EUDAMED

The role of Eudamed in MDR and IVDR compliance

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Key Points

1. EUDAMED is being developed with stakeholders from industry and competent authorities, which comprise a steering committee and several working groups.
2. The implementation of EUDAMED has been delayed, with the new go-live date expected in Q2 2024. Mandatory use of the database will begin in Q4 2024 for actors registration, clinical investigations, performance studies, vigilance and post-market surveillance. Mandatory use will begin in Q2 2026 for Unique Device Identifier (UDI)/Devices registration.
3. Most economic operators must obtain a single registration number (SRN), assigned by their competent authority to gain access to EUDAMED. Each role (manufacturer, authorized representative (AR), importer and system/procedure pack producer) needs its own SRN; distributors are excluded.
4. Clinical investigations and performance studies will be registered in EUDAMED with assignment of the Single Identification Number (SIN). Incident reports and field safety corrective actions (FSCAs) will automatically be assigned a reference number in EUDAMED.
5. Affected stakeholders should prepare sufficient staff capacity, budgets and standard operating procedures ahead of the go-live date. Prioritizing the creation of device data records is important because this process will take the greatest amount of time to manage for most manufacturers.

Disclaimer
This paper presents an overview of the current state of play and the functionality of EUDAMED once it is fully operational.

What is EUDAMED?

EUDAMED—the European Database on Medical Devices—is an online electronic system that has been put in place by the European Commission (EC) to facilitate the regulation of medical devices and in vitro diagnostics (IVDs) throughout the European Union (EU) single market. It is a collaborative, multiplatform system into which data is added either by or on behalf of manufacturers, their ARs, importers, Notified Bodies and the EC itself. EUDAMED is divided into six complementary modules:

1. **Actors registration**
2. **UDI/Devices registration**
3. **Notified Bodies and Certificates**
4. **Clinical Investigations and performance studies**
5. **Vigilance and post-market surveillance**
6. **Market surveillance**

These modules are designed to work together to encourage further transparency with medical devices and IVDs by allowing users, manufacturers, government officials and the public[1] to access data on the identity, safety and performance of devices.

The use of EUDAMED will become mandatory for any manufacturer that sells devices in the EU.

General Concepts

EUDAMED is primarily intended as a database where information can be stored and viewed by users and the public. As such, the system is not able to perform analyses or manipulate the data within. Users can add new records to the system, update information in existing records, search the database (within authorized limits) and change the status of certain forms or documents. Any mistakes made when adding data can only be corrected by creating a new version of the record. It should be noted that previous versions will still be available to view in the system.

EUDAMED uses a number of identification systems to categorize certain datasets, including:

- SRNs, which will be automatically assigned to manufacturers, ARs, importers and system/procedure pack producers, referred to as actors, by EUDAMED upon registration.
- UDIs, assigned by the manufacturer to their device prior to entry into the device registration module.
- European Medical Device Nomenclature (EMDN) codes, used to identify and group devices by their use. This system supersedes the use of Global Medical Device Nomenclature (GMDN) codes in the EU and is assigned by the manufacturer.
- SINs, automatically assigned by the system to each clinical investigation and performance study to allow traceability.
- Incident reports and FSCAs, are also automatically assigned a reference number by the system (along with a case number from the competent authorities).

These identifiers will aid in the unambiguous identification of key information within the system and will assist users in searching and analyzing data.

EUDAMED Before the Regulations

In April 2010, the EC released Commission Decision 2010/227/EU,[2] which formally established the requirements for a European system that contained data relating to manufacturers and ARs, their certificates issued under the directives, vigilance data, and information regarding clinical investigations. This was the European Databank on Medical Devices, also known as EUDAMED, and after a number of updates, EUDAMED2. The system was only accessible by competent authorities to enable them to perform their tasks relating to the Medical Device Directives (MDD). Its use became mandatory in October 2012.

The Regulations and EUDAMED

EUDAMED3 (hereafter EUDAMED) was introduced in Article 33 and Article 30 of the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR), respectively, and is subsequently referenced in 50 articles. The importance of EUDAMED is also reflected by a large team formed by the EC that has hosted steering committees and working groups to periodically engage stakeholders.

