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European Union Medical Device Regulation and In Vitro Device Regulation: unique device identification

What is required, and how to manage it

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Glossary

Term	Lay explanation
AIDC	Automatic Identification and Data Capture
AIMDD	Active Implantable Medical Device Directive
CFS	Certificate of Free Sale
CMR	Carcinogenic, Mutagenic or toxic to Reproduction
DEHP	Di-2-ethylhexyl phthalate
DM	Direct Mark
DoC	Declaration of Conformity
DTX	Data exchange
DUNS	Data Universal Numbering System
EC	European Commission
EU	European Union
FDA	US Food and Drug Administration
GUDID	Global Unique Device Identification Database
HIBCC	Health Industry Business Communications Council
HRI	Human Readable Interpretation
ICCBBA	International Council for Commonality in Blood Banking Automation
IE	Issuing Entity
IFA	Informationsstelle für Arzneispezialitäten
IVD	In Vitro Device
IVDD	In Vitro Device Directive
IVDR	In Vitro Device Regulation
LS/LS	Life Sustaining/Life Supporting
MDCG	Medical Device Coordination Group
MDD	Medical Device Directive
MDR	Medical Device Regulation
MRI	Magnetic Resonance Imaging
PSUR	Periodic Safety Update Report
S/PPP	System/Procedure Pack Producer
SRN	Single Registration Number
SS(C)P	Summary of Safety and (Clinical) Performance
UDI	Unique Device Identifier
UDI-DI	Unique Device Identifier – Device Identifier
UDI-PI	Unique Device Identifier – Production Identifier
XML	Extensible Markup Language
XSD	XML Schema Definition

Overview of the EU UDI system

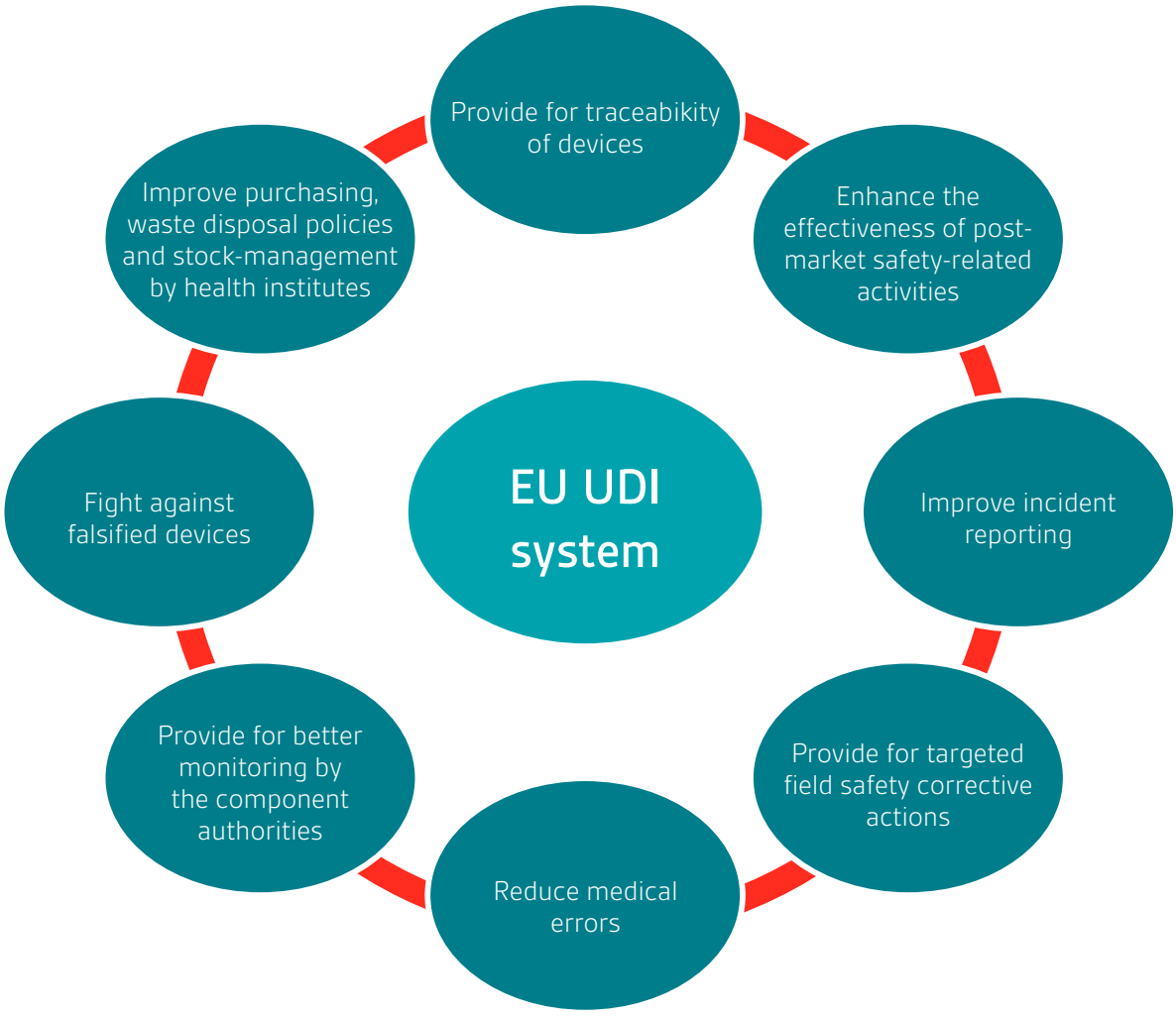
On 5 May 2017, the new EU MDR 2017/745 and IVDR 2017/746 regulations (referred to in this white paper as 'the Regulations') were published and formally introduced the UDI system in the EU. One of the components of a UDI system is the UDI itself, which allows for the unambiguous identification of a specific device on the market and is composed of the UDI-DI and UDI-PI. Together, these identify a unique medical device throughout its distribution and use. Medical devices compliant to the Regulations carry a UDI and the data from the devices is submitted to the UDI and Device Registration module of the European database on medical devices (EUDAMED).

