasks within an organization i.e., a person can act as an LAA/LUA for multiple actors (via delegation). The registrations need to be requested individually and accepted by each responsible CA. The LUA/LAA will then have the ability to switch between actors, without logging out of EUDAMED.

UDI and Device Registration Module (UDID)

Identification & traceability of devices by means of a UDI system that is based on international guidance,[16] is a fundamental concept introduced to the EU regulatory ecosystem by the Regulations. Many global jurisdictions have introduced UDI systems in recent years based on the IMDRF framework, which provides principles for globally harmonized application of UDI systems. These fundamental elements are incorporated in the EU UDI system:

- A standardized system of unique device identifiers (the EC has designated four Issuing Entities (IEs) for assignments of UDI – GS1, HIBCC, ICCBBA and IFA GmbH)17. IE assignment rules have to be followed when allocating Basic UDI-DI and UDI-DI.
- Placement of a UDI's carrier on the label of the device (or on the device itself for reusable devices) and on all higher-level package labels.
- Submission of UDI core data to a UDI database (UDID module of EUDAMED).

16 See https://www.imdrf.org/consultations/unique-device-identification-system-udi-system [accessed 24 March 2023].
17 See Commission Implementing Decision (EU) 2019/939 of 6 June 2019 designating issuing entities designated to operate a system for the assignment of Unique Device Identifiers (UDIs) in the field of medical devices.

- Appropriate transition and implementation arrangements to ensure a smooth UDI system implementation[18] (see Table 1 for registration timelines only).

The benefits of a UDI system are widely appreciated, and manufacturers can already have experience in UDI allocation to devices e.g., the US FDA first introduced UDI in their regulatory system in 2013. The benefits of UDI to manufacturers, health authorities, healthcare institutions and patients are significant[19]:

- Enhances post-market safety
  - Improves incident reporting
  - Targeted FSCAs
  - Better monitoring by health authorities
- Reduces medical errors
- Helps fight against falsified devices
- Improves purchasing and waste disposal policies and stock management by health institutions and other EOs
- Facilitates global trade

Global trade and the ability for manufacturers to market a device in multiple jurisdictions, are among the many reasons to ensure harmonization of global UDI system. However, we do see differences in data element definitions and specific local requirements that can impact how manufacturers implement UDI internally and how they utilize UDI for specific markets moving forwards. It is highly recommended to study the ECs UDI documentation and analyze any differences between EU requirements and other jurisdictions. The IMDRF has also developed a handy comparison between EU and US requirements.[20]

Basic UDI-DI and UDI-DI

Before placing a device on the Union market, other than custom-made or investigational/ performance study devices, the Basic UDI-DI and at least one associated UDI-DI has to be registered in EUDAMED. One major difference between the EU and other jurisdictions is that device and UDI-DI registration (UDID) is only one of six modules of the database introduced by the Regulations. EUDAMED incorporates the whole lifecycle of devices from pre-market to post-market. To identify devices throughout their lifecycle and connect UDI-DIs with information in the other modules, the EU developed a new concept called the Basic UDI-DI, which:

- is the primary identifier of a device model[21]
- is the main key in the EUDAMED database
- is referenced in relevant regulatory documentation e.g., certificates, DoCs, technical documentation, CFS, SS(C)P etc.
- connects devices with the same intended purpose, risk class and essential design and manufacturing characteristics

Table 2: Key differences between Basic UDI-DIs and UDI-DIs

	Basic UDI-DI	UDI-DI
Purpose	Regulatory	Identification and traceability
Application	EUDAMED Regulatory documentation	Label Package levels
Use	Conformity assessments – certificate scope	Supply chain

*Source: BSI White Paper – EU MDR and IVDR: unique device identification, what is required and how to manage it

- is independent from packaging/labelling of the device and does not appear on any trade item, although it can appear in the IFU[22,23].

UDI-DI is a well understood concept applicable to multiple jurisdictions, so this white paper does not go into further details. However, as the Basic UDI-DI is currently unique to the EU, it is important to cover the key differences between UDI-DI and Basic UDI-DI.

Manufactures need to assign Basic UDI-DI and UDI-DI to devices and register both in EUDAMED. Some key considerations are as follows:

- ✓ To register a Basic UDI-DI in EUDAMED, you need to register at least one associated UDI-DI.
- ✓ Manufacturers should understand the Basic UDI-DI and UDI-DI data elements that are required to be submitted to EUDAMED and establish a source of truth internally for these data elements.
- ✓ Manufacturers should understand what data elements trigger a new Basic UDI-DI and/or UDI-DI if changed. Look at the Regulations and the MDCG documents for triggers and pay close attention to the EUDAMED UDI/Device Data Dictionary

18 See https://www.imdrf.org/sites/default/files/2021-09/imdrf-cons-udi-system-n48-180712.pdf [accessed 24 March 2023].
19 See Whereas 38 (IVDR) and 41 (MDR).
20 See Use of UDI data elements across different IMDRF jurisdictions, https://www.imdrf.org/consultations/unique-device-identification-system-udi-system [accessed 24 March 2023].
21 See Annex VI Part C (1) MDR and IVDR.
22 See MDCG 2018-1 Rev.4 Guidance on Basic UDI-DI and changes to UDI-DI.
23 See MDCG 2019-9 Rev.1 Summary of safety and clinical performance, A guide for manufacturers and notified bodies.