The MDR and IVDR state that EUDAMED's original go-live date would be March 25, 2020 at the latest (Article 34(1) of the MDR and Article 30(1) of the IVDR). In October 2019, the EC announced a delay until May 2022,[3] at which point EUDAMED was planned for release with both medical devices and IVDs. At the end of 2021, Commission Implementing Regulation (EU) 2021/2078 on EUDAMED was published, outlining requirements and specifications for the new system.[4] However, the implementation was further delayed, in part, due to the coronavirus pandemic. The EC now expects EUDAMED to achieve full functionality by Q2 2024,[5] with the remaining modules released as available.

Where are we today?

The drafters of the MDR and IVDR expected a notice to be published by the EC in the Official Journal of European Union (OJEU) declaring that EUDAMED had been audited independently and was ready to go live by March 25, 2020. However, at the Medical Device Coordination Group (MDCG) meeting on March 12, 2020, it was agreed that EUDAMED was not ready. Thus, the EC would make individual modules available on a progressive schedule as they became functional rather than all at once. This would allow users time to become familiar with the system and begin adding information to the database ahead of the mandatory date.

Of the six modules in EUDAMED, three are currently live and available for voluntary use: Actors registration (December 2020), UDI/Devices registration (October 2021), and Notified Bodies and Certificates (October 2021). Users are able to register in the system, obtain the associated SRN, and begin providing details of associated economic operators and any devices they make available in the EU.

In June 2022, the EC published a revised timeline for the implementation, audit and go-live of EUDAMED. It is expected that the system will be fully functional by Q2 2024, at which point the notice should be published in the OJEU. After that date, two transitional periods allow users to input all required information before it becomes mandatory:

- **Q4 2024:** 6 months after the publication in the OJEU, the use of the Actors registration; Clinical investigations and performance studies; Vigilance and post-market surveillance; and Market surveillance modules becomes mandatory.
- **Q2 2026:** 24 months after the publication in the OJEU, the use of the UDI/Devices Registration as well as the Notified Bodies and Certificates modules becomes mandatory.

By the aforementioned dates, all existing information and data relating to the associated modules must have been entered. Going forward, the use of EUDAMED will be mandatory.

Accessing EUDAMED

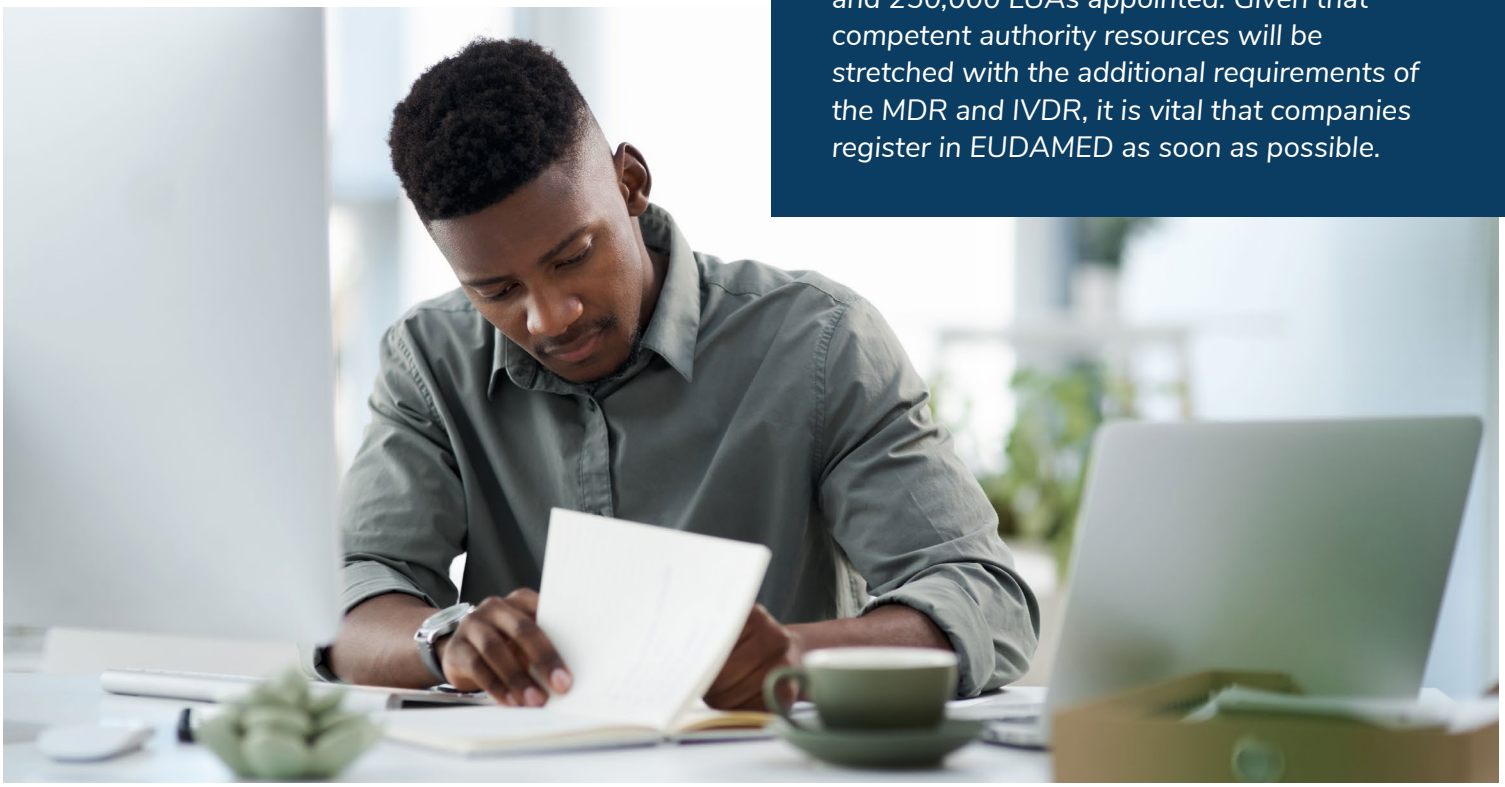
Actors will be able to access the "restricted" EUDAMED site. All other entities, such as users of medical devices and IVDs, patients, distributors and the public, will only be allowed access to the public site.