The objective of the UDI system is to uniformly identify medical devices within the EU healthcare supply chain. Once the system is implemented, the intended benefits (see Figure 1) are that it can:

- create a common vocabulary to facilitate easier traceability of medical devices, significantly enhance the effectiveness of post-market safety-related activities for devices and allow for better monitoring by competent authorities
- help to reduce medical errors and support the initiative to combat falsified devices
- improve purchasing, waste disposal policies and stock-management by health institutes and other economic operators.[1]

This white paper provides an overview of the EU UDI system, its requirements and the status of EUDAMED, along with some practical recommendations for manufacturers to support their UDI system compliance efforts.

Figure 1: Benefits of the EU UDI system

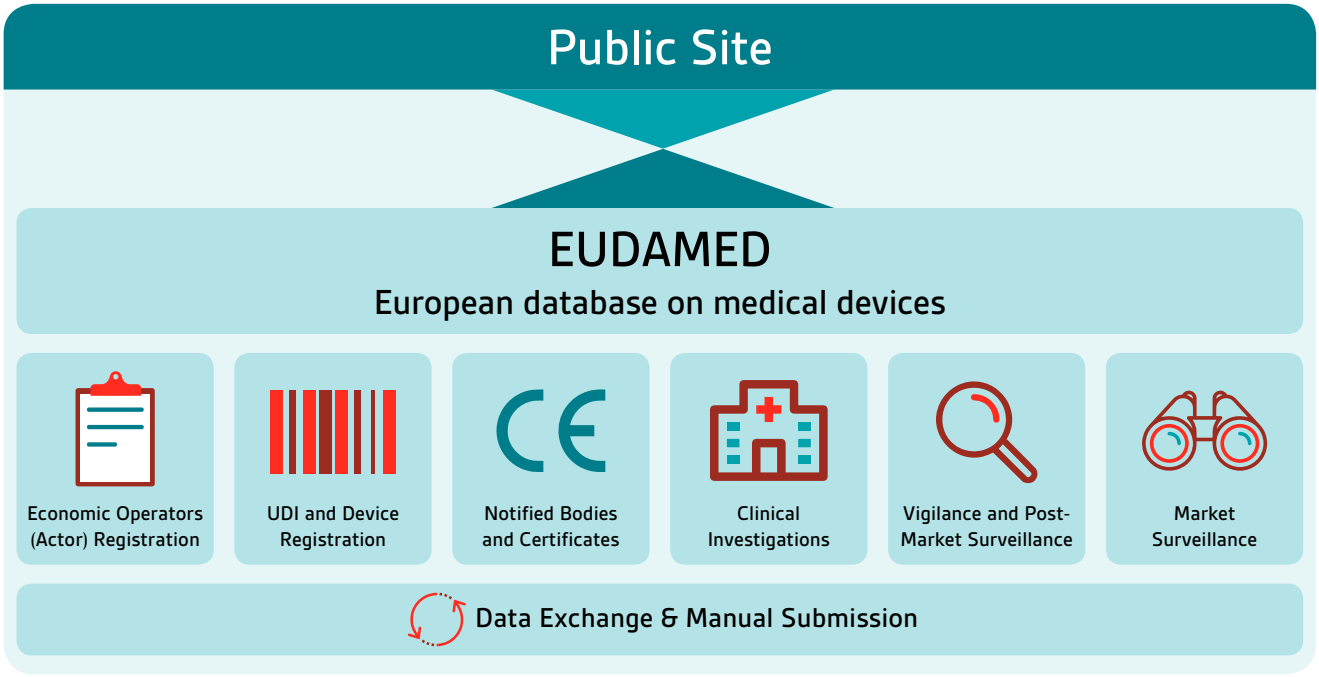


The UDI and Device Registration module (originally two separate modules within EUDAMED) is one of six. The other modules (see Figure 2) are:

- Economic Operators (Actor) Registration
- Notified Bodies and Certificates
- Clinical Investigations
- Vigilance and Post-Market Surveillance
- Market Surveillance

EUDAMED functionality is intended to provide for the exchange of information regarding vigilance reporting, clinical investigations, certificate notifications and registration of devices and economic operators, as well as exchange of information between competent authorities. All the information collated and processed by EUDAMED shall be accessible to EU Member States and to the EC. The information shall be accessible to notified bodies, economic operators, sponsors and the public to the extent specified in the provisions on the electronic systems.[2]

Figure 2: EUDAMED framework



As many manufacturers were introduced to the UDI system with the issuance of the FDA's UDI Final Rule on 24 September 2013,[3] this white paper addresses aspects of a UDI system that is similar to the system in use in the US (which is the most advanced UDI database created, to date), while highlighting those aspects that are specific to the EU. It aims to provide an overview of several EU UDI system requirements and how to manage and assess data as UDI information is incorporated within multiple regulatory processes. General recommendations for manufacturers are highlighted ✔ throughout this white paper, along with some closing insights on the UDI system to aid in compliance activities.

It should be noted that there are several differences between the EU MDR UDI system and the US FDA UDI system (see Table 1). Several attributes listed in Table 1 also identify differences that trigger the need to assign a new device identifier. The differences listed are not exhaustive, and a thorough verification of the Regulations and supporting EUDAMED documentation is strongly recommended.

