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The Evolving UDI Landscape
Update on EU UDI System

Jay Crowley, VP
UDI Solutions and Services

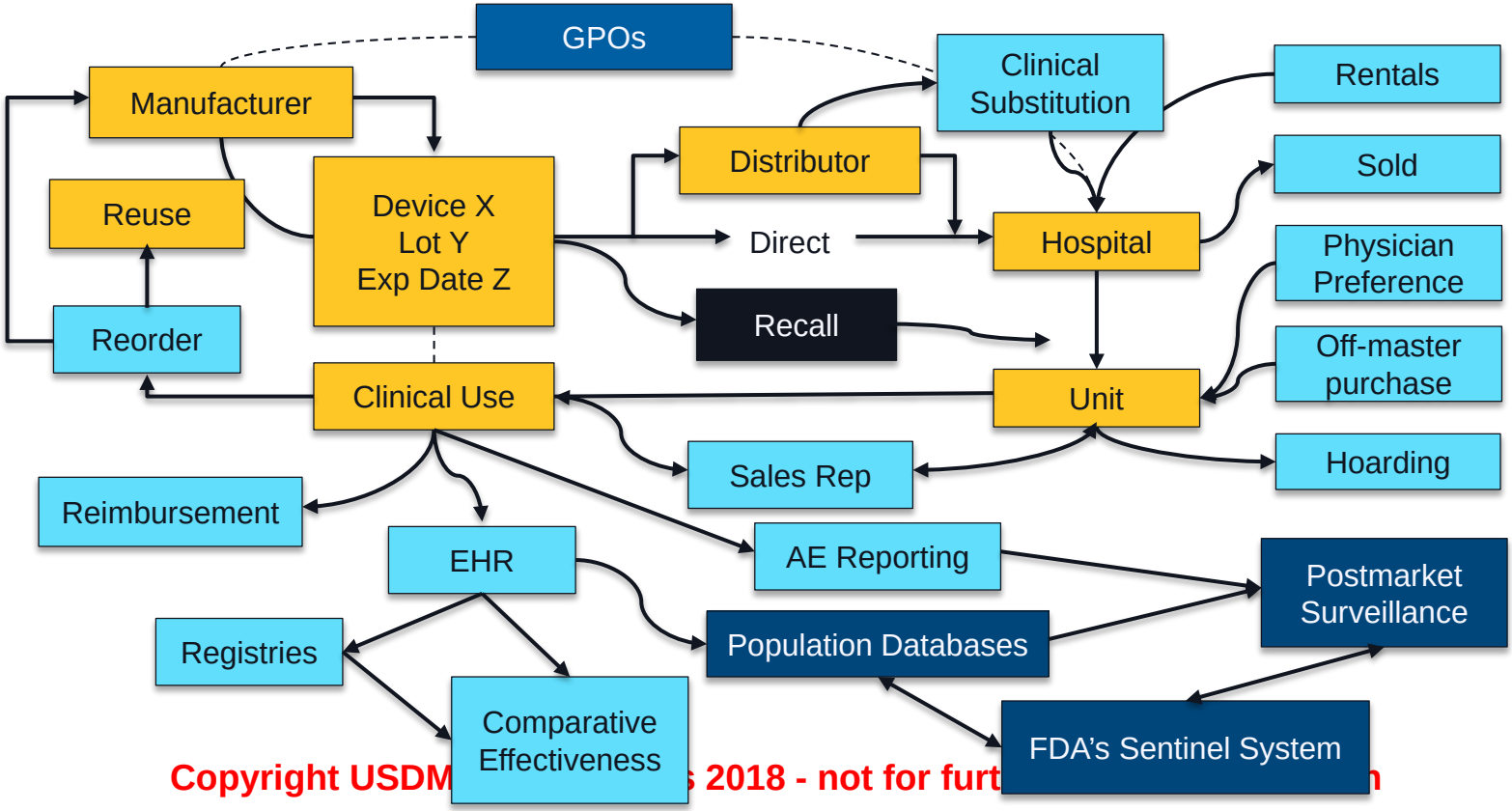
jcrowley@usdm.com
+1-805-880-2591

Drug Registration and Listing in the US

- Name and DUNS of the establishment (not corporate HQ)
- Contact information of responsible person for that establishment
- All applicable business operations that establishment performs
- Foreign establishments – name & DUNS of US agent and importers

- Full 10-digit NDC
- Proprietary and non-proprietary name
- Dosage form and route of administration;
- The name (+UNII) and amount/strength of each active ingredient
- Each inactive ingredient (name and UNII)
- *Copy of the most up-to-date labeling*
- *A photo (JPG) of the outer packaging and principal display panel*
- Name and DUNS for each establishment involved in manufacturing

Why UDI…?