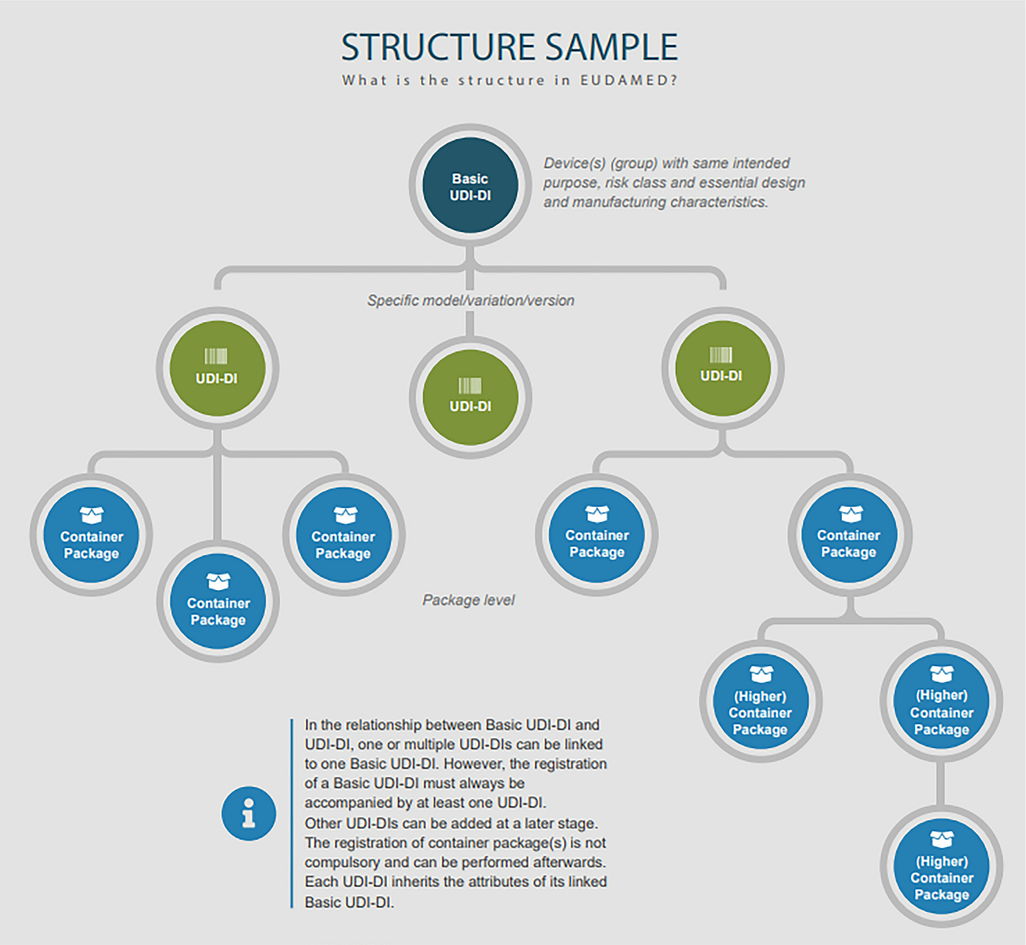
to understand which data fields are not updateable or only conditionally updateable — as these may be de-facto triggers.

- ✓ An individual Basic UDI-DI can be associated with one or many UDI-DIs.
- ✓ An UDI-DI can be associated with only one Basic UDI-DI. If the Basic UDI-DI needs to change, then all of the associated UDI-DIs also need to change.
- ✓ Both Basic UDI-DIs and UDI-DIs can only have one instance in EUDAMED as they are unique identifiers.
- ✓ The public can use the Basic UDI-DI or UDI-DI to search for devices in EUDAMED. Other search criteria are also available.
- ✓ The UDID module of EUDAMED is currently available on a voluntary basis. However, manufacturers of contact lenses, spectacle frames, spectacle lenses and ready readers are not expected to use the UDID module voluntarily until specific solutions for registration of these product types are finalized[24].
- ✓ After submitting a device to EUDAMED, the state of the device will be "registered" if the Basic UDI-DI/UDI-DI data does not require confirmation from a notified body. It will have a state of "submitted" if the Basic UDI-DI/UDI-DI data requires a confirmation from the notified body before being "registered" and pushed to the public site e.g., high risk devices covered by a Type Examination or Technical Documentation Certificate[25] require Notified Body confirmation of device data before the device can be publically available via EUDAMED[26].
- ✓ Although EUDAMED requirements in the Regulations (illustrated in the EUDAMED deployment Table 1) allow for 24 months after EUDAMED is fully functional to register devices/UDI-DI, it is understood that any interaction with the vigilance and post-market surveillance module triggers a registration requirement for the device. The device must be registered prior to the final report being submitted to EUDAMED[27]. The EC has confirmed that for devices that require NB interaction, a status of submitted in EUDAMED is sufficient.
- ✓ The Basic UDI-DI and UDI-DI are included in Vigilance and Post-market Surveillance module and CI/PS module reports where applicable e.g., the Basic UDI-DI & UDI-DI may not be applicable for pre-market CI/PS reports.
- ✓ Manufacturers should compare UDI requirements across jurisdictions where

24 See MDCG 2021-09 MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses and ready readers.

25 See MDR Article 29(3) or IVDR Article 26(2).
26 See EC Infographic EUDAMED Registration Process for Regulation Devices, https://health.ec.europa.eu/system/files/2021-11/md_eudamed-udi-registration-process_en_0.pdf [accessed 24 March 2023].
27 See MDCG 2019-5 Registration of legacy devices in EUDAMED.

Figure 7: Basic UDI-DI & UDI-DI structure sample



*Source: EC Infographic – Basic UDI-DI and UDI-DI Concept

they are marketing devices to ensure compliance.