Table 1: Differences between the EU and US UDI systems

	EU	US
IEs	GS1 HIBCC ICCBBA **IFA**	GS1 HIBCC ICCBBA
Basic UDI-DI	**Required**	N/A
Identification of manufacturer	EUDAMED-issued **SRN**	**DUNS** number
UDI-PI	Serial number Lot/batch **Software identification*** Expiry date Manufacturing date**	Serial number Lot/batch Expiry date Manufacturing date
Change in UDI-PI identification	**Trigger**	**Non-trigger**
Nomenclature	**European Medical Device Nomenclature (EMDN)**	**Global Medical Device Nomenclature (GMDN)**
Request of exceptions or alternative methods	**Not provided** within the Regulations	**Provided** within the regulations
Trade name or brand name change	Trigger and non-trigger	**Trigger**
Software	**Same UDI-DI** required for software and package	**Different UDI-DI** allowed for physical mediums (packaging) containing software
Direct Marking	See Table 3	See Table 3
Critical warnings	Latex **DEHP and CMR or endocrine disruptors**	Latex MRI

NOTE Major differences between the two systems are shown in bold.
* Not all IEs have a specific software identifier. GS1 Application Identifiers (AIs) for software became available after the US regulation was published.
** If the manufacturing date is the only production identifier on the label, it must be used as the UDI-PI. If the label has any other UDI-PI(s), the manufacturing date does not need to be included or stated as a UDI-PI.[4]

NOTE: The EU UDI and Device Registration module has several attributes identified as updateable (conditionally) within its data dictionaries. Manufacturers should assess the conditions in which attributes are allowed to be updated versus the requirement to issue new UDI-DIs, and incorporate these into their systems.

✔ *Manufacturers should identify not only the differences but also some of the nuances between the EU and US UDI systems, to establish processes and procedures that can support global compliance and apply appropriate measures. Other UDI systems and databases are being developed in various regions of the world, so manufacturers should consider these at the beginning of their analysis so that processes, standards and systems can grow and adapt to any new regulations without too much disruption.*

The EU UDI system

The EU UDI system requirements follow many of the international principles for a UDI system:

- development of a standardized system of UDIs
- placement of the UDIs in HRI and AIDC formats or forms on package labels and, in some cases, on the device itself
- submission of core UDI data elements to a UDI database
- setting of appropriate transitional and implementation arrangements to ensure a smooth UDI system implementation[5]

Development of a standard system: accredited IEs

One of the key elements of a UDI system is the accreditation of IEs by the regulatory authority to operate a system for the assignment of UDIs in the field of medical devices.[6] Following a call for application launched at the end of 2018, the Commission Implementing Decision (EU) 2019/939 of 6 June 2019,[7] designated four IEs:

- GS1
- HIBCC
- ICCBBA
- IFA GmbH

The designations are valid for five years from 27 June 2019, at which time they can be renewed if the IE remains in compliance with the criteria for designation and the terms of designation.

Each IE has standards or guidelines for the application and assignment of UDIs to medical devices.

- ✔ *Manufacturers, if they have not done so already to meet US requirements, should evaluate which IE meets their business needs and establish the appropriate processes for assignment and maintenance of device identifiers.*[8]
- ✔ *Various economic operators should determine how they place products on the market and if these activities define them as manufacturers or as S/PPPs.*[9] *If defined as either, they should ensure that their choice of IE can meet their business needs, and establish the appropriate processes for assignment and maintenance of device identifiers.*

As part of their accreditation, these same IEs had to establish new standards or guidelines to support the EU's requirement regarding Basic UDI-DIs.

EU Basic UDI-DI

The Regulations require the assignment of a Basic UDI-DI to medical devices. The concept of a Basic UDI-DI is new and currently unique to the EU. The purpose and use of the Basic UDI-DI is different from the use of the device UDI-DI (see Table 2).

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

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

The Basic UDI-DI is an EU approach for linking devices to their regulatory documentation and it is intended to uniquely identify the product model throughout the entire life cycle of the product. The MDCG's definition of it is:

The Basic UDI-DI is the main key in the database and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and clinical performance) to connect devices with the same intended purpose, risk class and essential design and manufacturing characteristics. It is independent/separate from the packaging/labelling of the device and it does not appear on any trade item.[10]

NOTE: Several different definitions of Basic UDI-DIs are found within various EU documents, including the Regulations.

✔ *This white paper recommends that the MDCG's definition is used.*

The key functional aspects of the Basic UDI-DI are that it is:

- the primary identifier of a device model
  - it connects devices with the same intended purpose, risk class and essential design and manufacturing characteristics
- the main record key in the UDI database
  - it connects all associated UDI-DIs in the UDI database with the information in other EUDAMED modules
- the main key within (regulatory) documentation
  - in technical documentation
  - in SS(C)P
  - in EU DoCs
  - in notified body certificates as well as CFSs
  - in PSUR
  - in post-market clinical investigation or performance study application
  - in regulatory forms (e.g. Manufacturer's Incident Report)
- independent from labelling
  - separate from the packaging or labelling of the device and it does not appear on any trade item (it may appear on the instructions for use)[11]

Before placing a device (other than one that is custom-made), clinical investigational device (subject to the MDR)[12] or device for performance evaluation (subject to the IVDR)[13] on the market, the manufacturer has to assign – in accordance with the rules of the IE – a Basic UDI-DI to the device and input it into the UDI and Device Registration module of EUDAMED, together with the other core data elements related to that device.[14]

