THE ULTIMATE GUIDE

EU MDR/IVDR UDI

Rimsys® | Regulatory Management Software

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OVERVIEW

The EU Medical Device Regulation (2017/745) ("MDR") and EU In Vitro Diagnosis Regulation (2017/746) ("IVDR") introduce two new systems for information exchange: (1) UDI (Unique Device Identifier) for device identification and (2) EUDAMED (**Eu**ropean **Da**tabank on **Me**dical **D**evices) to centralize and disseminate information. UDI is a specific code assigned to all devices and higher levels of packaging. This will allow for devices being sold in the European market to be identified and traced through a globally harmonized approach. EUDAMED is the IT system developed by the European Commission to replace the EUDAMED2 database previously in place under the Medical Device Directives (MDD). EUDAMED is a multi-functional system that will be used to coordinate device registration, provide information about devices to industry professionals and the public, and highlight necessary safety details.

01

UDI BASICS AND BENEFITS

The EU MDR and IVDR UDI system is based upon the guidance of the International Medical Device Regulators Forum (IMDRF). It's a globally harmonized system that's designed to increase patient safety and optimize care.

UDI system goals:

INCREASE PATIENT SAFETY	• Improve tracing of devices • Reduce the presence of counterfeit devices
IMPROVE POST-MARKET SURVEILLANCE	• Improve accessibility of adverse event reports
ENSURE ACCESS TO ACCURATE INFORMATION	• Unambiguous identification of devices throughout distribution and use
ENHANCE SUPPLY CHAIN MANAGEMENT	• Streamline supply chain process and inventory management • Simplify medical device documentation processes

The UDI system has four key elements:

ELEMENT 1

Assignment of a UDI, consisting of:

BASIC UDI-DI

UDI-DI AND UDI-PI

PACKAGING UDI

ELEMENT 2

Placing UDI on Device or Packaging through UDI Carrier

ELEMENT 3

Storage of UDI Information by Economic Operators

ELEMENT 4

UDI Database to Access Information

ELEMENT 1: ASSIGNMENT OF UDI (UDI COMPONENTS)

The first element of the UDI system is the assignment of a UDI. The UDI is a code of alphanumeric characters that acts as the access key to information about a specific medical device on the market. The EU MDR and EU IVDR requires that a UDI be assigned to all medical devices except for custom-made or investigational devices. There are three components of a UDI:

1. Basic UDI-DI
2. UDI (consisting of UDI-DI and UDI-PI)
3. Packaging UDI *(Note: This is not an official term used in the EU MDR and IVDR, but we're using it to help explain the concept. The Packaging UDI is part of the UDI itself.)*

1) Basic UDI-DI

The Basic UDI-DI identifies the device group that a particular device fits into. A device group is a group of products that all share the same intended purpose, risk class, essential design, and manufacturing characteristics. A device group is generally classified by medical device manufacturers as a "Product Family" or "Product Category," depending on the internal nomenclature used within the company. The Basic UDI-DI functions as a parent or higher-level descriptor of a device.

NOTE: There can only be one Basic UDI-DI per UDI-DI.

The Basic UDI-DI is *not* printed on the product itself or on the packaging of a product, but rather it must be included in the following documents and applications:

- Certificates (Including Certificate of Free Sale)
- EU Declarations of Conformity
- Technical Documentation
- Summary of Safety and Clinical Performance

2) UDI (UDI-DI and UDI-PI)

The second component is the UDI itself, which consists of two parts:

Device **I**dentifier (DI)

Production **I**dentifier (PI)

The UDI-DI (Device Identifier DI, also referred to as "static") identifies specific, detailed information about a particular device. If any of the below details should change, the device will need a new UDI-DI.