✓ All devices CE marked to the regulations, even if they are not intended to be placed on the union market, are required to be registered in UDID.

Registration of Legacy Devices

Devices that continue to be placed on the market after the Date of Application (DoA) of the Regulations, are known as legacy devices. These devices are either:

- Class I devices under Directive 93/42/EEC that have a DoC drawn up prior to DoA of the MDR and conformity assessment under the MDR requires the involvement of a notified body i.e., reusable surgical instruments; or
- Are devices covered by a valid certificate issued in accordance with the Directives prior to DoA of the Regulations.

Registration of legacy devices in EUDAMED will only be required once EUDAMED is fully functional and one of the following scenarios is met:

1. Prior to the end of the 24-month grace period (see Table 1) an equivalent device has not transitioned to the Regulations and been registered in EUDAMED.
2. There is a post-market surveillance and/or vigilance report required to be submitted in EUDAMED, and an equivalent device has not transitioned to the Regulations and been registered in EUDAMED[28].

As neither Basic UDI-DI nor UDI-DI are a requirement for legacy devices, the EC has adapted EUDAMED to allow for registration of legacy devices without (Basic) UDI-DI. Unique access keys to replace (Basic) UDI-DI have been developed:

- EUDAMED DI – is assigned for the Basic UDI-DI and prefaced by the letter B
- EUDAMED ID – is assigned for the UDI-DI and is prefaced by the letter D
- The EUDAMED DI and ID have the same format, only the prefix letter is different – B for a EUDAMED DI and D for a EUDAMED ID.

As there is a 1:1 relationship in EUDAMED between the EUDAMED DI and EUDAMED ID.

✓ If a manufacturer already has a UDI-DI assigned to a legacy device, it can be used in the legacy device registration in EUDAMED as part of the EUDAMED ID and prefaced by the letter B. This will automatically generate a EUDAMED DI that includes the manufacturers UDI-DI for the legacy device.

✓ If a registered legacy device is the equivalent to an MDR device that is being registered in EUDAMED, the system will allow the devices to be linked. If an UDI-DI exists for a legacy device and was used in the EUDAMED registration as part of the EUDAMED DI and therefore EUDAMED ID, EUDAMED will automatically link the devices. If there is no UDI-DI for a legacy device or it has not been used as part of the legacy device EUDAMED registration, the manufacturer can manually link the devices. It is important to understand the validation checks between the registration of the legacy and Regulation device, as listed in the UDI/Device Business Rules document[29]. If these validation checks fail, a new UDI-DI can be required for the Regulation device.

Notified Body and Certificates Module (CRF)

The restricted site of the notified body and certificates module (CRF) is only accessible to the NBs, their designating authority (DA), CA and the EC. As always, it is good for other EOs to understand what information will be housed in the CRF module of EUDAMED.

Conformity Assessment Procedure & Certificate Information:

The CRF module houses certain aspects of the conformity assessment procedure for devices, including notification of conformity assessment procedures and informing other NBs if an application for conformity assessment by a manufacturer has been withdrawn prior to the NBs decision or if an application for conformity assessment has been refused by a NB.

Clinical Evaluation Consultation Procedure:

The Clinical Evaluation Consultation Procedure (CECP) is applicable to class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product under Rule 12 of the MDR[30]. In certain cases,

28 See EC Infographic Legacy device identifiers, https://health.ec.europa.eu/system/files/2021-11/md_eudamed-eudamed-di-concept_en_0.pdf [accessed 24 March 2023].

29 See EUDAMED UDI/Device business rules, https://health.ec.europa.eu/system/files/2022-08/md_udi-device-business-rules_en_0.pdf [accessed 24 March 2023].

30 See Article 54(1) MDR.

there are exceptions to this procedure[31]. The following functionality is foreseen for CECPs in the CRF module:

- ✓ In the CECP management section of EUDAMED the CAs/DAs/EC are informed whether a CECP is to be applied during the conformity assessment procedure and the clinical evaluation assessment report (CEAR) is uploaded.
- ✓ If CECP is going ahead additional documentation is submitted. The expert panel who is assigned the CECP notifies the EC on its decision to provide an expert opinion or not. If the expert panel has decided not to provide an opinion, the reasons for this decision are communicated to the NB and EC. If the expert panel has decided to provide an opinion, once finalised the opinion is made available in the CRF module.

Certificates:

NBs upload certificate data for all Quality and Product Certificate types to CRF i.e.:

- Quality Certificates
  - EU Quality Management System certificate[32]
  - EU Quality Assurance certificate[33]
  - EU Production Quality Assurance certificate[34]
- Product Certificates
  - EU Type Examination certificate[35]
  - EU Technical Documentation certificate[36]
  - EU Product Verification certificate[37].

Core data provided to the CRF module includes the certificate number and a revision number (if applicable). The date of issue, the starting date of the certificate validity and the date of expiry. There is also relevant information related to the certificate status i.e., whether the certificate is issued, re-issued, suspended, reinstated, withdrawn or cancelled and any restrictions imposed on a certificate (as applicable). As well as any amendments and supplements.

- ✓ If a certificate has been withdrawn or suspended, the NB informs the CA of the country where the manufacturer or their EU authorized representative has its registered place of business.
- ✓ Note: Regulatory Authorities outside of the Union sometimes request NB letters from manufacturers, confirming that relevant certificates are valid. Once the CRF module is mandatory (see Figure 1), EUDAMED could be a useful source of truth, minimizing the need for these NB letters.