- ✔ *Manufacturers should establish processes for the assignment and maintenance of Basic UDI-DIs based on the above criteria. This is an imperative first step as device identifiers (once registered) cannot be moved between Basic UDI-DIs, and a change in the linkage would require enumeration of new UDI-DIs, which would have downstream impacts on, for example, labels, product certificates and customers.*
- ✔ *Many regulatory documents necessitate the identification of the Basic UDI-DI (e.g. the SS(C)P, PSUR, DoC, certificates and CFS), so manufacturers have to consider the association requirements of these documents during the assignment of Basic UDI-DIs.*
- ✔ *Manufacturers should also consider the use of searchable terms with device name or device model data attributes.*

The EUDAMED UDI data dictionary defines all the data elements associated with the Basic UDI-DI, and identifies those that can be updateable.[15] Other useful documents for the identification of data attributes requiring the assignment and registration of a new Basic UDI-DI for devices subject to the MDR[16] and IVDR[17] are available. However, it should be noted that updates to these documents are needed to reflect the data dictionary.

- ✔ *Manufacturers should understand the EUDAMED data attributes for the Basic UDI-DI, and recognize that if some of the data attributes were changed, that would trigger the need to issue a new Basic UDI-DI. With a change in the Basic UDI-DI, all associated UDI-DIs would also need to change.*

NOTE: One change that can cause this trigger of a new Basic UDI-DI is if a manufacturer's EUDAMED SRN changes – e.g. if a manufacturer were to relocate to another country (meaning change(s) to the name and address on the label), that would require a different competent authority to issue a new SRN, with verification and validation of that manufacturer's information required to be submitted into the Economic Operators (Actor) Registration module of EUDAMED.

UDI

A UDI is a unique identifier for the trade item that is created through a globally accepted device identification and coding standard, in the form of a series of numeric or alphanumeric characters. It allows for the unambiguous identification of a specific device on the market and is composed of the UDI-DI and UDI-PI that, together, identify a unique medical device throughout its distribution and use.

A UDI carrier is the format of this information. It is provided in AIDC and HRI formats, using the IE's standards and guidelines while maintaining compliance to the requirements of the Regulations.

The Regulations also establish the requirements of a UDI system and for the application of UDIs.[18] These include:

- definitions relative to a UDI system
- general requirements
    - rules on format
        - application to specific devices (e.g. home use, retail)
- general rules for the UDI
    - allowances with label space constraints
- application of the UDI carrier
    - placement of the UDI
        - on a device label or on the device itself and on all higher levels* of device packaging
        - can be accessed during normal operation or storage
- general principles of the UDI database

- rules for specific device types
    - retail point of sale
    - implantable
    - reusable devices requiring cleaning, disinfection, sterilization or refurbishing between uses
    - systems and procedure packs as referred to in Article 22 of the MDR
    - configurable devices
    - device software
    - reusable devices that are part of kits and require cleaning, disinfection, sterilization or refurbishing between uses (IVDR only)

*package level is defined by different quantities – not packaging layers, e.g. a sterile barrier.

While many UDI requirements are provided within the Regulations, MDCG guidance documents have also been developed and issued, to provide further clarifications for specific device types and/or to identify policy positions supporting specific requirements or exemptions.[19]

✔ *Manufacturers should establish processes for assignment and maintenance of UDI-DIs.*

✔ *Manufacturers should establish procedures that identify and apply UDI requirements for their devices, and ensure specific device type requirements are incorporated and consistent with IE standards.*

✔ *Manufacturers may wish to document their rationales for the use of any UDI allowance (e.g. space constraints) to support future questions related to compliance.*

UDI-DI triggers

As part of a UDI system, there are instances in which changes to a device or its label require the need to identify it with a new UDI-DI. According to the Regulations, a new UDI-DI is required in the case of any change to the following elements:

- name or trade name
- device version or model
- labelled as single use
- packaged sterile
- need for sterilization before use
- quantity of devices provided in a package
- critical warnings or contra-indications (e.g. containing latex or DEHP)
- CMR/endocrine disruptors*
- colour*
- language*

* MDCG guidance details the specific circumstances in which a change to CMR/endocrine disruptors would trigger a new UDI-DI to be required, as well as identifying changes to colour and language as triggers.[20]

It should be noted that the MDCG guidance states a new UDI-DI is required whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability. This is consistent with the IE standards and guidelines. However, it should be noted that there are other UDI triggers identified within various documents related to EUDAMED, e.g. the UDI data dictionary.

As with the Basic UDI-DI, the EUDAMED UDI data dictionary defines all the data elements associated with a UDI-DI and identifies those that can be updateable.[21] Other useful documents for the identification of data attributes requiring the assignment and registration of a new UDI-DI for devices subject to the MDR[22] and IVDR[23] are available.

✔ *Manufacturers should analyze these documents with the development of their processes and procedures to ensure that all triggers are identified, that the appropriate steps are taken for compliance when a new UDI-DI is required for a device (from issuance, applying to label/DM and submission to EUDAMED), and that the potential global impacts are assessed.*

Direct Marking

Both the EU and US regulations require direct marking of reusable devices; however, there are differences between the two UDI systems. The key differences are in the:

- devices that require direct marking
- format of the DM and for which device classes
- database entries

An overview of the UDI DM differences, including differences between EUDAMED and GUDID (the FDA's UDI database) are summarized in Table 3.