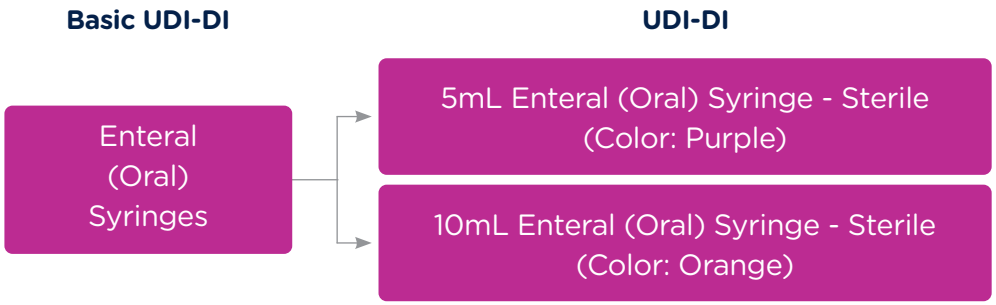
- Name or trade name of the device
- Device version or model
- If labelled as a single use device
- Packaged as sterile
- Maximum number of uses
- Need for sterilization before use
- Quantity of devices provided in a package
- Critical warnings or contra-indication
- CMR/endocrine disruptors

NOTE: There can be several UDI-DIs for one Basic UDI-DI.

Meanwhile, the UDI-PI (Production Identifier PI, also referred to as "dynamic") contains manufacturing information (including serial number, lot/batch number, software identification, and manufacturing or expiry date or both types of dates.)

To better illustrate this concept of Basic UDI-DI and UDI (UDI-DI and UDI-PI), let's use a syringe as an example. The Basic UDI-DI would identify the category of a syringe, for example, "Enteral (Oral) Syringe."

A **5ml Enteral (Oral) Syringe - Sterile (Color: Purple)** would get a unique UDI-DI and a **10m Enteral (Oral) Syringe – Sterile (Color: Orange)** would get a unique UDI-DI. Both products would be associated to the same Basic UDI-DI. In this case, the "Enteral (Oral) Syringe," which defines the category.



Each time that **5ml Enteral (Oral) Syringe - Sterile (Color: Purple)** is manufactured at the same revision, it will get a new UDI-PI per lot. See the graphic below.

The UDI-PI for Different Lots

Manufacture Date	Product	Version	Lot
May 26, 2021	5ml Enteral (Oral) Syringe - Sterile (Color: Purple)	3	Lot #1 with Qty=100
May 27, 2021			
May 28, 2021	5ml Enteral (Oral) Syringe - Sterile (Color: Purple)	3	Lot #2 with Qty=200
May 29, 2021	5ml Enteral (Oral) Syringe - Sterile (Color: Purple)	3	Lot #3 with Qty=100

Each product is identical and therefore has the same UDI-DI. However, the UDI-PI changes to reflect the manufacturing date, lot number, expiry date, and serial number, as applicable.

The UDI will contain all device-specific information and have the same functions as the comparable database (GUDID) of the United States FDA. The main difference (in EUDAMED) is that the UDI data is divided into components of Basic UDI-DI, UDI, and Packaging UDI.

3) Packaging UDI

The third component of UDI is the Packaging UDI. *(Note: This is not an official term used in the EU MDR and IVDR, but we're using it to help explain the concept.)*

Each level of packaging, except shipping containers, must receive its own unique UDI. Packaging UDI refers to the unique UDI assigned to higher levels of packaging instead of the device itself.

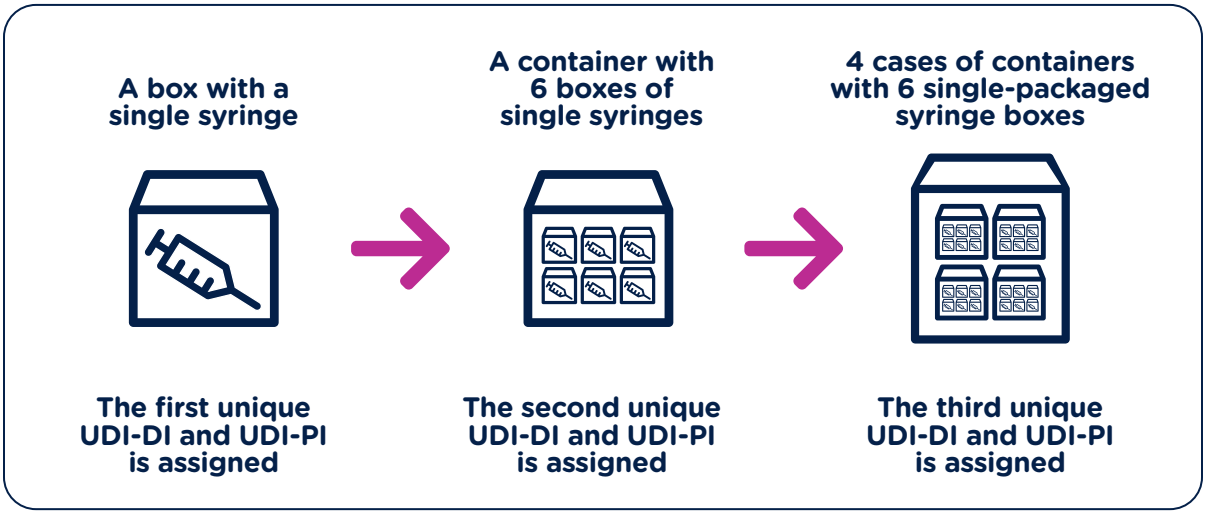
In the event of significant space constraints on the unit of use packaging, the UDI Carrier may be placed on the next higher packaging level.