Summary of Safety and (Clinical) Performance (SS(C)P):

For implantable and Class III devices (MDR), as well as Class C and D devices (IVDR), other than investigational/performance study and custom-made implantable devices, the NB uploads the SS(C)P during certificate registration, to the CRF module. In the CRF module, the SSCP needs to have a reference number and revision number.

- ✓ An issue date for the SS(C)P (YYYY-MM-DD) is also needed.
- ✓ Currently NBs upload the translations of the SS(C)P in the languages of the Member States where the devices are to be placed on the market. In the future it may be possible for manufacturers to upload SS(C)P translations to EUDAMED[38]. This would decrease burden on the NBs for a purely administrative task and allow manufacturers more dominion over when devices can be placed on the market, as the translations need to be uploaded to EUDAMED prior to placing associated devices on the market[39].
- ✓ Notified bodies manage interim updates to SS(C)Ps through the SS(C)P management module of EUDAMED.

Mechanism for Scrutiny of Conformity Assessments:

The mechanism for scrutiny takes place during the last stage of certificate registration and enables notification to CAs, authorities responsible for NBs designation (DAs) and the EC about certificates granted to Class D devices under IVDR, and for devices where CECP has been performed under MDR. Exceptions to the scrutiny process under IVDR are outlined in the regulation40. The NBs provide the following documents for the scrutiny process via the CRF module:

- Summary of safety and (clinical) performance
- Instructions for use
- Assessment report from the NB
  - MDR — Clinical evaluation assessment report (CEAR)
  - IVDR — Performance evaluation assessment report (PEAR)

31 See Article 54 (2) MDR and MDCG 2019-3 Rev.1 Interpretation of Article 54(2)b.
32 See Annex IX, Chapter I.
33 See Annex XI, Part A.
34 See Annex XI.
35 See Annex X.
36 See Annex IX, Chapter II.
37 See Annex XI, Part B.
38 See MDCG 2022-14 Transition to the MDR and IVDR — Notified Body capacity and availability of medical devices and IVDs.
39 See MDCG 2019-9 Rev.1 Summary of safety and clinical performance.
40 See Article 50 (1) IVDR.

- Laboratory tests and the scientific opinion of the EU reference laboratory (IVDR) (if applicable)
- Scientific opinion of the expert panel (if applicable)
- Justification if the NB has a divergent opinion to the expert panel.

Additional CRF functionalities & information:

✓ NBs need to list subsidiaries where they subcontract work related to conformity assessment.

✓ DAs upload their summary report related to monitoring and on-site assessments of NBs.

✓ If a DA has decided to restrict, suspend, or withdraw a NBs designation, the information related to impacted certificates is provided to the CA where any impacted manufacturers are located, and that CA will take appropriate measure to avoid a potential risk to the health and safety of patients, users or others.

✓ While the CRF module is already available for voluntary use by relevant actors, the CECP and scrutiny process functionalities are not currently available in the production environment (March 2023). This functionality is included in EUDAMED MVP.

✓ The list of expert panels, related experts and opinions provided to date under the CECP/PECP procedures are currently available on the EC website[41].

41 See https://health.ec.europa.eu/medical-devices-expert-panels_en [accessed 24 March 2023].

Clinical Investigation and Performance Study Module (CI/PS)

The CI/PS module of EUDAMED is still being developed by the EC and current timelines indicate that mandatory use of this module will begin six months after EUDAMED had been declared fully functional in the OJEU i.e., Q4 2024. To use the CI/PS module, a sponsor first needs to have registered in the ACT module of EUDAMED. There will be four sponsor types available for registration in the ACT module of EUDAMED — Company, Individual, Institution or Organization. Although the ACT module is currently available to use on a voluntary basis, the sponsor registration functionality in ACT will not be available until EDUAMED is fully functional and the CI/PS module is available for use.

✓ If the sponsor is not established in the Union, the Sponsor needs to have a natural or legal person established in the EU as their legal representative — the legal representative is responsible for the sponsors obligations in the MDR/IVDR and is the person to whom all communications are sent for the MDR/IVDR.

✓ If a CI/PS is being conducted in only one MS or in a third country and one MS only — the CA of that MS may choose not to require a legal representative of the sponsor in the union, only a contact person in their MS — who will be the addressee for all communications[42].

We expect the process to register a sponsor in EUDAMED to be similar to the registration process of the EOs. A signed declaration of information security will be required, along with other information and the individual who registers the sponsor will automatically become the LAA. The user hierarchy should be similar: LAA → LUA → various user roles to be communicated by the EC. One expected difference is that a sponsor application is automatically validated by EUDAMED once verified by the sponsor and does not require CA approval prior to EUDAMED generation of the Actor ID.

Clinical Investigation/Performance Study Registration & Adverse Events Reporting:

Once a sponsor is registered in EUDAMED they can submit clinical investigation (MDR) or performance study (IVDR) application to the Member State(s) where the CI/PS will be conducted. The following documentation needs to be completed/submitted:

- CI/PS application
- Clinical investigation Plan (CIP-MDR) or Clinical Performance Study Plan (CPSP – IVDR)

42 See Article 58(4) IVDR and Article 60(2) MDR.

- Investigator's brochure
- Other documentation[43].

Once the CI/PS is successfully validated, EUDAMED generates a union wide Single Identification Number (SIN) for the CI/PS, that is used in all documentation/communication related to the CI/PS.