Table 3: DM differences between the EU and US UDI systems

	EU	US
Device scope	Devices that are reusable shall bear a UDI carrier on the device itself. The UDI carrier for reusable devices that require cleaning, disinfection, sterilization or refurbishing between patient uses shall be permanent and readable after each process performed, to make the device ready for subsequent use throughout its intended lifetime. The scope does not distinguish between different patient use and single patient use.	A device that is intended to be cleaned and either sterilized or disinfected before each use or between uses. It is intended only to be cleaned between uses on or by different patients, and not considered reprocessing for the purposes of the UDI direct marking requirements. Disinfection or sterilization is now defined as high-level disinfection* or high-level sterilization before each use or between uses.
UDI format	Both HRI and AIDC	HRI and/or AIDC Class I – UDI-DI only
Exceptions	• any type of direct marking that would interfere with the safety or performance of the device • a device that cannot be directly marked because it is not technologically feasible[24]	• direct marking that would interfere with the safety or effectiveness of the device • direct marking that is not technologically feasible • the device is a single-use device • the device has been previously marked • guidance on the DM • non-UDI direct marking required for patient safety could be a justification for an exception under paragraph(d)(1) of 21CFR801.45[25] • for situations in which a production identifier (e.g. the lot number that appears on the device label) was unknown at the time a device was directly marked during the manufacturing process, the FDA does not intend to enforce the requirement that the UDI directly marked on the device must include that production identifier

	EU	US
Applicable device classification or type	As per Article 123(3), point (g) of the MDR on reusable devices: reusable implantable Class III Class IIb Class IIa Class I	Class III LS/LS (non-implantable) Class II Class I
Database entries	Identification of all DM UDI-DIs	Identification of only DM UDI-DIs that are different from the primary UDI-DI
	Change of DM status (Yes to No): Trigger (EUDAMED)	Change to DM does not trigger a new UDI-DI
	EUDAMED does not identify when an exception is being applied	Identification that the device requires a DM, but manufacturer use is an exception

NOTE: Some of the US requirements were established after the FDA's UDI Final Rule was issued, as a result of collaboration between the FDA, manufacturers and trade associations.
* For UDI system purposes, high-level disinfection is a lethal process using a sterilant under less than sterilizing conditions. The process kills all forms of microbial life except for large numbers of bacterial spores.

NOTE: The IVDR states that for 'reusable devices that are part of kits and that require cleaning, disinfection, sterilization or refurbishing between uses:

- the UDI of such devices shall be placed on the device and shall be readable after each procedure to make the device ready for the next use
- the UDI-PI characteristics such as the lot or serial number shall be defined by the manufacturer.'[26]

Additional DM differences

The Regulations state that the UDI carrier is required to be in both AIDC and HRI formats not only for the device label and all higher packaging, but also for direct marking. If there are significant space constraints limiting the use of both formats, they state that only the AIDC format shall be required for devices used in healthcare facilities. For home care devices the application of the HRI format is required, even if the result is no space for the corresponding AIDC format.[27]

✔ *Manufacturers should assess the differences between UDI systems for direct marking conditions, and apply the more stringent requirements to support global devices. This approach could ensure compliance within other regions that are developing their own UDI systems.*

✔ *This white paper considers it essential for manufacturers to document their reason(s) for use of the DM exception(s), or the identification of the limitations that do not allow for a full UDI carrier to be present. The device design history record was identified within the US regulations as the means to identify the manufacturer's decision. Use of device technical documentation could be used to record these exception decisions.*

✔ *Manufacturers of IVDs should assess the devices that make up their kits, to determine if they fall under the definition of reusable requiring cleaning, disinfection, sterilization or refurbishing between uses. If devices within their kits meet those conditions, then direct marking requirements apply, and manufacturers should ensure processes and procedures are in place to comply with, and meet, required timelines.*

EU UDI due dates

For placing MDR- and IVDR-compliant devices on the market, the date of application – 26 May 2021 (MDR) and 26 May 2022 (IVDR) – is key, even though most devices can benefit from an additional transition period until 26 May 2024 (MDR) and 26 May 2025 (IVDR). While the date of application signifies the requirement to comply with the Regulations, there are several dates to know regarding the application of the UDI carrier on the label and direct marking for applicable device types (see Table 4 and Table 5).

Table 4: UDI label and UDI DM compliance dates (MDR)

Devices as per the MDR	Implantable devices and Class III devices	Class IIa and Class IIb devices	Class I devices
Placing UDI carriers on the labels of devices[29]	26 May 2021	26 May 2023	26 May 2025
Direct marking of the reusable devices[30]	26 May 2023	26 May 2025	26 May 2027
NOTE: Other label compliance dates for specific devices' sub-classes are not represented in this table.			

Table 5: UDI label and UDI DM compliance dates (IVDR)[31]

Device as per the IVDR	Class D IVDs	Class C and B IVDs	Class A IVDs
Placing UDI carriers on the labels of devices[32]	26 May 2023	26 May 2025	26 May 2027
NOTE: Other label compliance dates for specific devices' sub-classes are not represented in this table.			

✔ *Manufacturers should ensure that the established processes and procedures for label and direct marking of devices incorporate the EU requirements and timelines for compliance.*

EUDAMED and the UDI and Device Registration module

As EUDAMED is structured around six interconnected modules, manufacturers need to work towards the development and implementation of policies and procedures that ensure the connectivity and interdependencies of each module are identified and managed. However, this is complicated by the fact that in October 2019 the EC announced that the launch of EUDAMED would be postponed. This was then followed by a delay of the MDR date of application from 26 May 2020 to 26 May 2021 due to the COVID-19 pandemic (there was no change to the IVDR date of application).

The revised EUDAMED launch date coincides with the implementation date of the IVDR, and in October 2020 the EC confirmed that a 'Minimum Viable Product (MVP)' approach to EUDAMED is to be implemented and that EUDAMED is to be declared fully functional when the MVP is reached.