Returning to our earlier example of syringes, if a manufacturer first packages a single sellable syringe into an individual box, this package would receive its own UDI-DI and UDI-PI.

If then the manufacturer packages those individual boxes into containers of six (6), those containers would receive their own UDI-DI and UDI-PI.

And finally, if the manufacturer packages those six (6) containers into cases of four (4), those cases would receive their own UDI-DI and UDI-PI.

Each of those levels of packaging must be assigned its own UDI-DI and UDI-PI. The initial syringe did not change, but the way it is packaged did, therefore, requiring its own UDI-DI and UDI-PI.



ELEMENT 2: PLACING UDI ON THE DEVICE AND/OR PACKAGING

The second element to the UDI system is the placing of the UDI on the device or on its packaging through what is referred to as a "UDI Carrier." The UDI Carrier is the part of the label that contains the UDI information that is applied directly to the device or included on the device packaging. The UDI Carrier should have both a machine-readable portion (AIDC) and a human-readable portion (HRI). (Specific details about each element of the UDI will be covered in Chapter 2.)

Machine-readable form – AIDC – (**A**utomatic **I**dentification and **D**ata **C**apture) is a barcode or other machine-readable technology that can be accessed automatically by scanning the UDI information.

Human-readable form – HRI – (**H**uman **R**eadable **I**nterpretation) is the numeric or alphanumeric code, which can be manually entered into the system for access to the UDI information.

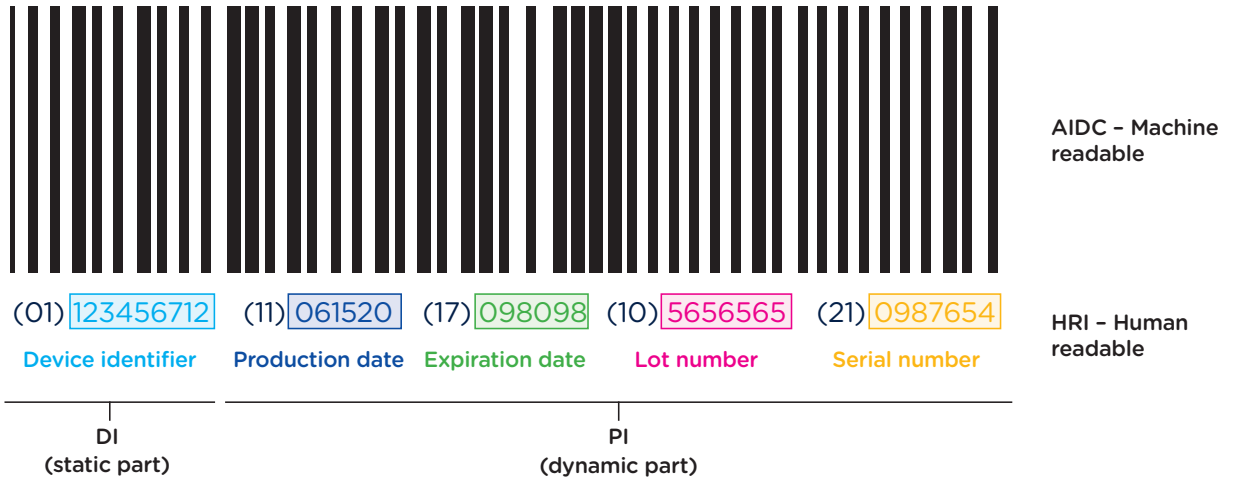
If there are space constraints limiting the use of both the AIDC and HRI on the label, then only the AIDC is required to appear. However, on devices that are intended to be used in home-health care or other non-medical facility settings, the HRI would be required to appear.