✓ A Coordinated assessment procedure for CI/PS will be available via EUDAMED, when a CI/PS is to be conducted in more than one country. The sponsor will be able to submit one single application and the CI/PS module will send to all individual Member State where the CI/PS is being conducted. The sponsor will propose one Member State to act as the coordinating Member State (CMS). Even when EUDAMED is fully functional, the coordinated assessment procedure will only involve Member States that agree to voluntarily participate, until it becomes mandatory on 27 May 2027 for MDR and 27 May 2029 for IVDR.

✓ During the period when the application is being assessed, the Member State can request additional information from the sponsor.

✓ Any changes to relevant data in the CI/PS that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the clinical data generated by the investigation must be updated within one week of the change occurring.

✓ All SAEs related to the procedure, study device, comparators or device deficiencies that might have led to a serious adverse event must be reported without delay — whether they occur in the union or a third country if they are under the same CI/PS plan.

  ○ SAEs related to a CE marked device which is part of the investigational procedure (e.g., a CE marked implanting tool used in combination with a non-CE marked investigational device) are reportable if there is a causal (or reasonably possible) relationship to the device, the comparator, or the investigation procedure[44].

✓ Note: SAEs concerning CE marked devices which meet the vigilance reporting criteria also need to be handled under the vigilance & post-market surveillance module.

✓ A coordinated assessment procedure will also be available to allow CAs and the CMS associated with a CI/PS to coordinate their assessments of SAEs and device deficiencies to determine whether they modify, suspend, or terminate the CI/PS.

✓ A notification that the CI/PS has ended must be submitted to the CI/PS module within 15 days of the end of the investigation/study.

✓ Sponsors are required to submit CI/PS outcome report along with a summary within one year of the of the end of the CI/PS or within three months of an early termination or temporary halt.

Post-market Clinical Follow up (PMCF)/ Post-market Performance follow up (PMPF):

Sponsors are required to notify their PMCF investigation (MDR) or PMPF study (IVDR) to the CI/PS module at least 30 days prior to the commencement date with all the required documentation and data.

✓ For SAEs or device deficiencies that occur during a PMCF investigation or a PMPF study where the study device is used within the intended use — the vigilance provisions apply. These are reported in the vigilance and post-market surveillance module as an incident report.

✓ PMCF investigations that involve procedures additional to those performed under the normal conditions of use of the device, and where those additional procedures imposed by the clinical investigation plan are invasive or burdensome, require the reporting of SAEs where a causal relationship to the preceding investigational procedure has been established.

✓ A notification that the PMCF/PMPF has ended needs to be submitted to the CI/PS module within 15 days of the end of the PMCF/PMPF.

✓ Sponsors are required to submit PMCF/PMPF outcome report along with a summary within one year of the of the end of the PMCF/PMPF or within three months of an early termination or temporary halt.

CI/PS Additional Information:

The CI/PS module will enable enhanced communication between the EC & Member State regarding any decisions that have been taken at national level, the reasons for those decisions and any corrective measures taken in the country.

✓ Notified bodies will only have access to publicly accessible information in CI/PS as there is no legal basis to grant access to the module foreseen in the regulations.

✓ Personal data in EUDAMED CI/PS is protected and so is commercially confidential information. The extent of what/which commercially sensitive information is to be made publicly available is still under discussion.

43 See Annex XIV Chapter I (IVDR) and Annex XV Chapter II (MDR).

44 See Article 76(1) IVDR and 80 (2) MDR.

- ✓ There are provisions under the MDR to allow interoperability between EUDAMED and the EU database for clinical trials (CTIS) on medicinal products for human use where there are combined clinical investigations of devices with a clinical trial under the medicinal products regulation (EU 536/2014). This functionality is not expected to be available under MVP when CI/PS first becomes available for use.

Vigilance and Post-market Surveillance module (VGL)

The vigilance and post-market surveillance module (VGL) of EUDAMED is still being developed by the EC and current timelines indicate that mandatory use of this module will begin six months after EUDAMED had been declared fully functional in the OJEU i.e., Q4 2024. To use the VGL module, a manufacturer needs to first have registered in the ACT module of EUDAMED.

- ✓ During registration in ACT, a third country manufacturer can indicate in the mandate summary whether they will allow their EU Authorized Representative to submit vigilance reports on their behalf.

CAs will use EUDAMED to exchange information on the evaluation, outcome of assessments and any corrective actions for serious incidents and/or field safety corrective actions (FSCAs). EUDAMED will also be used to monitor vigilance and post-market surveillance data actively to identify trends, patterns and signals that could reveal new risks or safety concerns to be communicated to the EC, CAs and Coordinating CAs (CCAs). This information will be available to all CAs and the EC.

There are several types of vigilance and post-market surveillance reports to be submitted to EUDAMED by manufacturers or their authorized representative.

Reports to be submitted to EUDAMED:

Periodic Safety Update Report (PSUR)

Manufacturers of class IIa, IIb and class III devices and class C and D IVD devices are required to create PSURs for each device or category of device as applicable. The PSUR summarizes the results and conclusions of the post-market surveillance plan, together with a rationale and description of any preventative and corrective actions taken. Only PSURs for class III and implantable devices under the MDR (excluding custom-made implants) and class D IVD devices under the IVDR are required to be submitted to EUDAMED. The PSURs are submitted via EUDAMED to the NB involved in the conformity assessment of the devices. The NB then adds their evaluation report to the PSUR. The CAs are provided with access to the PSUR as soon as the manufacturer has submitted it and to the NB evaluation as soon as it is available.

- ✓ It is possible to reference >1 Basic UDI-DI in the PSUR. However, only one Basic UDI-DI can be the leading device.
- ✓ In EUDAMED every Class III or Implantable device should have at least one linked PSUR45.
- ✓ If more than two NBs have issued certificates related to a device, the NB referenced will the one who issued the type examination certificate.
- ✓ The PSUR needs to have a reference number and revision number.

