
Whereas: (41/38) The \textit{traceability of devices} by means of a \textit{Unique Device Identification (UDI) system} ... should significantly enhance the effectiveness of the \textit{post-market safety-related activities} for devices, which is owing to \textit{improved incident reporting, targeted field safety corrective actions} and \textit{better monitoring by competent authorities}. It should also help to \textit{reduce medical errors} and to \textit{fight against falsified devices}. Use of the UDI system should also \textit{improve purchasing and waste disposal policies} and \textit{stock-management} by health institutions and other economic operators and, where possible, be compatible with other authentication systems already in place in those settings.
The EU MDR and IVDR UDI Requirements
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IMDRF Guidances – Goal Largely Realized
The Evolving UDI Global Landscape

In the US – Also IDNs (Kaiser); GPOs ONC/EHRs, CMS

“Commercial” or (Ministry of) Health/Cost/Import Control Requirements

Regulatory Requirements
South Korea – 2019-2022
India – 2022
Saudi Arabia – ~2018-2020
Taiwan – ~2018-2020
Canada – “IMDRF” (like?)...
China – could be any day...
Singapore – coming...

Traceability Requirements
US GUDID, UK NHS and EU MDR/IVDR

Various, exponentially growing data needs – to meet multiple regulatory and commercial purposes.

• In the US – tying together device meta-data (e.g., brand name, device attributes), premarket (e.g., 510k, PMA), and Registration and Listing (R&L – listing number – used for import control)

• In the EU – similar – but more... (see next slides)

• In the UK – GDSN product/packaging data – and pricing...?

• Other countries... where is it manufactured (country of origin – is that product allowed in that country?), who (contract) manufactured it, parent-child relationships (parent-accessory relationships), contents of kits, combination products...?
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
Before placing a device on the market...

1. Manufacturers, authorised representatives and importers submit information (Annex VI, Part A, Section 1) – and keeps updated
2. The competent authority provides a single registration number (SRN) – used when applying to a NB and for accessing Eudamed
3. MNF assigns a Basic UDI-DI (BUDI) to the device
4. MNF enters/verifies the BUDI and device registration information (Annex VI, Part A, Section 2) – and keeps updated
5. MNF assigns UDI-DI(s) to the device and (higher levels) packaging
6. MNF provides the BUDI, UDI-DI(s), SRN and core data elements to the UDI database (Annex VI, Part B) – and keeps updated
7. UDI carriers placed on device label and higher levels of packaging
Overview of MDR/IVDR UDI Regulations

Article 10 General obligations of manufacturers

• 7[/6]. Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27[/24] and with the registration obligations referred to in Articles 29[/26] and 31[/28].

• 9[/8]. The quality management system shall address at least the following aspects: (h) verification of the UDI assignments made in accordance with Article 27[/24](3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29[/26].
Overview of MDR/IVDR UDI Regulations

Article 13 *General obligations of importers*
2. In order to place a device on the market, importers shall verify that:
   (d) where applicable, a **UDI has been assigned by the manufacturer** in accordance with Article 27[/24].

Article 14 *General obligations of distributors*
2. Before making a device available on the market, distributors shall verify that:
   (d) where applicable, a **UDI has been assigned by the manufacturer**.
Overview of MDR/IVDR UDI Regulations

Article 18 [MDR only] *Implant card and information to be supplied to the patient with an implanted device*

1. The manufacturer of an implantable device shall provide together with the device the following:
   (a) information allowing the identification of the device, including the device name, …. the UDI, … as well as the name, address and...

In addition, the manufacturer shall provide the information referred to in point (a) ... on an implant card delivered with the device.
Overview of MDR/IVDR UDI Regulations

• Article 27[24] Unique Device Identification system
• Article 28[25] UDI database
• Article 29[26] Registration of devices
• Article 33[30] European database on medical devices – including the UDI Database
• Article 87[82] Reporting of serious incidents and field safety corrective actions (Article 27[24]-5 The UDI shall be used for reporting serious incidents and field safety corrective actions)
• Article 92[87] Electronic system on vigilance and on post-market surveillance – “That electronic system shall include relevant links to the UDI database.”
Overview of MDR/IVDR UDI Regulations

• Annex VI – Part A: Information to be submitted upon the registration of devices and economic operators in accordance with articles 29(4)[/26(3)] and 31[/28] (Basic UDI-DI)

• Annex VI – Part B: Core data elements to be provided to the UDI database together with the UDI-DI in accordance with articles 28[/25] and 29[/26]

• Annex VI – Part C: The UDI System
  2.1. The affixing of the UDI is an additional requirement – it does not replace any other marking or labelling requirements laid down in Annex I to this Regulation.
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], 29[/26]
- Article 32[/29] Summary of safety and clinical performance
- 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
Overview of MDR/IVDR UDI Regulations

Classification Changes Affecting UDI:
• For example: spinal, joints to Class III; reusable surgical instruments from class I to Class IIa
• 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

• The UDI system shall allow the identification and *facilitate the traceability* of devices.
• “The *label* shall bear ... (h[/g]) *the UDI Carrier* as referred to in Article 27[/24] and Part C of Annex VI” [Annex I, Chap 3, 23[/20].2]
• UDI – UDI-DI (Device Identifier – specific to a model) + UDI-PI (Production Identifier(s) – include lot, serial number, software identification or expiration date); manufacturing date if only PI.
• UDI assigned to device itself or its package.
• Developed using global standard (e.g., GS1, HIBCC, ICCBBA)
• The UDI-DI shall be unique at each level of device packaging.
• Accessories are considered devices and subject to UDI.
The EU UDI System

The UDI Carrier (Annex VI, Part C) “…is the means of conveying the UDI by using AIDC and, if applicable, its HRI.”

