GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

Proposed Document

Title: Creation and Placement of Unique Device Identifier

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Introduction

The implementation of the UDI System will help to establish a single, globally harmonized system, so that medical device stakeholders will no longer have to access multiple, inconsistent, and incomplete sources in an attempt to identify a medical device and, its key attributes. It is critical to note that the benefits of UDI can only accrue if all stakeholders integrate and utilize UDI throughout their respective systems and processes. Therefore, strengthening training and guidance in production, distribution, and use is of great significance in the implementation of the UDI System.

A UDI System comprises three parts: the unique device identifier, the UDI data carrier and the UDI database, corresponding to UDI creation, placement and data upload respectively. To address UDI creation and placement, this document stipulates the requirements for implementation and application by stakeholders, and is a useful supplement to the relevant regulations. Given the diverse nature of medical devices, discrepancies may exist in UDI implementation for different device types. This document also specifies the requirements for UDI creation and placement for specific device types, with the intent to provide references for UDI implementation and application by medical device stakeholders.

Creation and Placement of Unique Device Identifier

1 Scope

This document specifies the requirements for UDI creation and placement.

This document applies to UDI implementation and application by all stakeholders.

2 References

[1] ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

[2] IMDRF UDI WG. UDI Guidance: Unique Device Identification (UDI) of Medical Devices.

[3] IMDRF UDI WG. Unique Device Identification system (UDI system) Application Guide.

[4] BS EN 1556:1998 Bar coding. Terminology

[5] ISO 13485: 2016 Medical devices — Quality management systems — Requirements for regulatory purposes

* For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

[6] MDR Regulation.Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.)

[7] MDR Regulation.MDCG 2019-8 v2 Guidance document Implant Card relating to the application of Article 18 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

[8] YY/T 1879-2022 Creation and placement of unique device identifier. Pharmaceutical Industry Standard of the People’s Republic of China.

3 Terms, Definitions and Abbreviations

3.1 Terms and Definitions

1) General Terms

Unique Device Identification system

The identification system for medical devices composed of a device identifier, a production identifier, a unique device identifier data carrier, and unique device identification database.

Label

The literal instructions, graphic information appearing on the medical device itself or on its packaging, which are used to identify the product features and indicate the safety warnings and other information.

Labelling

The label, instructions for use and any other information related to the identification, technical description, intended use and proper use of the medical device, not including shipping document.

Direct Marking

The process of applying the unique device identifier permanently to the device itself.

Note1: For devices intended to be used more than once and intended to be reprocessed before each use, direct marking can make the device identifiable after reprocessing. Some jurisdictions may place direct marking mandatory for certain kind of device. While the definition of reprocessing can be further outlined in national regulations.

Note2: If the medical device is packaged, the direct marking may be accepted different than UDI-DI on the device label.

Shipping Container

A container where the traceability is controlled by a logistics system process whose contents may vary from one shipment to another.

Packaging Level

The various levels of device packages that contain a fixed quantity of medical devices.

Note: This does not include shipping containers.

Minimum sales unit

For the purpose of product sales, the minimum sales package of the product assigned by

the manufacturer.

Note1: The minimum sales unit is usually the lowest level of packaging with UDI.

Note2: When the minimum sales unit contains multiple medical devices, healthcare facilities should have access to the minimum sales unit packaging to ensure the traceability of the medical device.

2) Unique Device Identifier

Unique Device Identifier(UDI)

A series of codes composed of numbers, letters and/or symbols and created based on a standard. It is comprised of device identifier and production identifier and used for the uniqueness identification of a medical device.

Note 1: The word “unique” does not imply serialization management of individual products.

Note 2: It can be used for the management and tracing of medical device products.

Device Identifier (UDI-DI)

A unique code specific to a specification, model or packaging of medical device.

Note: Device identifier can be used as the “access key” to information stored in a unique device identification database to associate the product information, manufacturer information and registration information of the medical device.

Production Identifier (UDI-PI)

A code that identifies the data related to the production process of the medical device.