To enter the restricted site, companies must obtain an EU login and register in EUDAMED to obtain an SRN for their business. This requirement is also placed on manufacturers who are not based in the EU. Each actor will receive a unique SRN for each role they perform. For example, a company that imports devices and assembles them into a procedure pack (per Article 22) will receive two SRNs.

A number of roles within EUDAMED can be assigned to a user, depending on the level of access and control a company wants that user to have over their data. During the setup of an SRN, both a local actor administrator (LAA) and a local user administrator (LUA) need to be appointed. The LAA has the highest level of control over the actor's SRN and is able to make changes to all editable data, and can grant access to all other users within the system (including the LUA).[6] The LUA, on the other hand, has the ability to grant access to additional users but does not have control over the actor's data. It should be noted that the LAA and LUA roles must be linked to separate email addresses, and the EC suggests that companies should appoint at least two LAAs and two LUAs for redundancy. Finally, the lowest level of access in EUDAMED is the viewer. Every user account assigned to an SRN in EUDAMED is granted the viewer role and can search and view the actor's information. However, additional access rights can be granted to viewers throughout the modules, such as the "proposer" or "confirmer" traits, which allow the drafting and submission of device records, respectively, in the UDI module.

Access to EUDAMED is part of the process of demonstrating compliance with the requirements of the MDR and IVDR and is an obligation of economic operators therein. Therefore, the issuing of SRNs and appointing of LAAs/LUAs is a process that requires great care.

Emergo estimates there will be somewhere between 75,000 and 100,000 SRNs issued, and with an average of 2.5 LUAs per SRN, there could be between 187,500 and 250,000 LUAs appointed. Given that competent authority resources will be stretched with the additional requirements of the MDR and IVDR, it is vital that companies register in EUDAMED as soon as possible.



The modules

The information in EUDAMED is primarily intended for the identification and localization of relevant actors and devices, and to provide an understanding of risks from the perspective of the population involved. As previously discussed, EUDAMED is designed to be a database. While some may lament the limited data analysis capabilities, EUDAMED does facilitate communication regarding market surveillance cases in a clear and unambiguous way. This is reflected in how its modules are structured.

Actors registration

The actors registration (ACT) module was released in December 2020 and allows actors to register their details. This is the first module that needs to be populated. Actors within EUDAMED are manufacturers, ARs, importers, and system/procedure pack producers. The EC, national competent authorities (including designating authorities), and Notified Bodies will also be registered as actors in EUDAMED following a separate path and will accordingly have access to the restricted component of the system.

Every actor is expected to enter their administrative details as part of the registration process, including but not limited to their name, business address, contact details, etc., along with specific individuals named in the MDR, such as the person responsible for regulatory compliance (PRRC).