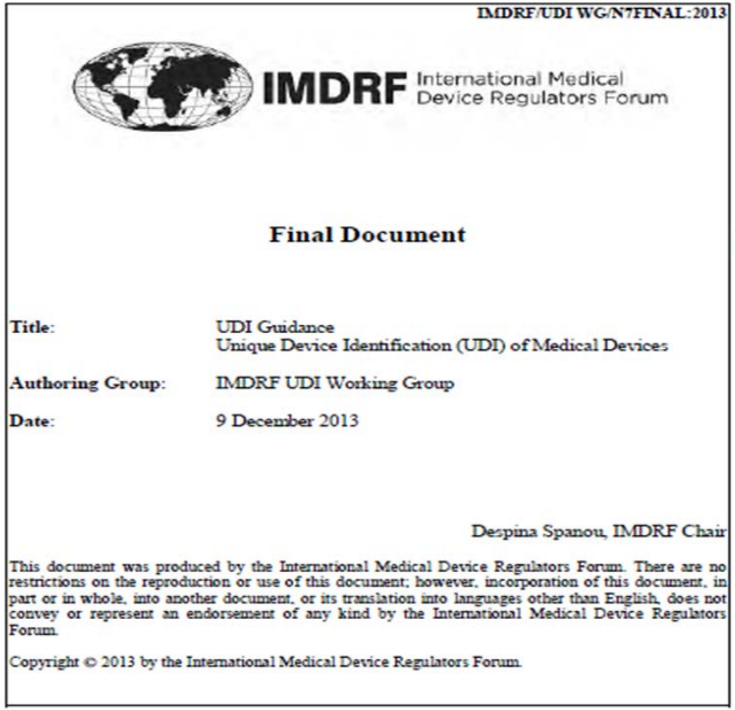


Public Health Benefits

UDI and GUDID provides global visibility and supports:

- Medical device recalls
- Adverse event reporting
- Tracking and tracing
- Supply chain security
- Anti-counterfeiting/diversion
- Disaster/terror preparation
- Shortages/substitutions
- Reduction of medical errors (e.g., bedside scanning)
- An easily accessible source of device information for patients and clinicians

IMDRF Guidance – Goal Largely Realized



IMDRF/UDI WG/N7FINAL:2013

IMDRF International Medical Device Regulators Forum

Final Document

Title:	UDI Guidance Unique Device Identification (UDI) of Medical Devices
Authoring Group:	IMDRF UDI Working Group
Date:	9 December 2013

Despina Spanou, IMDRF Chair

The Evolving UDI Global Landscape (GHTF/IMDRF based)

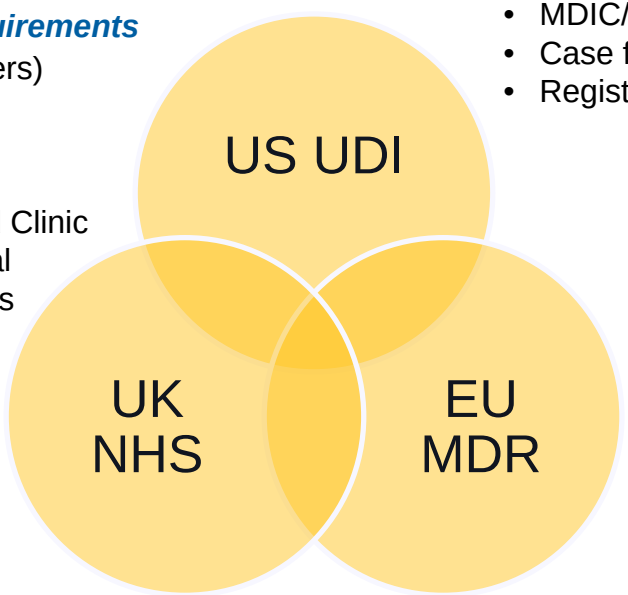
Commercial (Market) Requirements

- US IDNs (Kaiser, others)
- US GPOs
- US ONC/EHRs, CMS
- Canadian GPOs
- Abu Dhabi, Cleveland Clinic
- Qatar, Hamad Medical
- Netherlands, Hospitals

