WHITEPAPER

DDi
Smarter Technology

FDA UDI *vs* EU UDI

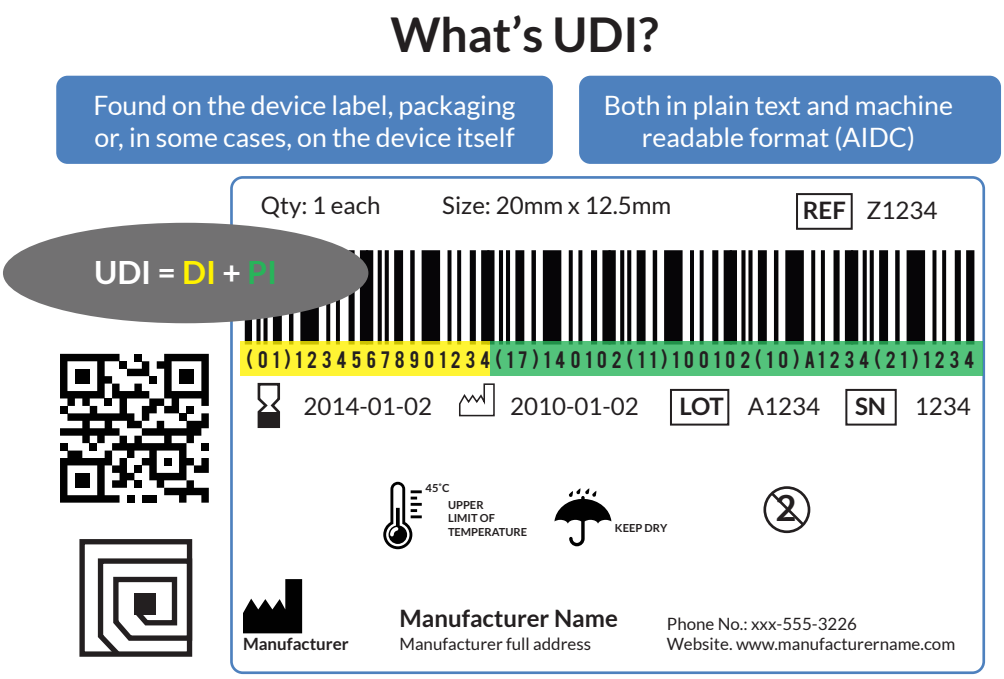
What is UDI

Unique Device Identification (UDI) is intended to assign a unique identifier to medical devices within the United States it marks and identifies individual medical devices throughout their distribution and product life. The UDI system was initially created, developed and maintained by the device manufacturer based on global device identification standards. Today, it also helps with procurement and reimbursement.

With certain exceptions, a UDI will be required to appear on the label of a medical device and be composed of two parts:

1. Device Identifier (DI) - a mandatory, fixed portion of a UDI that identifies the specific version or model of a device; and
2. Production Identifier(s) (PI) – a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device. This will be dependent upon the manufacturer's internal quality system.
    - the lot or batch number within which a device was manufactured;
    - the serial number of a specific device
    - the expiration date of a specific device
    - the date a specific device was manufactured

Therefore, UDI = DI + PI.



UDI History

In 2007, the U.S. FDA developed a labeling system that would uniquely identify every single medical device (MD) on the market. The Global Harmonization Task Force (GHTF) soon recognized the global relevance of such a system and adopted a respective guidance that was last released in 2013 by the International Medical Device Regulators Forum (IMDRF), an international cooperation of regulators made up of industry stakeholders and GHTF successors. (Interestingly, Medical device manufacturers experienced in the U.S. market have quickly recognized the similarity of the EU regulation as compared to the U.S. Food and Drug Administration's (FDA) UDI guidelines.