45 See MDCG 2022-21 Guidance on periodic safety update report (PSUR) according to Regulation (EU) 2017/745.

Serious Incidents

Manufacturers of devices & IVDs, other than investigational devices, made available on the union market are required to report serious incidents in EUDAMED. The serious incident should be reported as soon as the manufacturer has established a causal or possible causal relationship between the incident and their device and no later than 15 calendar days after they become aware of the incident. In the event of a serious health threat, no later than two calendar days and, in the event of a death or unanticipated serious deterioration in a person state of health, no more than ten calendar days. In the VGL module, serious incident reports will be transmitted to the relevant CA in the country where the incident occurred and to the NB that issued related certificate(s). EUDAMED allows an initial report to be submitted first to allow timely compliance to the requirements and a follow-up final report can be completed at a later date.

Field Safety Corrective Actions (FSCA)

FSCAs are undertaken by the manufacturer for technical or medical reasons to prevent

or reduce the risk of a serious incident for devices, other than CI/PS devices, available on union market. FSCAs undertaken in countries outside of the Union are only reported in the VGL module where the device concerned is also made available on the Union market and if the reason for FSCA is not limited to the devices made available in the third country. The FSCA is transmitted to the CAs of the country in which the FSCA is being or will be undertaken, to the CA of the country where the manufacturer or their EU Authorized Representative is established, and to the NB(s) that issued the certificate(s) of the device or IVD concerned. Once a final FSCA report is available, it is transmitted to the relevant CA(s).

- ✓ Where an FSCA is or will be initiated in more than one country, a coordinated assessment procedure is possible via the VGL module. The CCA should be from one of the countries affected by the FSCA or the CA where the manufacturer or, if applicable, their EU Authorized Representative is located.

Field Safety Notice (FSN)

FSNs are communications created by manufacturers related to FSCAs and include information that is relevant for health professionals, users and patients. Except in cases of urgency, a draft FSN is first submitted to the evaluating CA or if applicable the CCA to allow them to make comments, after which a final FSN is then submitted to the VGL module.

Periodic Summary Report (PSR)

This is an alternative reporting regime where a manufacturer can report similar serious incidents that occur with the same device or device type in a consolidated way in place of individual reporting. This may be applicable where the root cause has been identified, an FSCA has been implemented or where the incidents are common and well documented. The format and frequency of PSRs are agreed upon with the manufacturer, the participating CA(s), as well as the CA in the country where the manufacturer or their EU authorized representative is located. EUDAMED enables transmission of the submitted PSR to the applicable CA(s) involved in the agreement and to the NB(s) that issued the certificate(s) of the device.

- ✓ Where more than one CA is involved, there has to be agreement between the CAs regarding the possibility of a PSR and participation in a coordinated assessment.

Trend Report (TR)

A TR is required when there has been a statistically significant increase in the frequency or severity of non-serious incidents, expected side effects (MDR), or expected erroneous results (IVDR) that could have a significant impact on the benefit risk analysis of the device or IVD. This requirement provides a consistent and systemic review of the aforementioned incidents by the manufactures. Upon submission into EUDAMED, the TR is transmitted to CAs of the countries where the incidents occurred and to the NB(s) that issued the certificate for the device(s) or IVD(s) concerned. The CAs may assess the TR and require the manufacturer to adopt any relevant measure to ensure public health and patient safety. The results of the assessment and of the adoption of such measures will be made available to all other CAs, to the EC and the NB that issued the certificate.

VGL Considerations:

- ✓ Once EUDAMED is fully functional, devices including ‘legacy’ devices (if the Regulation device is not already submitted), need to be registered in EUDAMED prior to a final vigilance or PMS report being submitted[46]. For higher class devices that require NB approval, the devices may be in a submitted state as opposed to a registered state until the end of the transitional period for the UDID and CRF module (see Table 1).
- ✓ Note: Where old devices (not placed on the market after DoA) require a vigilance report to be submitted, the devices do not require registration in UDID. The EC have communicated that the registration will have been deemed to have taken place in the VGL module for old devices.
- ✓ All vigilance and post-market surveillance reports reference the manufacturers and, if applicable, the EU authorized representatives Actor ID/SRN and the Basic UDI-DI(s)/UDI-DI(s) of the relevant device(s) or IVD(s) concerned.
- ✓ NBs can view all post-market surveillance and vigilance information for devices for which they issued the certificate(s).
- ✓ In future, access may be granted to CAs of third countries and international organizations to some post-market and vigilance data in EUDAMED, dependent on an access level agreed with the EC[47]. We do not yet know what this will look like.

46 MDCG 2019-5 Registration of legacy device in EUDAMED.

47 See Article 87(4) IVDR and Article 92(4) MDR.

Market Surveillance Module (MSU)

The market surveillance module of EUDAMED is still being developed by the EC and current timelines indicate that mandatory use of this module will begin six months after EUDAMED had been declared fully functional in the OJEU i.e., Q4 2024. The market surveillance module is primarily used for communication between the CAs and the EC. The market surveillance module will provide the following functionalities:

- CAs provide and make available to other CAs the annual summary of their surveillance activities.
- Following inspections of EOs for the purpose of market surveillance, the final inspection report will be provided to EUDAMED.
- Member States will communicate to other Member States and the EC the results of the review and assessment of their market surveillance activities. A summary of these results will be made accessible to the public via MSU and transmitted to all CAs concerned at least every four years.
- For devices representing an unacceptable risk to health and safety, the results of the evaluation and the actions to be taken by the EO. These are transmitted to the EC, CAs and NB that issues the certificate(s) of the device(s) concerned.
    - Where the EO does not take adequate corrective action within the time allowed, the information is immediately transmitted to the EC, the CAs and applicable NB(s).
- Notification of preventative health protection measures taken by a Member State related to a device, or a specific category or group of devices, and the reasons for this decision to other Member states, CAs, the EC, the NB and its designating authority.