Country Requirements

(Ministry of Health, others)

- UK NHS
- Taiwan: (Voluntary)
- Japan MHLW (Already in place)



Postmarket Requirements

- MDIC/NEST
- Case for Quality
- Registries, Sentinel

Regulatory Requirements

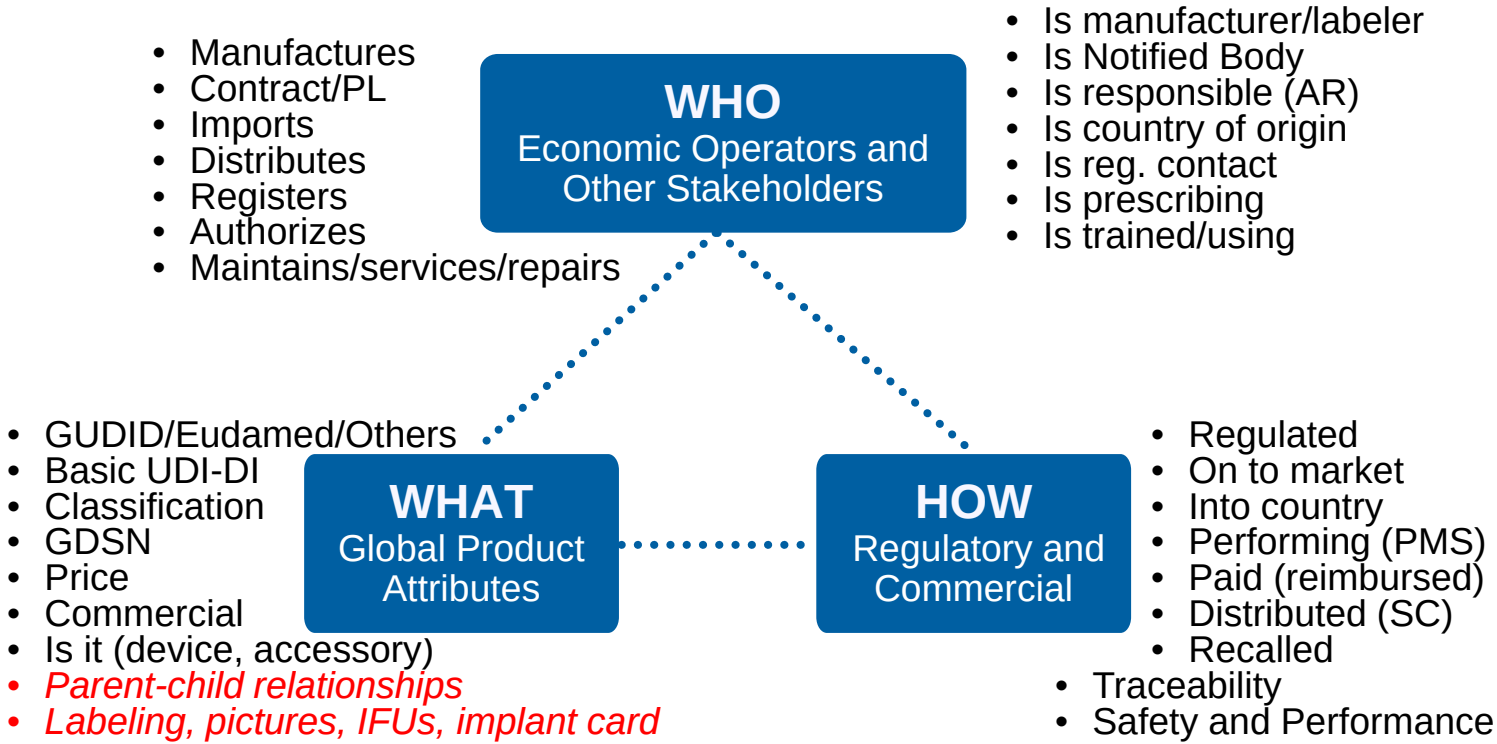
- Turkey: 2018 and beyond
- India: 2022
- Saudi Arabia: 2019?
- Taiwan: 2018-2020?
- China: Spring 2018?
- South Korea: 2019-2022?
- Singapore?
- Health Canada?