• The UDI carrier (AIDC and HRI representation of the UDI) shall be placed on the label or on the device itself and on all higher levels of device packaging (4.1).

• The HRI format shall follow the rules of the … issuing entity (4.8).

• The DI and PI may be concatenated or non-concatenated (4.6).

• If the manufacturer is using RFID … a linear or 2D bar code … shall also be provided on the label (4.9).

• The UDI carrier (label and DM) shall be readable during normal use and throughout the intended lifetime of the device (4.11).
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, sterilisation 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.
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 interconnected 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

A new UDI-DI is required when there is a change:

• That could lead to misidentification of the device and/or ambiguity in its traceability.

• In the UDI Database for information in fields: Brand 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; or Critical warnings or contraindications.

• For software, whenever there is a modification that affects the original performance and effectiveness; the safety or the intended use; or interpretation of data.
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.
A medical (“combination”) product is subject to the MDR – and therefore UDI – if the device:

- Incorporates as an integral part an IVD medical device [MDR].
- Incorporates a medicinal product ... including a product derived from human blood or plasma ... with action ancillary to the device [PMOA device].
- Is intended to administer gene therapy medicinal products.
- Incorporates tissues or cells of human origin or their derivatives with action ancillary to the device [PMOA device].
The EU UDI System

Exceptions – a (“combination”) medical product is subject to the applicable non-device directive/regulation:

• If the action of the medicinal substance is principal, not ancillary to that of the device [PMOA drug].

• If the device is intended to administer a medicinal product and it forms a single integral product which is intended exclusively for use in the given combination and which is not reusable [“single entity” CP].

• If the action of the tissues or cells or their derivatives is principal, not ancillary to that of the device and the product is not governed by the advanced therapy medicinal products [PMOA biologic].
The EU UDI System

The manufacturer must provide the UDI-DI and the following core data elements to the UDI Database (Part B of Annex VI):

1. quantity per package configuration,
2. if applicable, the Basic UDI-DI according to article 24(4b),
3. the device PI(s) appearing on the label/package,
4. if applicable, the unit of use DI (when a UDI is not assigned at the level of its unit of use, a 'unit of use' DI must be assigned to associate use of a device with a patient),
5. name and address of the manufacturer (as indicated on the label),
5a. the single registration number according to article 25a(2),
6. if applicable, name and address of the authorized representative (as on the label),
7. Medical Device Nomenclature code according to article 23a,
7a. risk class of the device,
8. if applicable, trade/brand name,
The EU UDI System

9. if applicable, device model, reference, or catalogue number,
10. if applicable, clinical size (including volume, length, gauge, diameter),
11. additional product description (optional),
12. if applicable, storage and/or handling conditions (as indicated on the label or IFU),
13. if applicable, additional trade names of the device,
14. labelled as single use device (y/n),
15. if applicable, restricted number of reuses,
16. device packaged sterile (y/n),
17. need for sterilization before use (y/n),
18. labelled as containing latex (y/n),
19. labelled in accordance with Annex I, section 7.4.5..
20. URL for additional information, e.g. electronic instructions for use (optional),
21. if applicable, critical warnings or contraindications.
22. status of the device on the market
Obligations of Responsible Parties (1/2)

• 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.
Obligations of Responsible Parties (2/2)

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) the UDI of:

• Class III implantable devices, and
• Others devices added by member states.
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...
Implementation – Registration of Devices

Article 29(4) shall apply 18 months later (26 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...

Section 2 of Part A of Annex VI - Information relating to the device
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. in the case of class IIa, class IIb or class III devices: Member States where the device is or is to be made available,
Implementation – Registration of Devices

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. ... to be a product derived from human blood or human 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 – US UDI Similarities (1/2)

- As in the US, largely based on GHTF + IMDRF UDI guidances
- UDI assigned/marked with AIDC+HRI on device labels & packages
- Use of global Issuing Agencies (GS1, HIBCC, ICCBBA)
- UDI for accessories, systems (and configurable devices), and procedure packs/convenience kits
- “Combination products” – if regulated as device – needs UDI
- UDI for SaS/SaMD in embedded screen and label/physical media
- Shipping containers, custom and investigational devices – exempt
- PIs (generally) not specified
- Retail/POS do not require PIs in UDI (US class I, others by request)
Implementation – US UDI Similarities (2/2)

- Technology neutral approach (no specific AIDC required)
- Reusable devices need “direct mark” (permanent) UDI on device
- UDI for implants MUST be identifiable prior to implantation.
- UDI Database – submit (static) core data attributes for each device
- Data for a new UDI-DI must be entered before the device is placed on the market; other changes within 30 days.
- New UDI-DI is required when there is a change to the device or in certain UDI Database fields
- Barcode verification
Implementation – US UDI Differences (1/2)

- Responsibility: US Labeler vs EU Manufacturer
- SUD packaging exception: EU limited to class I/IIa [/class A/B]
- Procedure packs (aka kits) and Systems: EU individual devices must ALSO be UDI compliant – unless SUD or already exempted
- Configurable device: EU UDI on separately distributed components
- IVD Kits: EU UDI for individually distributed reagents and articles
- Standardized date format (YYYY-MM-DD): EU not required
- Software: EU label and software UDI must be identical
- GMP-exempt Class I devices: EU does not have
Implementation – US UDI Differences (2/2)

• Class I devices: EU needs both DI and PI
• 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
Questions?
Thank You for Attending!

Follow-up Resources
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