Single-use devices may contain the UDI Carrier on its lowest level of packaging rather than on the device itself.

Reusable devices must include the UDI Carrier on the device itself, unless any type of direct marking would interfere with the safety or performance of the device, or if it is not technologically feasible to directly mark the device. If so, this should be properly documented in your design history file.

Most importantly, the UDI Carrier must be readable for the intended lifecycle of the device.

Below is an example of a GS1 AIDC and HRI barcode label.



ELEMENT 3: STORAGE OF UDI INFORMATION BY ECONOMIC OPERATORS

Storage of UDI information by "Economic Operators" is the third element of the UDI system. 2017/745 Articles 2(35), 22(1), and 22(3) define an economic operator as:

- A manufacturer
- An authorized representative
- A distributor
- An importer
- An investigator for clinical investigations
- A person who sterilizes systems or procedure packs

Class III, implantable device:
According to EU MDR 2017/745 Annex II, the manufacturer shall keep an updated list of all UDIs that it has assigned. Economic operators and all health institutions are required to store, preferably by electronic means, the UDI of all the devices for which they have supplied or with which they have been supplied.

For devices other than Class III:
Member States are encouraged, and in some cases require, health institutions to store, preferably by electronic means, the UDI of the devices with which they have been supplied. The UDI must also be included in any field safety notice for reporting serious incidents and field safety corrective actions.

The EU MDR and EU IVDR also give the European Commission authority to make additional requirements regarding the submission or maintenance of UDI information. In making those decisions, the European Commission must consider six (6) areas:

- Confidentiality and data protection
- Risk-based approach
- Cost-effectiveness of the additional measures
- The need to avoid duplications in the UDI system
- The needs of the healthcare systems of the member states
- Harmonization with other medical device identification systems

ELEMENT 4: UDI DATABASE (EUDAMED)

The fourth component of the UDI system is entry of UDI and device information into the UDI database through EUDAMED. The MDR and IVDR require manufacturers to register all devices and submit specific information to the database before placing a device on the market. The core data elements provided through the UDI database will be accessible to the public free of charge. The list below outlines all of the required information for device registration.

Annex VI, Part A of 2017/745, states that the UDI database will contain all information about devices presently on the market and discontinued products. The database is designed to allow for linking across all packaging levels of the device. For all devices currently on the market, manufacturers are required to periodically verify the accuracy of the information in the database. **If any changes are made to a device that *do not* require a new UDI-DI, manufacturers must still update the database within 30 days.**

Information to be submitted with the device and economic operator registration must include:

1. Economic operator information (2017/745 Annex VI, Part A(1)):
2. Information relating to the device
3. Manufacturing information

The tables below outline all of the specific information that must be submitted to the UDI database:

Economic Operator Information

- Type of economic operator
  - manufacturer, authorized representative, importer, distributor, a person who sterilizes systems or procedure packs, an investigator for clinical investigations
- Name, address, and contact details of the economic operator or of any person submitting information on behalf of the economic operator
- Name, address, and contact details of person responsible for regulatory compliance
- Presence of human blood, human plasma, tissues, or cells of human or animal origin
- Single Identification Number of the clinical investigation

Information Relating to the Device

- Information regarding the certificate issued by the notified body
- Member State in which the device will be placed on the market, and for all class IIa, IIb, or III devices, all Member States where the device will be made available
- Risk class of the device
- Whether the device is single-use
- Whether the device contains any substance which may independently be considered a medicinal product, and name of that substance
- Presence of human blood, human plasma, tissues, or cells of human or animal origin
- Single Identification Number of the clinical investigation
- Whether the device is intended for any non-medical purpose
- Summary of safety and clinical performance for any class III or implantable devices
- Status of the device (on market, recalled, discontinued, field safety corrective action initiated)