Traceability Requirements

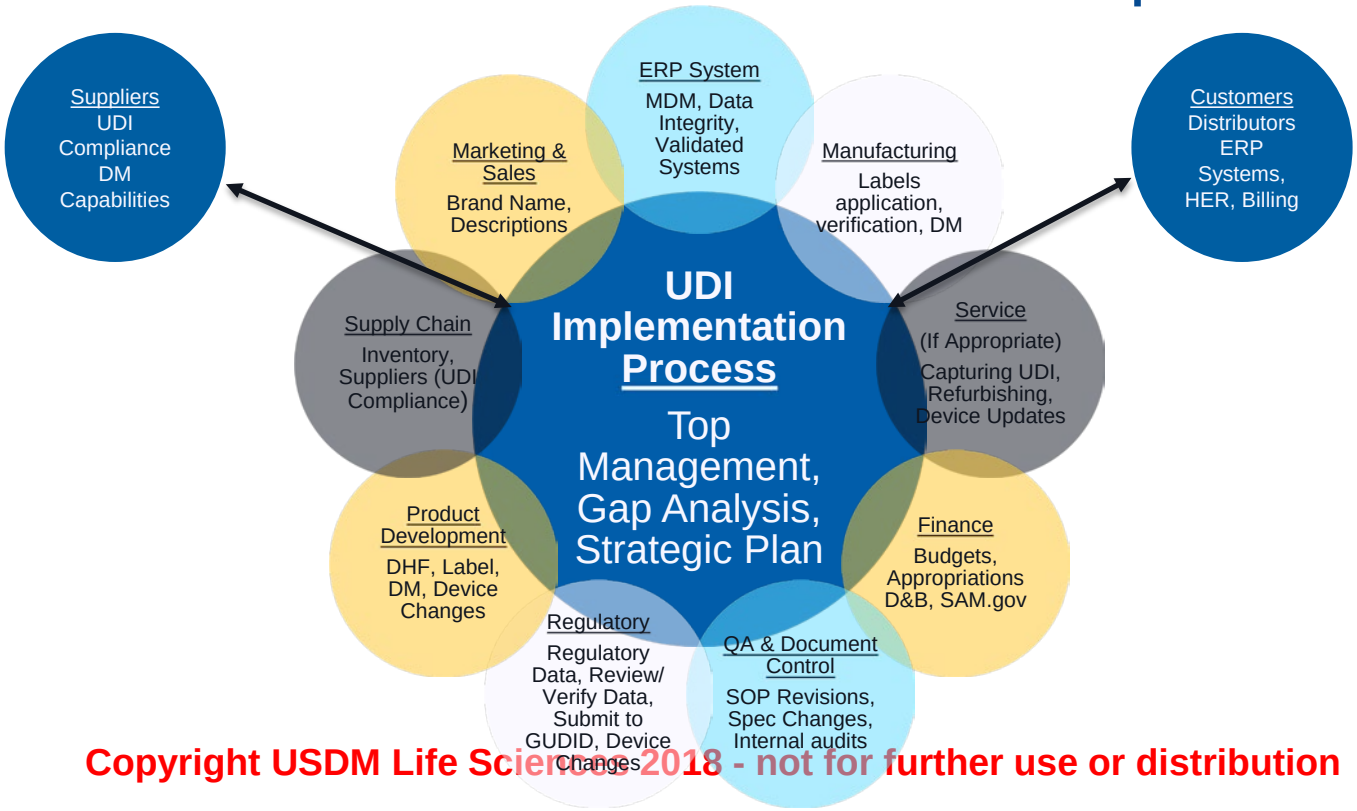
- EU class III implants
- Turkey UTS

Requirements are evolving and may vary by product!