MVP overview

- solution that just meets the bare-minimum specifications
- simpler features without losing critical functionalities
- only basic functionalities allowing the actors to fulfil their MDR obligations

Since October 2020 the implementation and functionality of a subset of modules has been the EC's focus, and a staggered release is now planned with the full launch to be completed by May 2022. At the time of publication of this white paper, the Economic Operators (Actor) Registration module has been released (December 2020)

and it is expected that the UDI and Device Registration and Notified Bodies and Certificates modules will be released in September 2021, with their use identified as voluntary.

The use of EUDAMED and the UDI and Device Registration module is voluntary until the fourth quarter of 2022 (which is when the EC expects EUDAMED to be fully functional). The Regulations do require UDI system compliance upon date of application or before placing an MDR- or IVDR-compliant device on the market for the assignment of the Basic UDI-DI and UDI, but they take a risk-based approach to the label and DM compliance (see Table 4 and Table 5). For MDR Class III and implantable devices, the UDI label compliance date coincides with the date of application.

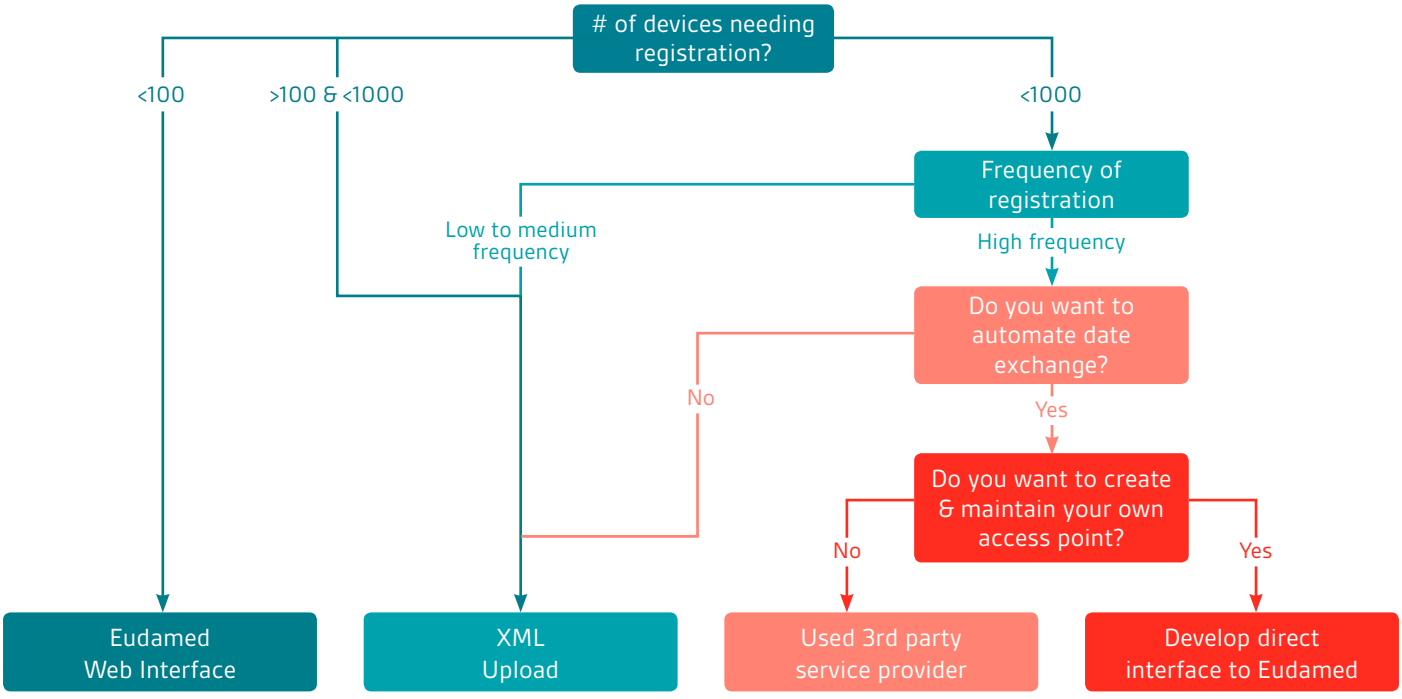
The EC has also provided several mechanisms to EUDAMED stakeholders for the inputting and downloading of data, and guidance to assess the most cost-efficient mechanism to meet the Regulations.

The different entry points include (see Figure 3):

- user interface: a manual input of data through the application
- XML upload: a semi-automated input, in which data can be uploaded by means of XML files. The XML data must be validated against the provided EUDAMED DTX service and entity model XSDs. Generation of the files can be automated, but the action of uploading (or downloading) them remains manual.
    - NOTE: At the time of publication of this white paper, testing of the XML upload/download functionality has not yet been possible.
- the DTX machine to machine (M2M) system: this option allows for automatic DTX between an external backend system and EUDAMED backend services (including exchanges in bulk). The end-user enters information in the external system and the data is automatically transmitted to EUDAMED, in XML format and following the same conditions as above, without any human intervention. However, if the frequency and/or volume of transmission remains low, the connection of two systems in a fully automatic way may be too costly considering the many architectural, technological and operational aspects involved (e.g. local application readiness, interoperability, infrastructure, security and support)[33].

Figure 3: DTX mechanisms

Tactical decisions to make when sending data to Eudamed*



*Source: EU Commission Guidelines for Member States in the use of Data Exchange solutions

To date, the EC's Guidelines for Member States on the use of Data Exchange solutions covers only the assessment on data related to three modules: Economic Operators (Actor) Registration, UDI and Device Registration and Notified Bodies and Certificates. They intend to include the Vigilance and Post-Market Surveillance and Clinical Investigations modules at a later stage.