Manufacturing Information

- Quantity per package configuration
- Basic UDI-DI and any additional UDI-DIs
- Production information including expiration date or manufacturing date, lot number, serial number
- The unit of use UDI-DI, if applicable
- Name and address of the manufacturer
- The Single Registration Number (SRN)
- Name and address of the authorized representative, if applicable
- Medical device nomenclature code
- Risk class of the device
- The name or trade name of the device
- Device model, reference, or catalogue number
- Clinical size information, including volume, length, gauge, diameter
- Additional product description, if applicable
- Storage and/or handling conditions
- Whether it is a single-use device
- Maximum number of reuses allowed
- Whether it is sterile
- Need for sterilization before use
- Containing latex
- URL for any additional information
- Critical warnings or contra-indications

In addition to this information, the European Commission recently released the UDI HelpDesk. The HelpDesk will provide support to economic operators in the implementation of the obligations and requirements introduced by the new UDI system.

02

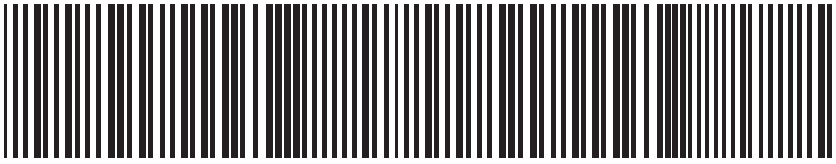
UDI FORMAT REQUIREMENTS AND ISSUING ENTITIES

The EU MDR/IVDR established a process to standardize the UDI format. The regulations task the European Commission with approving issuing entities to develop a system of standard rules and conditions for the assignment of a UDI. All UDIs issued must conform to the requirements of a particular issuing entity that has been approved by the European Commission. The Medical Devices Coordination Group (MDCG) created a guiding principles document on the rules for the Basic UDI-DI, for issuing entities, MDCG 2019-1. Every UDI contains a company identifier as a prefix to the UDI-DI to identify the issuing entity. The four approved issuing entities for Europe are:

Issuing Entity	Name of System	Company Identifier
GS1	Global Trade Item Number (GTIN)	(01)
HIBCC	Universal Product Number (UPN)	+
ICCBBA	ISBT 128 (Processor Product Identification Code) Specifically used for health products of human origin: blood, cells, tissues, organs, etc.	=
Informationsstelle für Arzneispezialitäten — IFA GmbH*	Pharmacy Product Number (PPN) *Mostly used by Pharma manufacturers	11

GS1

GS1 is the most commonly used issuing entity for UDI. GS1 is a non-profit organization that operates the leading international system for trade item identification. They are a neutral, global collaboration platform that brings industry leaders, government, regulators, academia, and associations together to develop standards-based solutions to address the challenges of data exchange.



(01) 04053213000004(17)270526(10)321TQS(21)6585HR7C08

HIBCC

The Health Industry Business Communications Council (HIBCC) is an industry-sponsored and supported non-profit council, founded in 1983 to develop a standard for data transfer using uniform bar code labeling. HIBCC was formed to administer the standard and issue the Labeler Identification Codes (LICs) which identify individual manufacturers and are included within each bar code.

*+A9991234A5/$$710X3/S77DEFG45/
16D20160831/14D20190831/Q255*

ICCBBA

ICCBBA is a non-governmental organization in official relations with the World Health Organization (WHO). ISBT 128 provides international consistency to support the transfer, transfusion, or transplantation of medical products of human origin. It also encodes information about biological products in a manner that allows the information to be transferred from one computer system to another in a way that is unambiguous and accurate.

=/A9999XYZ100T0479
=,000025=A99971412345600=>016008

IFA GmbH

The IFA GmbH provides information services for the pharmaceutical market, including economic, legal, and logistical data for nationwide availability in pharmacy goods.

03

UDI RULES FOR SPECIFIC DEVICE TYPES

As with all regulations, there are a number of exceptions and special rules for certain types of devices. These unique rules are covered in Annex VI of the MDR/IVDR, and we've summarized a number of the important considerations below:

Implantable Devices: Implantable devices themselves do not need to be marked with a UDI, but they must be marked using AIDC at their lowest level of packaging so that they can be clearly identified prior to implantation. The UDI-PI must include a serial number.