The Visibility and Control Imperative



UDI and Who/What/How Touchpoints



Benefits/Needs of the EU UDI System

The EU Unique Device Identification (UDI) System will:

1. Provide for the traceability of devices
2. Enhance the effectiveness of post-market safety-related activities
3. Improve incident reporting
4. Provide for targeted field safety corrective actions
5. Provide for better monitoring by competent authorities
6. Reduce medical errors
7. Fight against falsified devices
8. Improve purchasing, waste disposal policies and stock-management by health institutions

Basic UDI-DI (***not a UDI***)

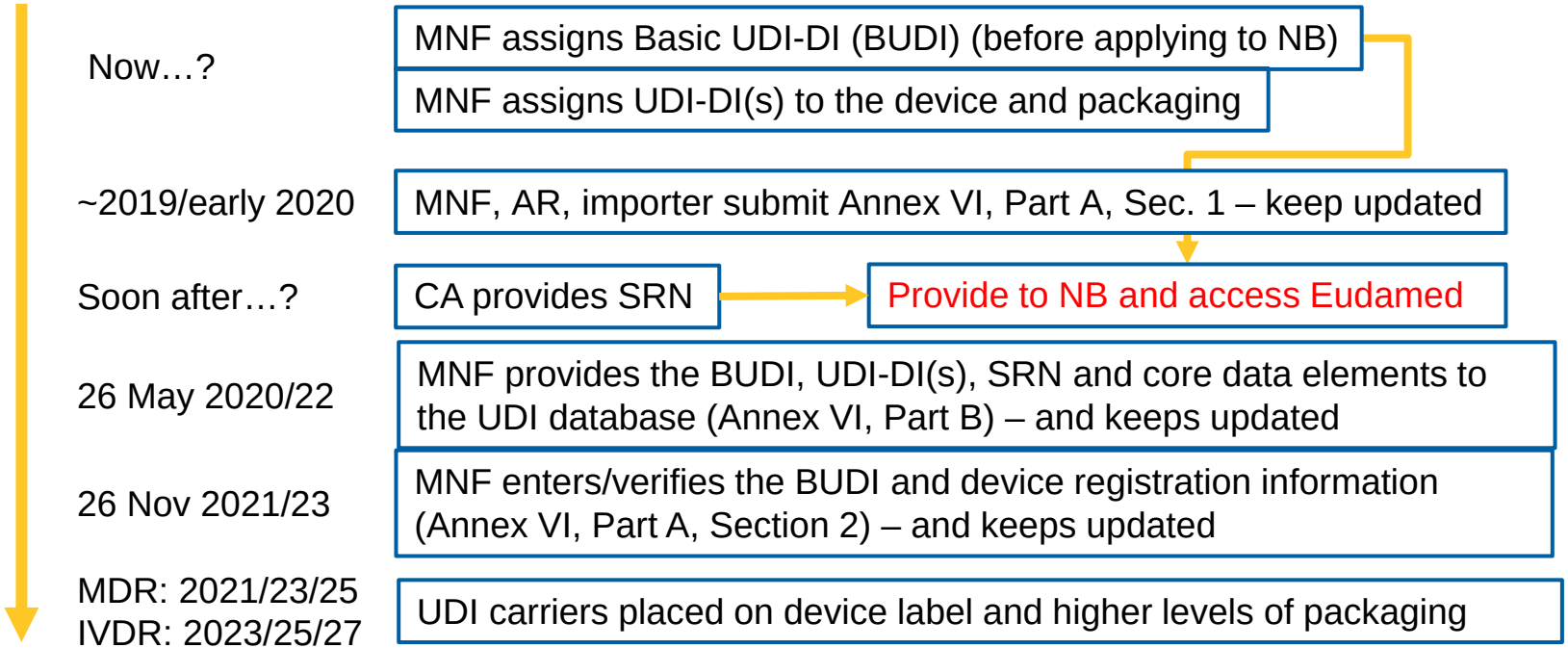
- The Basic UDI-DI is the main key in the database and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and clinical performance) to connect devices with same intended purpose, risk class and essential design and manufacturing characteristics.
- It is independent/separate from the packaging/labelling of the device and it does not appear on any trade item.
- Each certificate shall identify and cover all devices associated with the same Basic UDI-DI.
- A UDI-DI shall be associated with one and only one Basic UDI-DI.
- Does not (necessarily) apply to e.g. systems or procedure packs, software…

Overview of MDR/IVDR UDI Regulations

Basic UDI-DI – “is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.”