EUDAMED Public Site

The EUDAMED public site is key to fulfil the transparency obligations under the regulations. EUDAMED is being designed in a user friendly and easily searchable format. Each module will have a publicly accessible interface, that is available in all Union languages. The ACT, UDID and CRF modules are currently publicly accessible, however, the scientific opinions of the CECP are not yet available via the CRF module. In the interim, you can find CECP opinions on the EC website[48]. Please note that the extent of publicly available information for the modules still under development (CI/PS, VIG & MSU), is under discussion. However, the *"Factsheet on MDR requirements for Transparency and Public Information"*[49] and EUDAMED functional specification[50], give a general indication of the type of information that will be available at MVP. A high-level summary of this information is provided in Table 3.

Members of the public who have an implant card, can use the public module of EUDAMED to search for device information related to their implanted device[51]. The implant card includes the UDI-DI of the device in human readable format and other searchable terms such as the device name[52].

Table 3: EUDAMED Publicly accessible information at MVP

EUDAMED Module	Publicly Accessible Information
Actor Registration (ACT)	• Actor details for CAs, DAs, EOs and sponsors (with an authorized application for CI/PS), excluding any confidential information.
UDI and Device Registration (UDID)	• View and download information related to registered devices, their Basic UDI-DI & UDI-DI data and SS(C)P.
NB and Certificates (CRF)	• Certificates issued by NBs, their scope and any amendments or supplements. The certificates status i.e., issued, re-issued, suspended, reinstated, withdrawn or cancelled and any restrictions imposed on certificates. • View a list of NBs under the Regulations and their subsidiaries. Provide a link to NANDO for details on scope of designation, conformity assessment activities and types of devices. • Summary of monitoring activities performed by the DA. • Scientific opinions of the expert panel on CECPs and the written justification provided by the NB if they choose not to follow the advice of the expert panel.
Clinical Investigation and Performance Studies (CI/PS)	• CI/PS reports on the outcome of CI/PS or PMCF/PMPF and their summary.
Vigilance and Post-market Surveillance (VGL)	• View the public part of the final reportable serious incident reports. • View final FSNs.
Market surveillance (MSU)	• List and view summaries of the results of the reviews and assessments of the market surveillance activities of a Member State

EUDAMED database – public site: (https://ec.europa.eu/tools/eudamed/#/screen/home)

48 See https://health.ec.europa.eu/medical-devices-expert-panels_en [accessed 24 March 2023].
49 See https://health.ec.europa.eu/latest-updates/factsheet-mdr-requirements-transparency-and-public-information-2020-07-15-0_en [accessed 24 March 2023].
50 See Functional specifications for the European Database on Medical Devices (EUDAMED) — to be audited (only for Minimum Viable Product (MVP) Legal Priority), https://health.ec.europa.eu/system/files/2022-12/md_eudamed_fs_v7_2_en.pdf [accessed 24 March 2023].
51 Exceptions listed in Article 18(3) MDR.
52 See MDCG 2019-8 v2 Guidance document implant card on the application of Article 18 Regulation (EU) 2017/745 on medical devices.

Communicating with EUDAMED

There are three ways to communicate with EUDAMED. EOs need to decide which method of communication makes most sense for their organization. This will depend on both the volume and frequency of data transmission to EUDAMED, as well as the costs associated with each method.

The EC's *"Guidelines on Data Exchange"*[53] is essential reading to help EOs assess which communication method with EUDAMED best suits the data exchange needs of their organization.

✓ The EC will be auditing EUDAMED to minimum viable product (MVP) specifications. This means that EUDAMED will have reached a stage of development that implements at least the minimum requirements to allow all actors to comply with their legal obligations under the regulations. The EUDAMED functional specifications provide an overview of where M2M functionality could be available. All M2M functionalities might not be available at MVP.

Table 4: Communication methods with EUDAMED

Communication Method	Description
User Interface	Allows manual input of data directly in the user interface.
XML upload/download	A semi-automated option where data can be uploaded by means of XML files. The XML data must be validated against the provided EUDAMED data exchange (DTX) service and entity model XSDs. The generation of the files can be automated, but the action of uploading/downloading the files remains manual.
Machine to Machine (M2M)	Automatic DTX between an external backend system and EUDAMED backend services (including exchange in bulk). The end user enters information in the external system, and the data is automatically transmitted to EUDAMED, in XML format following the same conditions mentioned above, without any human intervention.

53 See Guidelines on Data Exchange, https://health.ec.europa.eu/system/files/2020-09/md_eudamed_guidelines_dtx_en_0.pdf [accessed 24 March 2023].

Suggested Next Steps and Considerations

- ✓ EUDAMED touches the entire lifecycle of devices and IVDs, as such, no one function within an organization owns all the data attributes required to be inputted into the individual modules of EUDAMED. Cross functional collaboration is imperative to ensure data accuracy and that a EUDAMED strategy is developed that works for the organization — dependant on the size, available resources, and internal IT capabilities. Suggested next steps include:
  - Identify compliance needs
  - Define and align on data definitions across the organization
  - Identify sources of truth for the data attributes
  - ap process flows and interdependencies throughout the organization
  - Assign roles and responsibilities
  - Collect and centralize data
  - Document processes and related procedures in the QMS via SOPs and WIs and keep them up to date
  - Evaluate training needs and ensure relevant training is completed.