Non-European manufacturers are also obliged to enter their details into EUDAMED. However, before they may do so, their duly appointed AR in the EU must first be registered and have obtained an SRN. The non-EU manufacturer must then designate their AR within the system and provide their mandate with the AR as part of the registration process, after which the AR verifies that the supplied details are correct. Only once the link between the two parties has been verified will the competent authority of the AR issue the SRN to the non-EU manufacturer.

Importers must also register and obtain an SRN. However, this does not require any additional validations from other economic operators within the supply chain. Once obtained, the importer will then link themselves to each relevant manufacturer whose devices they import into the EU market. The associated manufacturer will receive a notification that this process has been completed but will not be required to verify it in advance. This requirement works to maintain transparency throughout the supply chain by showing the flow of devices into the EU from third countries.

Distributors are not required to obtain an SRN as they are not obliged to register in EUDAMED (Article 31). They will therefore not have access to the restricted component of the system and must perform any required verifications through the public site.

Once actors have registered in EUDAMED, they must confirm that the data they originally supplied is still correct after one year. Subsequent reviews must then be carried out every two years to ensure that the database is kept up-to-date and accurate.

Number of entries in the actor registration module as of October 2022:

Role	Number of registrations
Manufacturer	17,183
AR	1,698
Importer	4,730
System/Procedure pack producer	631

UDI/Devices registration

After securing the SRN, manufacturers should ensure that the data on all devices they currently make available on the EU market (those CE marked under either the MDD or the MDR) is appropriately entered into the UDI/Devices registration module.

The UDI/Devices registration (UDI) module is one of the core components in EUDAMED. Therefore, its importance cannot be understated. The UDI has two components. The first is the UDI-DI (device identifier). The UDI-DI is linked to a specific device in a specific presentation of that device (e.g., a package of four devices vs. a package of eight of the same devices or a product with a Spanish label and instructions for use vs. the same product with a Mandarin label and instructions for use). The UDI-PI (production identifier) is the second. The UDI-PI identifies the lot number, serial number, date of manufacture and/or expiry date of products that have been produced with the same production batch of raw materials, components, subassemblies, etc. The UDI-PI will be important to identify a specific batch of products affected by a production error. To manage the UDI-PI, the manufacturer must select and control their suppliers as all devices carrying the same UDI-PI must have identical batches of raw materials and components; otherwise, the UDI-PI would not refer to a homogenous batch. The manufacturer must acquire a UDI from a UDI-issuing agency[7] and assign it accordingly.

The registration of devices in EUDAMED follows two different pathways—the registration of a legacy device (for MDD/In Vitro Diagnostic Directive/Active Implantable Medical Devices Directive devices) or the registration of a new Basic UDI-DI device (for MDR/IVDR devices). Under the legacy device route, each device variant must be added as an individual record to EUDAMED using either an existing UDI-DI or a EUDAMED DI that is automatically generated by the system based on the information provided by the manufacturer. Under the Basic UDI-DI route, each Basic UDI-DI (i.e., each device group) is first added to the system. EUDAMED then allows users to add specific models, variants and versions to this group in the form of multiple associated UDI-DIs. Finally, container packages can be added to each UDI-DI. They correspond to individual packaging variants.[8] The information required by each pathway is similar, with additional data required for devices registered under the MDR/IVDR.

For further clarity, devices are associated with a nomenclature code. The system chosen by the EC is the EMDN, which is based on the Classificazione Nazionale Dispositivi medici (CND) system used in Italy. The EMDN is an alphanumeric code that clarifies the specific nature of a device and provides additional detail when searching in EUDAMED. The codes are published by the EC[9] and are available for free, but the manufacturer needs to select the one that most closely relates to each device. Notified Bodies and competent authorities will use EMDN codes to enable technical documentation sampling, therefore it is important for the manufacturer to ensure that their codes are correct as “the most granular and terminal term available (lowest level in the tree)” and assigned prior to entry into EUDAMED.

Notified Bodies and Certificates

In the Notified Bodies and Certificates (CRF) module, Notified Bodies are required to register both details of their business (including their nominated experts) and of CE marking certificates that they have issued, refused or updated. The CRF module went online in October 2021. It should be noted that only Notified Bodies and the EC will have access to this module—manufacturers, importers, ARs and system/procedure pack producers will not have access.