- Article 27[/24] UDI System
- Article 28[/29] UDI Database
- Article 29[/26] Registration of Devices
- Article 32[/29] Summary of safety and clinical performance (and SRN)
- Article 60[/55] Certificate of free sale
- Annex II Technical documentation
- annex IV EU declaration of conformity
- Annex VI Parts A and B
- Annex XII Certificates issued by a notified body

Before placing a device on the EU market…



Overview of MDR/IVDR UDI Regulations

Classification Changes Affecting UDI:

- For example: spinal, joints to Class III
- Class I sterile, measuring function, reusable instrument – need NB
- Annex XV – products with no Medical Purpose regulated as devices (e.g., contact lenses, liposuction)
- Products specifically intended for the cleaning, disinfection or sterilization of medical devices are considered medical devices
- Devices for the purpose of control or support of conception shall be considered medical devices
- Significant IVD classification changes

The EU UDI System

A *separate* UDI must be on a:

- System (products combined to achieve a medical purpose),
- Configurable device (device consisting of several components),
- Procedural pack (products packaged for a medical purpose), and
- IVD kit (products packaged together to perform an IVD exam).

A UDI must *ALSO* be on the *individual devices/packages* or *components* of a system, configurable device or procedure pack [but NOT an IVD kit], except:

- SUDs which are not intended for use outside the system/pack, or
- Devices that are (already) exempt are not subject when included.

The EU UDI System

Differences between a “configurable device” and a “system”

- Configurable device – **is a device** that *consists of several* ***components*** [undefined?] which can be ***assembled by the manufacturer*** in *multiple configurations*.

- System – means a *combination of* ***products*** [undefined?], either packaged together or not, which are ***intended to be inter-connected or combined*** to achieve a specific medical purpose.

The EU UDI System

Configurable Device – **is a device**

- Only called out specifically in Annex VI (PART C The UDI System)
- *Configurable device UDI* assigned to the entire configurable device
- Configurable device *UDI-DI* assigned to *groups of configurations* – which is the collection of possible configurations
- The configurable device UDI *carrier* must be on the assembly that is most *unlikely* to be exchanged during the lifetime of the system.
- *Individual components* may be [???] devices in themselves
- A *component* commercially available on its own needs its *own UDI*
- Include CT systems, ultrasound systems, anaesthesia systems, physiological Monitoring systems, etc.

The EU UDI System

System – is a *combination of* ***products***

Natural/legal person:

- Must verify the mutual compatibility and develop statement if they intend to combine CE marked device with other CE marked devices, IVDs, or other conforming products –compatible with the intended purpose and use specified by their manufacturers
- Becomes the manufacturer of the “system” (then a device in its own right) if it *incorporates non-CE marked devices* or *uses not compatible with the original intended purpose.*
- Responsible for identifying the system with UDI-DI and UDI-PI.

The EU UDI System

Additional *Implantable Device* Requirements:

- The lowest level of packaging shall be marked with a UDI.
- Active implantable devices must have a serial number.
- The device's UDI must be identifiable prior to implantation.
- An implant card, including its UDI, must be provided with device.

Additional *Software* (as a Medical Device – SaMD) requirements:

- That is a device and separately distributed must have its own UDI.
- The UDI is assigned at the system level.
- The label (AIDC and HRI) and software UDI **must** be identical.
- The UDI must be in HRI on readily accessible (e.g., about) screen.

The EU UDI System

Direct Marking

- Devices that are *reusable* shall bear a *UDI carrier* (AIDC and HRI representation of the UDI) *on the device itself*.
- The UDI carrier for reusable devices that require cleaning, disinfection, sterilization or refurbishing between patient uses:
  - shall be *permanent*
  - must be *readable throughout the device's intended lifetime*
- This shall *not apply* to devices when the direct marking:
  - –(a) would interfere with the safety or performance;
  - –(b) is not technologically feasible.

The EU UDI System

Exceptions

- Custom + investigational [/performance studies] devices exempt.
- Devices for retail/POS do not require PIs in AIDC on *POS* UDI label.
- Individual class I and IIa [/class A and B] *SUDs* do not require the UDI Carrier – UDI can be on a higher level of packaging.
- If there are *significant space constraints* (???):
  - *on the unit of use packaging* – the UDI carrier may be placed on the next higher packaging level.
  - limiting *both AIDC and HRI* on the label – only AIDC is required.