Reusable Devices: The UDI Carrier for reusable devices must be directly marked, meaning the UDI Carrier is included on the device itself. The Carrier must be able to withstand wear and tear so that the UDI remains readable during normal use for the duration of the device's lifespan. If the reusable device requires disinfection, sterilization, or refurbishing between uses, the manufacturer must ensure that the UDI Carrier is permanent and readable after each process performed. Exceptions to these requirements will be made where marking would directly interfere with the safety or performance of the device, or where direct marking is not technologically feasible.

Single-Use Devices: For single-use devices of classes I and IIa (medical devices) and class A and class B (IVD medical devices) that are packaged and labeled individually, the UDI Carrier does not need to appear on the individual unit packaging. However, it is required to appear at the higher level(s) of packaging. For example, in a carton containing several individually packaged devices, a UDI Carrier may be printed on the carton rather than on each of the individually packaged units.

Non-IVD Kits: The manufacturer of the kit is responsible for identifying the kit with a UDI including both UDI-DI and UDI-PI. Medical device contents of kits should have a UDI Carrier on their packaging or on the device itself.

IVD Kits: The manufacturer of the IVD kit is responsible for identifying it with a UDI including both UDI-DI and UDI-PI, 2. Medical device contents of IVD kits should have a UDI Carrier on their packaging or on the device itself. The UDI must be readable, or in the case of AIDC, scannable, whether placed on the outside of the IVD kit package or inside a transparent package.

Systems and Procedure Packs: A procedure pack is a combination of products packaged together to be used for a specific medical purpose. An example of this is a first aid kit. A system is a combination of products, whether they're packaged together or not, which are intended

to be used in conjunction with one another. An X-Ray system is a good example. The MDR and IVDR treat systems and procedure packs as devices in their own right. Before placing a system or procedure pack on the market, the producer must assign a UDI that is different from the UDI assigned to the underlying components (this is detailed in MDCG 2018-3V1).

Configurable Devices: A configurable device is a device that consists of several components which can be assembled by the manufacturer in multiple configurations. One UDI should be assigned to the entire device that covers the possible configurations. A separate UDI should **not** be assigned for each configuration within the group. The UDI Carrier must be placed on the assembly that is most unlikely to be exchanged during the lifetime of the system. An individual component of the configurable device must receive its own UDI if it is considered a device and is commercially available on its own.

Software and Apps: Software and apps that fall under the definition of a medical device or an in vitro diagnostic medical device must comply with the UDI requirements of the MDR/IVDR. In accordance with Annex VI, Part C of 2017/745(MRD) and 2017/746 (IVDR), only software which is commercially available on its own, as well as software which constitutes a device in itself, is subject to UDI requirements.

- The UDI is assigned at the system level of the software. A new UDI-DI is required whenever there's a modification that changes the original performance, the safety or intended use of the software, or the interpretation of data. This could include new or modified algorithms, database structures, operating platforms, architecture or new user interfaces, or additional channels for interoperability. Minor software changes, such as bug fixes, usability enhancements not made for safety purposes, security patches, or improvements to operating efficiency, only require a new UDI-PI, not a new UDI-DI.
- UDI Carrier requirements for software: Software that is delivered on a physical medium, such as a CD or DVD, must be labeled with a UDI Carrier on each packaging level. The physical medium containing the software and its packaging should receive the same UDI that is assigned to the system level of the software.
- The human readable format UDI (HRI) should be provided on a readily accessible screen for the user, such as in an 'about' file or included on the start-up screen. Only the HRI is required on electronic displays of the software. The AIDC does not need to be displayed.
- Software that lacks a user interface, such as middleware for image conversion, should be capable of transmitting the UDI through an application programming interface (API).

Additional information on software can be found in Annex VI, Part C, 6.5.4 of the MDR and Annex VI, Part C, point 6.2.4 of the IVDR UDI placement criteria for software.

04

IMPLEMENTATION OF UDI AND EUDAMED IN THE EUROPEAN UNION

PART A: IMPLEMENTATION DEADLINES

UDI Assignment:
The UDI assignment requirements went into effect when the EU MDR and EU IVDR regulations became active on May 26, 2021 for medical devices and will become active on May 26, 2022 for in vitro diagnostics. From those dates forward, manufacturers must ensure that all devices and higher-level packaging are properly assigned a UDI.