The module's function is to allow for the registration of certificates that have been issued, amended, refused, restricted or suspended by the Notified Body. The certificate types in the system align with the possible routes to conformity assessment:

- EU Quality Management System (MDR and IVDR, Annex IX Chapter I)
- EU Technical Documentation certificate (MDR and IVDR, Annex IX Chapter II)
- EU type examination certificate (MDR and IVDR, Annex X)
- EU quality assurance certificate (MDR, Annex XI Part A)
- EU product verification certificate (MDR, Annex XI Part B)
- EU production quality assurance certificate (IVDR, Annex XI)

Should a manufacturer withdraw their application for any of the aforementioned certificates prior to a decision, EUDAMED will notify all other Notified Bodies registered in the system by creating a link to the manufacturer's data. All decisions made by Notified Bodies in relation to certification are made publicly available for transparency.

Finally, this module handles the Summary of Safety and Clinical Performance (SSCP) for medical devices and the Summary of Safety and Performance (SSP) for IVDs, a part of the technical documentation required to be submitted to the Notified Body on a regular basis by a manufacturer of Class III and/or implantable medical devices or Class C and D IVDs. The manufacturer is expected to submit the SSCP/SSP to their Notified Body directly which will then review the document. The Notified Body will upload a copy of the document to EUDAMED and link it to the manufacturer's device (which will have already been registered in the UDI/device registration module) along with their decision of satisfactory validation.

Clinical investigations and performance studies

The Clinical investigations and performance studies (CIPS) module enables the EU coordination of clinical investigations and performance studies required by the MDR and IVDR, respectively, to demonstrate conformance to the General Safety and Performance Requirements. Each study entered into the CIPS module will be assigned a unique SIN, which will be generated by the system in the data entry process. Currently, this module is under development.

The main actor within this module is the sponsor, who is responsible for the application for and/or notification of clinical investigations and performance studies in the EU prior to their commencement, along with managing the data associated with the studies. Updates to the studies in the form of substantial modifications will also be documented in the CIPS module, with competent authorities able to approve or reject these in the system. Sponsors will also record and report adverse events that occur in the studies and notify the competent authorities of early terminations, along with the appropriate reason in EUDAMED.

The data entered into the CIPS module will be mostly short-form, entered either by short free-text fields, drop-down lists or checkboxes. It is not expected that the manufacturer will be required to duplicate the data in documents required by Annex XV of the MDR and Annex XIII/XIV of the IVDR.

In the absence of the CIPS module, the MDCG has issued guidance and templates to facilitate the application and notification of clinical investigations to competent authorities.[10] These documents will be withdrawn and superseded by EUDAMED in the future.

Vigilance and post-market surveillance

The importance of public health and safety is highlighted in the Vigilance and Post-Market Surveillance (VGL) Module, where multiple actors are required to cooperate in the transmission, receipt and assessment of material related to vigilance and post-market surveillance (PMS). This is the most complex module to manage, as the consequences of an error or misunderstanding can lead to potential harm to the public.

Rather than report severe incidents to respective competent authorities through Manufacturer Incident Report (MIR) forms, manufacturers will be required to use the VGL module. Initial, follow-up and final reports will be submitted to all competent authorities in affected member states, who will then be able to assess and provide feedback on corrective actions proposed by the manufacturer. Where similar serious incidents occur with the same device or device type, the manufacturer can elect to provide periodic summary reports (PSRs) as opposed to individual severe incident reports if the relevant competent authorities agree this is acceptable. The VGL module will be used to transmit the PSRs to the competent authorities and Notified Bodies.

EUDAMED will also distribute FSCA reports to affected member states and enable the distribution of Field Safety Notices (FSNs), which will be accessible to the public. Where an incident occurs in a third country but also affects devices made available in the EU, EUDAMED will also support the submission of related FSCAs and FSNs. These records will link to the UDI module and will extract data from that module to populate fields within the reports.

Currently, manufacturers are still expected to follow existing standard practice when reporting serious incidents to competent authorities by using the MIR orm and manually submitting to each member state via electronic means.[11]

PMS is an important component in the lifecycle of a device that allows for the monitoring of its safety and performance after it has been made available for use in the EU. EUDAMED provides a number of tools within the VGL module to allow Notified Bodies and competent authorities to receive and analyze necessary information from economic operators. Manufacturers of Class III or implantable medical devices and Class D IVDs are required to submit periodic safety update reports (PSURs) to their Notified Body through EUDAMED on a regular basis through the VGL module. The PSUR will summarize the conclusions of benefit-risk determination, the main findings of post-market clinical follow-up (PMCF), information on sales volumes, the size and other characteristics of the population using the device, and (where practicable) the usage frequency of the device. Once submitted, the Notified Body will evaluate the PSUR and add their determination, making it available to the competent authorities once it has been completed.