- ✔ *Manufacturers should determine how they intend to submit and manage their data. EUDAMED allows two methods of submission: web interface and HL7 SPL (Health Level Seven Structured Product Labelling). It should be noted that several features of M2M capabilities are not expected to be available at the initial launch of the database, and manufacturers should take this into account with regard to their overall approach and the resources required for compliance.*

- ✔ *Manufacturers should source their device data and establish processes to manage and maintain (with identification of data) any attribute changes that would cause a trigger for a new UDI-DI.*

- ✔ *In addition, manufacturers should establish a process for the review and approval of data for electronic submissions and the interface between their internal systems (or a third-party provider) and EUDAMED.*

- ✔ *Manufacturers should establish communication processes with their notified bodies to coordinate the certificate linking and (when applicable) the SS(C)P, to ensure the completion of device registration. This process is also needed to support communication between the two parties to support certification changes (e.g. amendments and supplements).*

EUDAMED and legacy devices

Depending on device transition timing to the Regulations, manufacturers may need to submit UDI and Device Registration information for legacy devices in EUDAMED. The EC has issued guidance that identifies the mandatory registration of these device types when a serious incident occurs or when there is a field safety corrective action to apply on them, requiring their registration as soon as possible and at least before a follow-up or final vigilance report is submitted. Legacy devices need to be registered within 18 months after the date of application (or 24 months after the date of publication of the notice referred to in Article 34(3) of the MDR, if EUDAMED is not fully functional before the date of application of the MDR), unless the MDR or IVDR equivalent is placed on the market and registered in EUDAMED prior to the serious event or field safety corrective action occurring on the legacy device.

As Basic UDI-DIs and UDIs do not apply to legacy devices, the EC has created a mechanism in EUDAMED to assign a EUDAMED-DI (an equivalent of the Basic UDI-DI) and EUDAMED-ID (an equivalent of the UDI-DI). The purpose of these assignments is to keep the same standard structure and identification elements for all devices registered in EUDAMED. If a UDI-DI is already assigned, the manufacturer can use the UDI-DI for the EUDAMED-ID/UDI-DI. The two are differentiated by a B prefix (for the EUDAMED-DI) and a D prefix (for the UDI-DI). If the device is not yet assigned a UDI-DI by the manufacturer on registration, the system provides a EUDAMED-DI and auto-generates the appropriate EUDAMED-ID.

In either case, as manufacturers move towards compliance with the Regulations, EUDAMED is expected to provide the capability to link the legacy device to the Regulations-compliant device, as long as the Regulations-compliant device is the same (except that it is compliant with the Regulations). The link is to be made at the level of the UDI-DI. If the UDI-DI is the same, this linkage by EUDAMED may be automatic; if not, the manufacturer can create the link manually by providing the legacy device identifier.[35]

- ✔ *Manufacturers should determine the timing of MDR- or IVDR-compliance for their device data (if manufacturers submit MDR- or IVDR-compliant devices they are not required to submit the MDD- or IVDD-compliant devices).*

NOTE: Legacy devices with risk class I that are not sterile and/or that have a measuring function under the AIMDD or MDD cannot be considered as legacy devices because they do not require a certificate issued by a notified body. They must be registered only as Regulation devices in EUDAMED within 18 months after the date of application (or 24 months after the date of publication of the notice referred to in Article 34(3) of the MDR, if EUDAMED is not fully functional before the date of application of the MDR).[36]

- *Manufacturers should assess whether EUDAMED-DIs and EUDAMED-IDs are to be assigned for their MDD- or IVDD-compliant devices, and develop processes and procedures to ensure that the correct linkage to MDR- or IVDR-compliant devices can be performed.*
- *Manufacturers should develop processes and procedures to support the transition of MDD- or IVDD-compliant devices to MDR- or IVDR-compliant devices, and ensure they include EUDAMED activities in order to be compliant with the Regulations, including documenting rationales for maintaining existing device UDI-DIs with transition.*

Additional considerations for manufacturers to support EU UDI system compliance

- read the Regulations pertaining to your devices along with the supporting MDCG guidance and related EUDAMED documents (data dictionaries, functional specifications, business rules and guidelines for the Economic Operators (Actor) Registration, UDI and Device Registration and Notified Bodies and Certificates modules)
- take key learnings from other regions where the UDI system has been implemented, and apply them (if applicable)
- share your knowledge and educate internal and external stakeholders on the Regulations, IE standards and guidelines, and UDI application
- resource appropriately from implementation to execution and maintenance; the UDI system is part of the life cycle management of devices within the manufacturer's Quality Management System (QMS), and a process, not a project
- identify accurate data attribute sources and ensure processes and procedures are updated to support data uploads
- identify the regulatory documents and forms that require documentation of Basic UDI-DIs (this may play into how UDI-DIs are 'grouped' under Basic UDI-DIs), and assess the rules for Basic UDI-DI association
- develop processes to assess any product revisions that may impact Basic UDI-DI and UDI-DI assignment
- develop a submission plan for your devices (devices CE-marked under the Regulations as opposed to those CE-marked under the MDD/IVDD/AIMDD)
- identify EUDAMED interdependencies throughout your organization, including UDIs, and establish processes to capture and understand any downstream effects with changes
- identify how products are placed on the market (relationships with importers, distributors, repackagers or relabelers, S/PPPs), and ensure that contracts specify UDI system compliance activities and responsibilities
- understand that UDI triggers for one regulation may impact another