A well thought out EUDAMED strategy is a powerful resource that can help to streamline EO tasks cross functionally throughout an organization and ensure compliance with the Regulations.

- ✓ Consider all relevant sources of information i.e., the Regulations, implementing acts, EUDAMED documents (data dictionaries, functional specifications, business rules and user guidelines…) and supporting MDCG documents etc.
- ✓ Do not overlook the EUDAMED implementing Act[54] which provides rules for the application of EUDAMED, including but not limited to:
  - Rules pertaining to the provision of information directly to CAs if EUDAMED malfunctions.
  - Provisions requiring at least one successful submission of data via the EUDAMED website for testing and training, before using EUDAMED M2M data exchange capabilities for the first time.
- ✓ The EUDAMED website for testing and training will be made available for all modules and users once EUDAMED has been declared fully functional in the OJEU. It is recommended that members of your organization with EUDAMED responsibilities familiarize themselves with EUDAMED in the training environment.
- ✓ Transitional provisions: The EC has published MDCG guidances[55,56] that propose practices and solutions for the exchange of information until EUDAMED is fully functional. It is also recommended to communicate with any applicable NBs and/or the CA where the relevant EO is located to understand any expectations they may also have i.e., the German[57] authorities have made use of the ACT module mandatory for EOs located in Germany, and the Finnish[58] authorities have made use of the ACT and UDID modules mandatory for EO's located in Finland.
- ✓ The EUDAMED functional specifications are a good resource and link each functionality to the legal requirements in the Regulations citing where the specific references can be found in the texts. This is as well as indicating which functionalities will be available for MVP and those that will be coming at a later date, including priority.
- ✓ All current revisions of MDCG guidances are available on the EC website[59].
- ✓ The EC has set up a EUDAMED support team: SANTE-EUDAMED-SUPPORT@ec.europa.eu.
- ✓ The EC has a EUDAMED information centre[60] that includes information on getting started in EUDAMED, documentation, frequently

54 See Commission Implementing Regulation (EU) 2021/2078 of 26 November 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the European Database on Medical Devices (Eudamed).

55 See MDCG 2021-1 Rev.1 Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional.

56 See MDCG 2022-12 Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional (for Regulation (EU) 2017/746 on in vitro diagnostic medical devices).

57 See Bekanntmachung des Bundesministeriums für Gesundheit nach § 97 Absatz 1 Satz 2 und Absatz 2 des Medizinprodukterecht-Durchführungsgesetzes (MPDG) zur Regelung des Übergangszeitraums bis zur vollen Funktionsfähigkeit der Europäischen Datenbank für Medizinprodukte nach Artikel 33 der Verordnung (EU) 2017/745 vom 26. Mai 2021.

58 See https://www.fimea.fi/web/en/medical-devices/eudamed-database/operators-obligation-to-submit-a-notification [accessed 24 March 2023].

59 See https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec3 [accessed 24 March 2023].

60 See https://webgate.ec.europa.eu/eudamed-help/index.html?lang=en [accessed 24 March 2023].

asked questions, infographics and much more. The information centre will be built out as additional EUDAMED functionalities and modules become available.

- ✓ New functionalities and features of EUDAMED are released by the EC on an ongoing basis as the system is developed and refined. Release notes for every new version compared to the previous release are made available in the “News” section” of the EUDAMED public site[61] and “Release note” section of the restricted site[62]. Release notes are more extensive on the restricted site. Information as to when EUDAMED will not be accessible due to maintenance is also available.

61 See https://ec.europa.eu/tools/eudamed/#/screen/home [accessed 24 March 2023].
62 See https://webgate.ec.europa.eu/eudamed/landing-page#/ [accessed 24 March 2023].

Conclusion

The Regulations have wrought the most significant changes in the EU regulatory environment in over 20 years, and EUDAMED touches every part of a device's lifecycle, from pre-market studies, to placing a compliant device on the Union market and post-market requirements. EUDAMED is pivotal to the implementation of the regulations, and its importance cannot be overstated. Having a good understanding of EUDAMED provides actors with a clearer picture of the overall scope and reach of the regulatory requirements, and tasks required of them to bring a compliant device to the Union market and the sustaining requirements to keep those devices there.

There are approximately 80 references to EUDAMED in the regulations, 165 pages of dedicated MDCG guidance directly associated with EUDAMED/data requirements, and > 500 pages of EC EUDAMED documentation available for the three modules currently in use, excluding data dictionaries, XML and DTX documentation.

This white paper has provided a high-level overview of EUDAMED requirements only. Do not underestimate the time required to develop a comprehensive EUDAMED strategy, which can be both resource intensive and costly. The scale of which is dependent on the size of the organization/complexity (number and type of actors) and the overall number of devices in scope. Actors are recommended to pay continued attention to publications by the MDCG and EUDAMED documentation on the EC website, to stay up to date with new and/or changing EUDAMED requirements, especially as information pertaining to the remaining modules becomes available.

While we have seen delays to the EUDAMED implementation timelines, the sheer size and scale of the project is ambitious and impressive. No other global regulatory system has such a comprehensive database in place. Once fully functional, EUDAMED will be a powerful data source, which will enable vastly improved communication between the various actors, transparency for the public and other stakeholders and in a future state, even exchange of data with other global regulators.

Author

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