In addition, all manufacturers are required to submit trend reports through the VGL module in the event of any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side effects that could have a significant impact on the benefit-risk analysis. The determination criteria for reporting and the frequency of reports are to be defined by the manufacturer and documented in their PMS plan. It should be noted that competent authorities will be responsible for the assessment of trend reports and providing actions to maintain public health and safety—Notified Body access is for informational use only.

Regulators of third countries (outside the EU) or international organizations will also be able to view data in the VGL module to enable collaboration on matters related to patient safety.

Market surveillance

The final module in EUDAMED is Market Surveillance (MSU), which is intended to facilitate coordination between competent authorities in the EU. Currently, it is not yet functional.

As part of their obligations set out in the MDR (Article 93) and the IVDR (Article 88), all European competent authorities are expected to perform checks to ensure the conformity of devices made available in the EU. This will be based on a review of documentation and physical or laboratory-based checks using samples obtained from economic operators. The MSU module will enable the competent authorities to collaborate on market surveillance through access to inspection reports, conformity assessment reviews, notifications of devices that pose unacceptable risks and additional information related to noncompliance.

This information will be kept almost entirely between competent authorities and the EC. Notified Bodies will also be provided with device information related to their certificates. The public will be able to review annual summaries of surveillance activities carried out by the competent authorities.