Notable UDI compliance activities for other economic operators

- authorized representatives are required to comply with the registration obligations, and verify that the manufacturer has complied with them, as per the applicable regulation
- manufacturers that repackage and/or relabel devices with their own label shall retain a record of the original device manufacturer's UDI
- although distributors do not register in EUDAMED as an economic operator, they are required to verify that a UDI has been assigned to the device by the manufacturer
- importers are required to verify that a UDI has been assigned to the device by the manufacturer in accordance with the Regulations, and shall verify that the device is registered in the electronic system by the manufacturer
- the natural or legal person under Article 22(1) and Article 22(3) of the MDR is considered an S/PPP, and is expected to ensure UDI compliance within the EU system
- the S/PPP, under Article 22(4) of the MDR, is expected to assume the obligations of a manufacturer for an S/PPP; it is also expected to register as an S/PPP (as part of the Economic Operators (Actor) Registration module), assign Basic UDI-DIs and UDI-DIs as per Article 29(2) of the MDR, and register their devices

Other regulatory uses of UDIs

While not identified as a key component of a UDI system, there are several requirements within the Regulations that are expected to further enhance product traceability and patient safety in the EU.

Implant cards and UDIs

Before the MDR was published, several Member States required the use of implant cards (ICs) for specific medical devices. While an IC is not identified as an integral part of a UDI system, a UDI can be defined as an integral element of the IC as noted by the three main objectives given in MDCG guidance:

- enable the patient to identify the implanted devices and access other information related to the implanted device, e.g. via EUDAMED and other websites
- enable patients to identify themselves as persons requiring special care in relevant situations, e.g. security checks
- enabling emergency clinical staff or first responders to be informed about special care or needs for relevant patients in case of emergency situations[37]

According to Article 18(1a) of the MDR, the manufacturer has to provide information about the device on the IC, unless the implant is exempt from this obligation (e.g. well-established technology such as staples and screws). The medical device UDI is one of several pieces of information that is listed as a means for the identification of the implanted device.

The suggested formats of the UDI carrier for use by the healthcare provider or institution and the patient is also presented in MDCG guidance.[38] Manufacturers should use this guidance to identify the necessary data elements and their formats, including the specific requirements for UDIs. These are the UDI in AIDC format, the use of the UDI symbol (validated by users according to the BS ISO 15223-2 process) – which is required to be adjacent to the AIDC – and the UDI-DI information in HRI format, which should be introduced by the wording 'UDI-DI'.

Integration of the UDI system into healthcare institutions

Under Article 27(9) of the MDR, healthcare institutions are required to store and keep the UDIs of the Class III implantable devices they have supplied, or with which they have been supplied. The Regulations oblige Member States to encourage (and may require) healthcare institutions to store and keep the UDIs of the devices with which they have been supplied, irrespective of their class. Member States are also obliged to encourage (and may require) healthcare professionals to store and keep the UDIs of the devices with which they have been supplied.

The transition time provided to manufacturers and other economic operators that allows them to prepare for the implementation of the Regulations also provides healthcare institutions and healthcare professionals time to learn what is to be required of them, notably in terms of the traceability of devices.[39]

This is an area in which manufacturers, as well as Member States, could provide support by ensuring these institutions and healthcare professionals understand the Regulations' UDI requirements and how UDIs are applied to their devices (e.g. package levels and transition).

Conclusion

The Medical Device and In Vitro Medical Device Regulations represent the most significant change to the European legislation for medical devices in over 20 years. Understanding the requirements is essential to [manufacturers'] ability to provide the European Union market with safe medical devices that perform as intended and comply with the Regulations.[40]

The UDI system is a new requirement of these Regulations, and it is intended to bring about fundamental changes in device traceability and product life cycle management.

The UDI system is complex and technical, requiring the understanding and knowledge of both regulatory requirements and supply chain standards and activities. Timely preparation, integrated implementation and nimble execution is needed to ensure compliance and to accommodate for any potential future EU and global UDI requirements. While the International Medical Device Regulatory Forum (IMDRF) guidance documents provide the necessary framework for the UDI system, regulatory jurisdictions also have some specific requirements. The EU regulations are no exception. Manufacturers of global products need to understand these differences and integrate the requirements within their life cycle management processes to maintain compliance.

While most UDI requirements have been established within the MDR, IVDR and supporting MDCG guidance documents, at the time of publication of this white paper it should be noted that there are still some aspects of the EU UDI system that are being negotiated. As the scope of these requirements may go beyond the initial device groups, manufacturers should remain attentive to any additional conditions, as they may need to integrate them to support future UDI system compliance for their medical devices. It is imperative that manufacturers stay up-to-date with EU MDCG guidance.[41]

Author

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Published white papers

- The proposed EU regulations for medical and in vitro diagnostic devices: An overview of the likely outcomes and the consequences for the market, Gert Bos and Erik Vollebregt
- Generating clinical evaluation reports: A guide to effectively analysing medical device safety and performance, Hassan Achakri, Peter Fennema and Itoro Udofia
- Effective post-market surveillance: Understanding and conducting vigilance and post-market clinical follow-up, Ibim Tariah and Rebecca Pine
- What you need to know about the FDA's UDI system final rule, Jay Crowley and Amy Fowler
- Engaging stakeholders in the home medical device market: Delivering personalized and integrated care, Kristin Bayer, Laura Mitchell, Sharmila Gardner and Rebecca Pine
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Forthcoming white papers

- *Performance Evaluation under IVDR,* Fiona Gould
- *Guidance on MDCG 2019-9 – summary of Safety and Clinical Performance (working title),* Amy Smirthwaite
- *CER generation (working title),* Amy Smirthwaite
- *Requirements of EU-GDPR and PMCF studies, registries and surveys under the MDR (working title),* Richard Holborow

Endnotes

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BSI is keen to hear your views on this paper, or for further information please contact us here: julia.helmsley@bsigroup.com

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