UDI Data Submission to EUDAMED:
EUDAMED submissions follow a different implementation schedule. **Manufacturers must submit UDI data to the EUDAMED database by November 26, 2022 for medical devices and November 26, 2023 for in vitro diagnostics (or 24 months after EUDAMED becomes fully operational in the case of delays).** If manufacturers choose to voluntarily comply with the EUDAMED registration requirements sooner than those deadlines, they may now register their medical devices and can begin registration on May 26, 2022 for in vitro diagnostic products.

UDI Labeling and Packaging Requirements:
This table outlines the implementation deadlines for the UDI labeling and packaging requirements:

Device as per Regulation (EU) 2017/745 (MDR)	Implantable Devices and Class III Devices	Class IIa and Class IIb Devices	Class I Devices
Placing UDI Carriers on the labels of devices MDR Article 123(3)(f), Article 27(4)	26 May 2021	26 May 2023	26 May 2025
Direct marking of the resuable devices MDR Article 123(3)(f), Article 27(4)	26 May 2023	26 May 2025	26 May 2027
Device as per Regulation (EU) 2017/746 (IVDR)	**Class D IVDs**	**Class C and B IVDs**	**Class A IVDs**
Placing UDI Carriers on the labels of devices IVDR Article 113(3)(e), Article 24(4)	26 May 2023	26 May 2025	26 May 2027

EUDAMED Timelines:
The Actor Registration module was the first to become available in December 2020. The second module, UDI/Device Registration, and third module, Certificates and Notified Bodies, are expected to become available by September 2021. The European Commission published a notice stating that additional modules will become active as soon as they are functional.

PART B: LEGACY DEVICES AND TRANSITION FROM MDD/IVDD TO MDR/IVDR

Legacy devices are devices that were approved under the Medical Device Directive and In-Vitro Diagnostic Directive and have valid directive certificates. In order to facilitate the transition from the directives (MDD/IVDD) to the new regulations, legacy devices are exempt from some of the new requirements of the MDR/IVDR and may be placed on the market under their directive certificates. Legacy devices are not subject to assignment or labelling requirements of UDI, but they must all be registered in the EUDAMED database.

Typically, a device cannot be registered without a UDI, as UDI serves as the access key that is fundamental to EUDAMED registration. In order to create a work-around for legacy products, a unique access key will be assigned to replace the Basic UDI-DI and UDI-DI. The unique access key that replaces the Basic UDI-DI is called the EUDAMED DI and the unique access key that replaces the UDI-DI is called the EUDAMED ID.

Manufacturers are required to register legacy devices in EUDAMED by November 26, 2022 for medical devices, and November 26, 2023 for in vitro diagnostic medical devices. However, in the case of any serious incident or field safety corrective action, the device must be registered immediately upon the incident being reported if it has not been registered already.

APPENDIX

US vs EU UDI COMPARISON

The United States FDA originally developed the UDI labeling system in 2007 to uniquely identify all medical devices. Appreciating the benefits of the UDI system, the Global Harmonization Task Force (GHTF) adopted a guidance issued by the International Medical Device Regulators Forum (IMDRF) in 2013.

The two systems are fundamentally very similar, and both strive to achieve a globally harmonized approach. Here are some of the key differences:

	EU System	US System
Timelines for Implementation	The implementation process for the EU UDI system begins on May 26, 2021 for medical devices and May 26, 2022 for In vitro diagnostic devices.	The US UDI system was established by the FDA in September 2013. Therefore, it is further along in the implementation process.
Name of UDI Database	EUDAMED	Global Unique Device Identification Database, or GUDID (pronounced Good-ID)
Who's Responsible for UDI assignment, storage, and submissions?	Manufacturers	The entity that specifically labels devices, called a 'labeler' in the regulations (this is often also the manufacturer) is responsible for UDI assignment, storage, and submissions in the US.
Reusable Devices	The EU requires both the HRI and the AIDC formats to be directly marked on the device itself.	The US requires either the AIDC or the HRI to be directly marked but doesn't require both.
Single-Use Devices	The single-use device rules allow the UDI Carrier to be placed on the next higher level of packaging, rather than on the individual device packaging, but apply only to classes I and IIa for medical devices and class A and class B for IVD medical devices.	The labeling exception for single-use devices applies to all device classes.

GLOSSARY

Actor: A person or organization with a specific role that must be registered in the EUDAMED. It is one of six modules, and the first to be released as part of the EUDAMED database system.