–However, for devices intended for e.g., home care, the HRI must be on the label – even if then there is no space for the AIDC.

The EU UDI System

Shipping containers ("… a container in relation to which traceability is controlled by a process specific to logistics systems.") are exempt.

4.1 Higher levels do not include shipping containers.

3.2 Shipping containers shall be exempted from the requirement in Section 3.1. By way of example, a UDI shall not be required on a logistics unit; where a healthcare provider orders multiple devices using the UDI or model number of individual devices and the manufacturer places those devices in a container for shipping or to protect the individually packaged devices, the container (logistics unit) shall not be subject to UDI requirements.

Obligations of Responsible Parties

- The *manufacturer* [the person who manufactures … or has a device designed, manufactured … and markets that device under his name] *is responsible for UDI* assignment and the UDI database.
- A *distributor/importer*…*assumes the obligations* of a manufacturer if he markets a device *under his name*…except when an agreement states the manufacturer is identified (on label) and is responsible.
- A person who *reprocesses a SUD* is considered the (re-) manufacturer of the SUD; assumes the traceability obligations.
- Manufacturers, authorized representatives, or importers *must ensure the UDI-DI in the registration system is complete*, correct and updated by the relevant party.

Importers and Distributors

In order to place a device on the market, each shall verify that:

- The device is CE marked and has EU DoC
- The device is labelled correctly and accompanied by IFU
- A UDI has been assigned by the manufacturer.

Importer - An authorised representative has been designated and the device is registered

Distributor – verify that the importer has complied with the requirements

Traceability

Economic operators (the manufacturer, authorized representative, importer, distributor, and system or procedure pack producers or sterilizers) *must keep* (*preferably by electronic means*), the UDI of these devices that they have BOTH supplied and been supplied with:

- Class III implantable devices, and
- Other devices the EC adopts through delegated acts.

Health institutions *must keep* (*preferably by electronic means*) UDI of:

- Class III implantable devices, and
- Others devices added by member states.

Implementation – Registration of Device

Article 29(4) shall apply 18 months later (Nov 2021/2023):
Before placing a device on the market… the manufacturer shall enter or verify the information referred to in Section 2 of Part A of Annex VI … and shall thereafter keep the information updated…

Article 29(4) – The Registration of Devices

1. Basic UDI-DI,
2. Type, number and expiry date of the certificates
3. Member State in which the device is placed on the market…
4. For class III and IIa/b - member states where the device is made available
5. Risk class of the device
6. Reprocessed single-use device (y/n)
7. Presence of a substance considered to be a medicinal product
8. Presence of a substance derived from human blood or plasma
9. Presence of tissues or cells of human or animal origin
10. Where applicable, the number of the clinical investigation(s)
11. For Annex XVI products, intended purpose other than medical
12. Contact information for devices designed/manufactured by another person
13. For class III/implantable devices – summary of safety and clinical performance

Implementation – Label and Packages

The *UDI carrier* must be placed on the *label of the device and on all higher levels of packaging*:

- For implantable and Class III devices/class D IVDs – 1 year after the date of application [26 May 2021/2023]
- For Class IIa and Class IIb devices/class B and C IVDs – 3 years after the date of application [26 May 2023/2025]
- For Class I devices/Class A IVDs – 5 years after the date of application [26 May 2025/2027].

For *reusable devices* that require UDI Carrier on the device itself:

- 2 years after the applicable class compliance date.

Implementation – UDI Database

It will apply (date of application):

- for MDR – three years after entry into force [26 May 2020]
- for IVDR – five years after entry into force [26 May 2022]

Article 29 1-2 – Registration of devices – due the later of the date of application or 6 months after publication of notice in Article 34(3):
Before placing a device, system or procedure pack … on the market, the manufacturer shall … assign a Basic UDI-DI … and shall provide it to the *UDI database* together with the other core data elements referred to in *Part B of Annex VI*…

Article 29(1,2) – The UDI Database

For every UDI-DI – the core data elements referred to in Part B of Annex VI:

1. Quantity
2. The Basic UDI-DI
3. The type of PI(s)
4. The unit of use DI
5. Manufacturer's name and address
6. The SNR
7. AR name and address
8. Medical Device Nomenclature
9. Risk class
10. Trade/brand name
11. Model, reference, or cat. number
12. Clinical size
13. Product description (optional)
14. Storage and/or handling conditions
15. Additional trade names
16. labelled as single use
17. Restricted number of reuses
18. Device packaged sterile
19. Need for sterilisation before use
20. labelled as containing latex
21. labelled as carcinogenic, mutagenic or toxic to reproduction
22. URL for additional information (optional)
23. critical warnings or contraindications

Implementation – Database Similarities

	US GUDID	EU Eudamed
1	Primary DI number (and issuing agency)	UDI-DI
2	Labeler company name and physical address (as represented by labeler DUNS)	Name and address of the manufacturer (as on the label),
3	Brand name	**Name or trade name (optional)**
4	Version or model	Device model, reference, or catalogue number (optional)
5	Catalog number (optional)	
6	Device description (optional)	**Additional product description (optional)**
7	Clinically relevant size (size type, size value, and size unit of measure – or size type text)	**Clinical size – including volume, length, gauge, diameter (if labeled)**
8	Production identifier(s) – lot or batch number, manufacturing date, serial number, expiration date, and/or donation identification number	Manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number)
9	For single-use (y/n)	Labelled as a single-use device (y/n)
10	Device packaged as sterile (y/n)	Device labelled sterile (y/n)
11	Requires sterilization prior to use (y/n)	Need for sterilisation before use (y/n)
12	Device labeled as containing natural rubber latex or dry natural rubber (y/n)	Containing latex (y/n)
13	Storage and handling (type, low value, high value, and unit of measure)	**Storage and/or handling conditions – as indicated on the label *or in the instructions for use* (if labeled)**
14	Device Count (for primary DI)	Quantity per package configuration
15	Package DI number Quantity per package Contains DI package	
16	Unit of use DI number	The unit of use UDI-DI
17	DI record publish date Commercial distribution end date	Status of the device (on the market, no longer placed on the market

Implementation – Database Differences

Unique US GUDID Attributes	Unique EU Eudamed Attributes
Labeler DUNS Number (Company Name and Company Physical Address)	The Basic UDI-DI
Secondary DI Number (and Issuing Agency)	The Single Registration Number (SRN)
Device subject to direct marking DM), but exempt	If applicable, name and address of the authorised representative (as on the label)
DM DI different from primary DI (and DM DI number)	If applicable, additional trade names of the device
Customer Contact – phone and email	Risk class of the device
Prescription use (Rx) and/or Over the Counter (OTC)	The medical device nomenclature code as provided for in Article 26
Device is also a HCT/P, kit and/or combination product	If applicable, the maximum number of reuses
Premarket submission number (PMA, PMA supplement number, 510k, or device exempt)	Where applicable, information labelled in accordance with Section 10.4.5 of Annex I
FDA product code (auto-populates product code name)	URL for additional information, such as electronic instructions for use (optional)
FDA listing number	If applicable, critical warnings or contra-indications
GMDN code (auto-populates name and definition)	Status – recalled, field safety corrective action initiated
Device labeled as "Not made with natural rubber latex"	
MRI safety status (safe, unsafe, or conditional – or label does not contain)	
Special storage conditions	
Sterilization method (specified list of values)	
Package type	

Implementation – Database Translations

These fields, which are common to GUDID and Eudamed, will most likely need to be translated into the **24 official languages of the EU**:

1. Name or trade name
2. Additional product description
3. Additional trade name
4. Clinical size – including volume, length, gauge, diameter
5. Storage and/or handling conditions – as indicated on label or IFU
6. Additional trade names of the device
7. Critical warnings or contra-indications
8. Name and address of authorized representative
9. CMR and/or endocrine-disrupting substances

US vs EU – Significant Differences

- Class I devices: EU needs both DI and PI
- SUD packaging exception: EU limited to class I/IIa [/class A/B]
- Software: EU label and software UDI must be identical
- DM UDI: EU UDI must be both AIDC and HRI
- Direct Mark: EU does NOT exempt devices that are only cleaned between different patient use and single patient use.
- “Existing inventory” exemption: EU does not have

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Questions?

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Web: usdm.com
Email: usdm@usdm.com
Phone: 888-231-0816