Data exchange

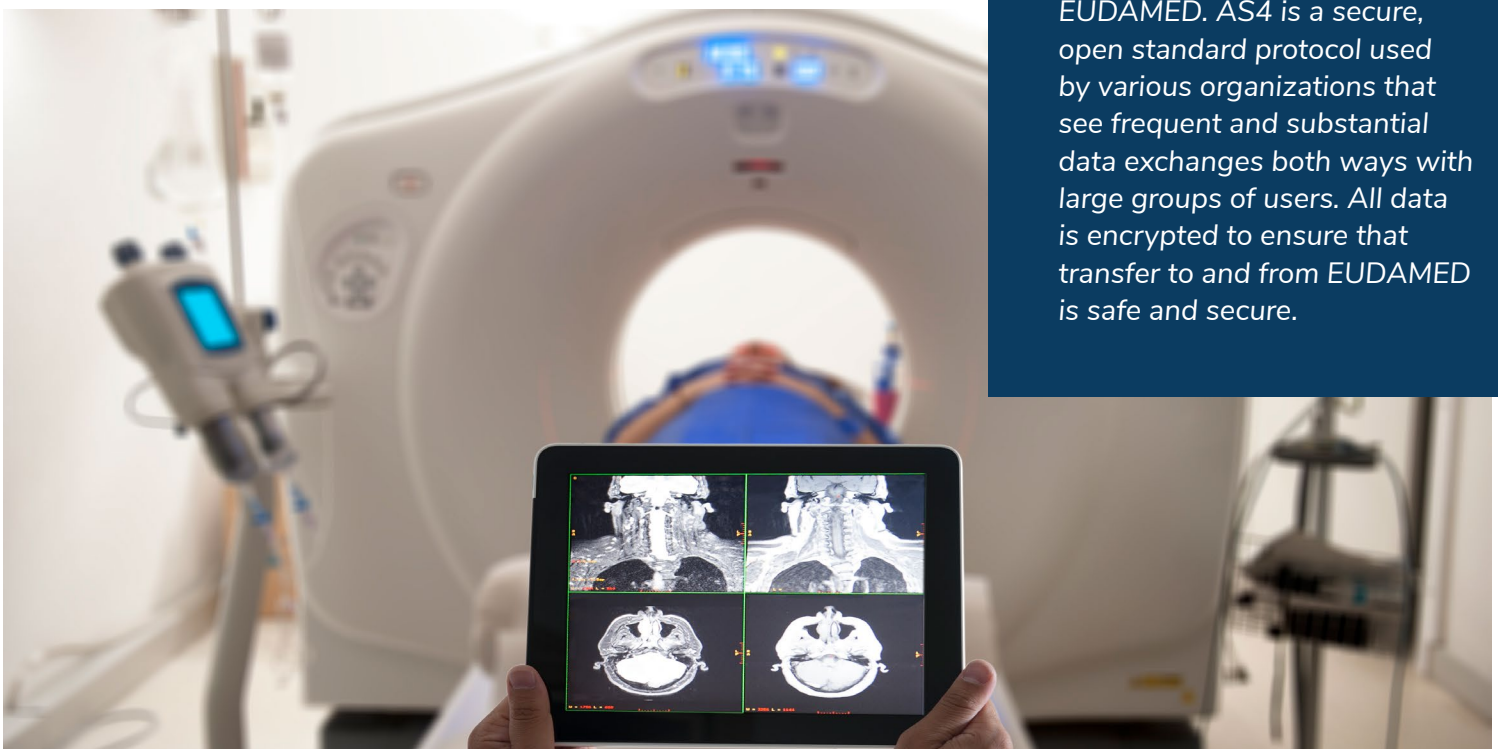
Manual uploads and downloads

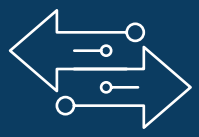
EUDAMED's main method of data exchange is through manual entry. Users can log into the system by using their user identity provided by their LUAs, adding records and data through checkboxes, drop-down lists, and free text fields, and attaching documents to certain datasets.

Users can also search EUDAMED and download information. Depending on the role of a particular user, such files can be quite extensive, although it is not expected that information downloads will be performed manually. The general public cannot download large amounts of data from EUDAMED.

Machine-to-machine uploads and downloads

The EC, competent authorities and Notified Bodies will have to perform mass uploads and downloads. A large portion of manufacturers may also need to use machine-to-machine (M2M) communication if they are handling thousands of records.[12] The MDR and IVDR require frequent updates of data, and the consistency of record-keeping is inherently more difficult to maintain through manual submissions. Frequent users will therefore need their own internal databases that are capable of interfacing with EUDAMED. Manufacturers should either develop these systems in-house or source them from third-party database developers, as the EC will not provide such technologies.





Some technical details:
The EUDAMED API (application program interface) will use the AS4 (Applicability Statement 4) protocol. This is based on SOAP (Simple Object Access Protocol—a proven standard-based Web services access protocol), allowing for the transfer of various types of information, such as XML files. AS4 allows for data push as well as pull, meaning a manufacturer's database can be fully synchronized with EUDAMED. AS4 is a secure, open standard protocol used by various organizations that see frequent and substantial data exchanges both ways with large groups of users. All data is encrypted to ensure that transfer to and from EUDAMED is safe and secure.

Other considerations

EUDAMED will be available in all 24 EU languages. In practice, this means that a user (actor, representative or member of the public) can choose their desired language in the opening screen. The user interface and any help screens will then appear in said language, along with checkboxes and drop-down lists. The use of free text will be limited as much as possible but cannot be ruled out completely; therefore, the EC is now looking at automatic translation tools, including the possible use of artificial intelligence.

There is a test environment where users can test their procedures and train staff through "play."[13] The test environment includes an interface identical to the live system, although any data entered will not be stored for an extended period, and the user can easily correct errors and delete any records after testing. A comprehensive help function is provided in both the test environment and the live system.

Regulators in third countries may also be interested in accessing EUDAMED, especially in markets that rely heavily on CE-marked devices. The data in EUDAMED would allow these regulators to leverage experience gained from the EU market for their own market surveillance activities. The EC has indicated that other markets may indeed join EUDAMED; however, based on the principle of reciprocity, information exchange needs to be mutual. Additionally, these authorities should take part in the International Medical Device Regulators Forum (IMDRF) National Competent Authority Report (NCAR) system. IMDRF members will gain priority access to EUDAMED.

How to prepare

Although EUDAMED is not yet fully functional, the ACT, UDI and CRF modules are already live and available for voluntary use. In preparation for the mandatory use dates, all actors should register their details in EUDAMED and assign their LAAs and LUAs to allow time to prepare the remaining information for upload.

Manufacturers should begin preparing budgets and allocating sufficient staffing levels to ensure that they will be ready. Several key factors must be taken into account:

- A project team needs to be established to make sure the organization will be fully prepared once EUDAMED goes live.
- EUDAMED will most likely require an overhaul of a firm's medical device/IVD database if one is already established.
- Data for all devices needs to be entered into device databases in a way that allows for the extraction of EUDAMED-specific data.
- Procedures need to be written and should ensure that data uploads and downloads will be performed correctly and consistently.