AIDC: Automatic **I**dentification and **D**ata **C**apture is a technology used to automatically capture data. AIDC technology can include bar codes, smart cards, biometrics, and RFID.

Basic UDI-DI: The primary identifier of a device model summarizing the common characteristics of a group of products. It's the "main key" for record keeping in the UDI database and is referenced in relevant certificates and the EU Declaration of Conformity. It is not used on labeling.

Carrier: *See UDI Carrier*

Company Identifier: A prefix included before the UDI-DI on the UDI Carrier to identify the issuing entity for the UDI.

Competent Authority: A competent authority is any person or organization that has the legally delegated or invested authority, capacity, or power to perform a designated function. Similarly, once an authority is delegated to perform a certain act, only the competent authority is entitled to take accounts therefrom and no one else.

Device Identifier (DI): A mandatory, fixed portion of the UDI that identifies the manufacturer and specific, detailed information about the model of device. *(See also UDI-DI)*

Economic Operator: A manufacturer, system/procedure pack producer, authorized representative, or importer.

EUDAMED: The European Databank of Medical Devices is a secure IT web-based portal, developed by the European Commission that acts as a central hub for the exchange of information between national competent authorities and the EU to implement Regulation (EU) 2017/745 for medical devices and Regulation (EU) 2017/746 for in vitro diagnostics medical devices.

GS1: An Issuing Entity for UDI. *(See also GTIN)*

Global Trade Identification Number (GTIN): A system created and operated by GS1 that is used internationally for product identification and supply-chain management across a variety of industries. The GTIN format is used for the UDI-DI.

HRI: Human **R**eadable **I**nterpretation is a legible view of the data characters on a UDI label (or encoded directly on a device) and is required in case there is no automatic system to read the code.

Issuing Entities: Entities approved by the European Commission to develop a system of standard terms and conditions for UDI assignment. All UDI codes must conform to the requirements of the issuing entity. They are GS1, HIBCC, ICCBBA, and IFA GmbH.

MDCG: The **M**edical **D**evice **C**oordination **G**roup assists the Commission and the Member States in ensuring a harmonized implementation of medical devices Regulation (EU) 2017/745 and Regulation EU 2017/746.

Production Identifier (PI): A conditional, variable portion of the UDI that contains information about the manufacturing and production of that device. *(See also UDI-PI)*

SRN: The **S**ingle **R**egistration **N**umber that uniquely identifies every economic operator in EUDAMED. If the economic operator has multiple roles, separate registration requests are required to obtain a different and specific SRN for each actor role.

UDI: The **U**nique **D**evice **I**dentifier (UDI) is a specific code assigned to all devices and higher levels of packaging to provide identification of the device throughout its distribution and use history.

UDI Carrier: The portion of the device or packaging label that contains the UDI. The UDI Carrier contains a machine-readable component and a human-readable component.

UDI-DI: The unique **D**evice **I**dentifier is a mandatory, fixed portion of a UDI label that identifies the device manufacturer and the specific version, make or model of a device. It is the static part of the UDI number.

UDI-PI: The unique **P**roduction **I**dentifier is a mandatory, fixed portion of a UDI label that identifies the device's serial number, lot number, expiration date, and manufacturing date. It is the dynamic part of the UDI.

Unit of Use DI: Used to associate a device in which a UDI is not directly labeled on an individual device at the level of its intended use. Its purpose is to associate the use of a device being delivered to/or used on a patient when one base package contains more than one device. (i.e. packing several devices of the same product together in a box for a single shipment.)

SOURCES

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9. FDA UDI Rule and Guidances, Training, Resources, and Dockets
10. Medical Device Coordination Group (MDCG) Guiding Principles for Issuing Entities Rules on Basic UDI-DI: MDCG 2019-1
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ABOUT RIMSYS

Rimsys is the leading provider of Regulatory Information Management (RIM) software for medical technology companies. Built by and for regulatory affairs professionals, Rimsys digitizes, automates, and creates regulatory order to ensure products adhere to changing global regulations. It is the only holistic RIM software for medical devices, in-vitro diagnostics, and medical device software that makes it easy to manage global UDI requirements and navigate the pillars of regulatory affairs, including product registration, standards management, essential principles/GSPR, and regulatory intelligence.

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