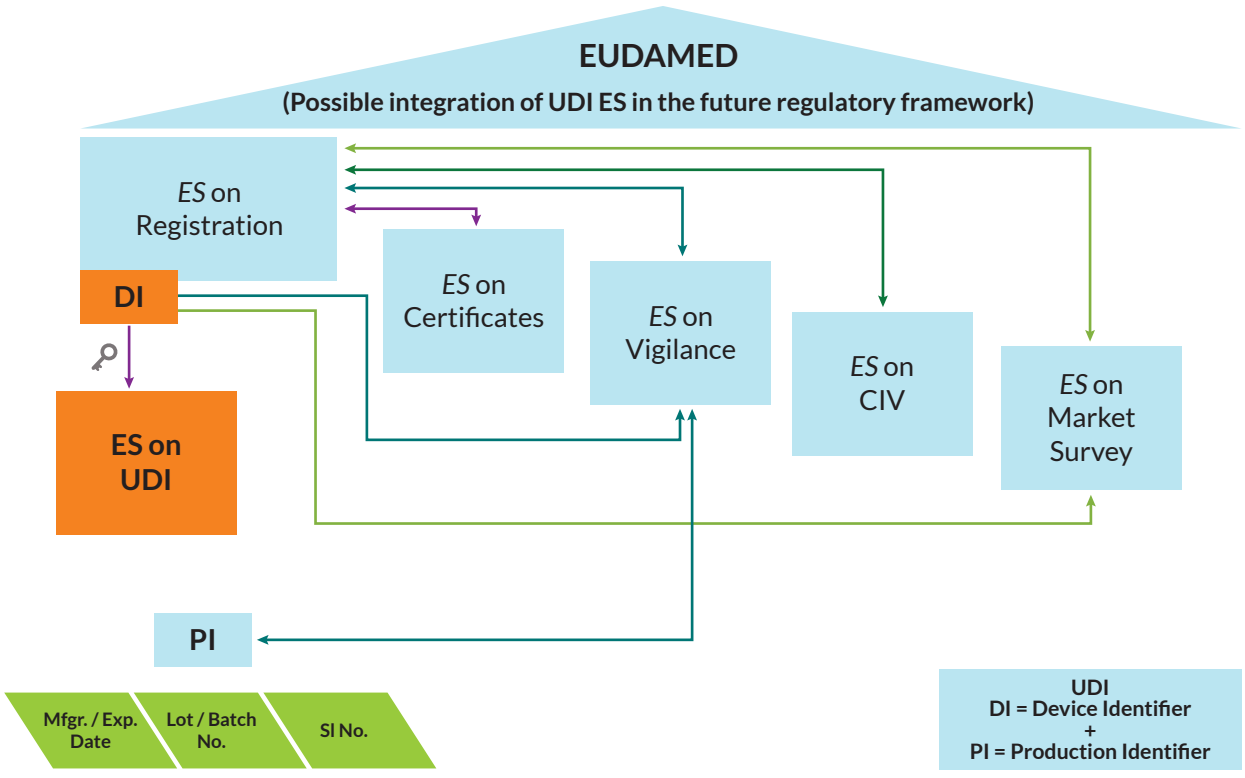
Following the global trend in handling the traceability of medical devices, the EU Commission has clearly defined the requirements for implementation of a Unique Device Identification (UDI) System in the final text of the new EU Medical Device Regulation (MDR) 2017/745.

The EU UDI System, like the U.S. UDI requirements, will be implemented in phases, starting with the highest risk classes first, and lowest risk classes last.

EUDAMED

EUDAMED will be an information system for exchanging legal information related to the application of European Union Directives on medical devices between the European Commission's Enterprise and Industry Directorate General and the Competent Authorities in the European Union Member States. Its legal basis is laid down in Directives 90/385/EEC, 93/42/EEC, 98/79/EC and 2000/70/EC.

Under these Directives, Member States need to ensure that medical devices that are placed on the market and put into service comply with all provisions of the Directives, including the 'essential requirements', and that no obstacles are encountered for the free movement of approved devices. The Directives also require that data be stored to a database in a standardized format. The EUDAMED project aims to address the effective implementation of this provision of the Directives.



Key Differences between US GUDID and EU EUDAMED elements

EUDAMED will be an information system for exchanging legal information related to the application of European Union Directives on medical devices between the European Commission's Enterprise and Industry Directorate General and the Competent Authorities in the European Union Member States. Its legal basis is laid down in Directives 90/385/EEC, 93/42/EEC, 98/79/EC and 2000/70/EC.

Under these Directives, Member States need to ensure that medical devices that are placed on the market and put into service comply with all provisions of the Directives, including the 'essential requirements', and that no obstacles are encountered for the free movement of approved devices. The Directives also require that data be stored to a database in a standardized format. The EUDAMED project aims to address the effective implementation of this provision of the Directives.

	US GUDID	EU EUDAMED
1	Labeler DUNS Number	The Basic UDI-DI
2	Secondary DI Number	Single Registration Number
3	Device Subject to Direct Marking (DM), but exempt	If applicable, name and address of the authorized representative
4	DM DI different from primary DI (and DM number)	If applicable, additional trade name of the device
5	Customer contact	Risk class of the device
6	Prescription use (Rx) and/or Over the Counter (OTC)	Medical device nomenclature code as provided for in Article 26
7	Device is also a HCT/P, kit and/or Combination product	If applicable maximum number of reuses
8	Premarket submission number (PMA, Supplement Number , 510k, or device exempt)	Where applicable, information labelled in line with Section 10.4.5 of Annex I
9	FDA product code	URL for additional information
10	FDA listing number	If applicable, critical warnings or contra-indication
11	GMDN code	Status- recalled, field safety corrective action initiated

Following are common elements between GUDID and EUDAMED but they likely need to be translated into 24 official languages of the EU:

1. Name or Trade name
2. Additional product description
3. Clinical size
4. Storage and handling conditions
5. Additional trade names of the device
6. Critical warning or contra indications

EU UDI Compliance Dates*

Unlike GUDID, EUDAMED is adopting risk based approach for UDI submissions. Class III and the implantable device must be compliant by 2021, Class IIa and IIb devices by 2023, whereas Class I by 2025. For IVDs, the implementation will also be risk based but delayed the implementation of the IVDR timeline will be different. Class D devices should be compliant by 2023, Class C & B devices by 2025, while Class A devices by 2027.

*These compliance deadlines are subject to change as a fulfillment of the requirements is dependent on the progress of the EUDAMED implementation and its availability.

DDI Smarter Technology