End Notes

1. Public access to EUDAMED is limited in order to protect confidential data and information supplied by manufacturers and Notified Bodies. Further information on the sections that are/will be made available to the public can be found in the "Draft functional specifications for EUDAMED" document released by the EC, available at: **https://health.ec.europa.eu/system/files/2020-09/md_eudamed_fs_v4_1_en_0.pdf**

2. **https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32010D0227**

3. "The Commission concluded that it would only be possible to make EUDAMED operational once the entire system and its different modules have achieved full functionality and have been subject to an independent audit. Therefore, EUDAMED's launch will be done together for medical and in-vitro medical devices, at the original date foreseen for in-vitro medical devices i.e. May 2022".

4. **https://eur-lex.europa.eu/eli/reg_impl/2021/2078/oj**

5. **https://health.ec.europa.eu/system/files/2022-07/md_eudamed_timeline_en.pdf**

6. Note: The user who performs the actor registration for the SRN will automatically become the LAA. It is therefore crucial that the account that has access as the LAA will not be closed in the future.

7. Four UDI issuing agencies have been recognized by the EC (**https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.149.01.0073.01.ENG&toc=OJ:L:2019:149:TOC**): GS1, Health Industry Business Communication Council (HIBCC), ICCBBA, and Informationsstelle für Arzneispezialitäten (IFA).

8. **https://health.ec.europa.eu/system/files/2021-11/md_eudamed-udi-concept_en_0.pdf**

9. **https://webgate.ec.europa.eu/dyna2/emdn/Z1206**

10. MDCG 2021-8 was issued in May 2021. It is available at: **https://health.ec.europa.eu/system/files/2021-05/mdcg_2021-8_en_0.pdf**

11. The MDCG provided general guidance on harmonized administrative practices and alternative technical solutions until EUDAMED is fully functional in May 2021 (MDCG 2021-1, available at: **https://health.ec.europa.eu/system/files/2022-07/md_mdcg_2022-12_guidance-admpractice_techsol_eudamed_en_0.pdf**), which was subsequently followed by IVD-specific guidance in July 2022 (**https://health.ec.europa.eu/system/files/2022-07/md_mdcg_2022-12_guidance-admpractice_techsol_eudamed_en_0.pdf**).

12. The EC has provided guidance on the use of manual or M2M methods for manufacturers. This is available at: **https://health.ec.europa.eu/system/files/2020-09/md_eudamed_guidelines_dtx_en_0.pdf**

13. The test environment is EUDAMED Play. It is available at: **https://webgate.training.ec.europa.eu/eudamed-play/landing-page#/**

About the authors

Evangeline Loh, Ph.D., RAC (US, EU) holds one of the most senior positions in the Emergo by UL consulting group and has over 15 years of global regulatory experience. Her background includes compiling European Technical Files and Design Dossiers; European Technical File reviews and gap assessments; borderline classifications; and 100+ peer reviews of Technical Files, including Clinical Evaluation Report reviews and responding to Notified Body findings. She specializes in borderline classification assessments, global vigilance, and global regulatory strategy. As the Global Regulatory Manager, Evangeline manages Emergo by UL's in-country representation services, including EU Authorized Representative, US Agent, and Australian Sponsor, and oversees global vigilance activities for these clients. She also supervises a team of international consultants and reviews dozens of device submissions and clinical evaluation reports each year. Prior to Emergo by UL, she held positions at Cook Incorporated and The Association of American Medical Colleges. Evangeline holds a PhD in pharmacology from The University of Texas Health Science Center at San Antonio and studied microbiology at Cornell University. She joined Emergo by UL in 2007.

Tom Ingless has over 7 years of experience in regulatory affairs throughout the healthcare industry, with a focus on successful MDR and IVDR transitions. Tom's background includes authoring high quality technical files and CERs; devising and implementing risk management processes; registrations and lifecycle management in the EU and Middle East; preparing devices for UKCA-marking. As a Senior Consultant, Tom focusses on compliance with European regulations and is part of Emergo's clinical evaluation and authorised representative programmes. Prior to joining Emergo, Tom held positions at Tristel Solutions, Oxford Gene Technology (part of the Sysmex Group) and Mundipharma Research.

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