Note: According to the actual application requirements, a production identifier may include the serial number, batch/lot number, software version, manufacturing date, and expiration date of the medical device.

Data Delimiter

A character or character set that defines a specific data element in a unique device identifier.

Note: Some examples of data delimiters include application identifier (AI) and object identifier (OID).

Unit of Use Device Identifier (UoU UDI-DI)

An identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient.

Note: For example, for one pack of N (N>1) blood collection tubes, an identifier assigned to an individual blood collection tube when a UDI is not labeled on the individual blood collection tube.

3) Unique Device Identifier Data Carrier

Unique Device Identifier Data Carrier

The data medium that stores or transfers the UDI. The UDI Carrier is the means to convey the UDI by using AIDC and, if applicable, its HRI.

One-dimensional bar code

A bar code symbol that represents information only in one-dimensional direction. Usually referred to as a linear bar code.

Two-dimensional bar code

A bar code symbol that represents information in two-dimensional directions. Contains information within its horizontal and vertical structure.

Radio frequency identification (RFID)

A technology that uses the electromagnetic or inductive coupling in the RF section of the spectrum to intercommunicate with an RF tag for the purpose of the unique reading of its identity through various modulation and coding schemes.

RF Tags

A data carrier that is used for the identification of an object or article and has the ability to store information, receive electromagnetic modulation signals from a reader-writer and send back corresponding signals.

4) Unique Device Identification Database

Unique Device Identification Database (UDID)

The database that stores the device identifier and other relevant information about specific devices.

3.2 Abbreviations

The following abbreviations are applicable to this document.

AIDC: automatic identification and data capture

HRI: human readable information/interpretation

UDI: unique device identifier

UDID: unique device identification database UDI-DI: device identifier

UDI-PI: production identifier

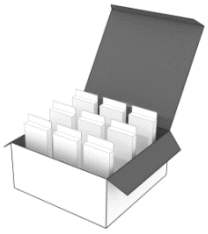
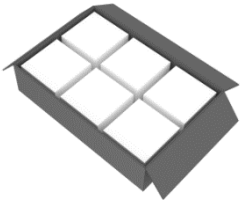
UoU UDI-DI: unit of use device identifier

4 General principles for UDI creation

UDI creation should follow the general principles listed below.

1) The UDI should contain two parts: an UDI-DI and an UDI-PI.
2) The UDI should be created according to the coding rules of the issuing agency selected; if the national regulations and standards provide otherwise, such provisions should be followed.
3) A UDI should be assigned to the device itself, its package, or the minimum sales unit of the medical device, and higher levels of packaging (not including shipping containers) should have their own UDI.
4) Different UDI-DIs should be assigned to each level of device packaging, see Table 1, and the linkage in the UDID should be maintained.

Table 1 Device Identification and Packaging Diagram of Medical Devices

		
Single device or minimum package	Box	Carton
Quantity=1	Quantity in each box=9	Quantity in each carton=54
Device identifier A	Device identifier B	Device identifier C

5) When the minimum sales unit contains more than one identical unit of use, a UoU UDI-DI should be assigned and stored in the UDID to associate the use of a device with a patient.

6) The UDI-DI should be stable. If there is no change in the essential characteristics of the medical device, the UDI-DI should remain the same, but whenever there is a change that could lead to misidentification of the medical device and/or ambiguity in its traceability, a new UDI-DI is required, for example, change in the quantity of products in the package, packaging sterility status and/or labeling for single use, etc.

Note: Essential characteristics of UDI-DI can be further outlined in national regulations. Whether this is the responsibility of an individual or an institution can depend on national regulations. It is recommended to minimize differences between regulatory agencies.

7) The composition of the UDI-PI should be consistent with the label. For example, when the label of the medical device contains one or more of the production batch number, serial number, manufacturing date and expiration date of the medical device, it is recommended that they should be part of the UDI-PI, and the content should be identical to the corresponding information on the label; if the representation format of the date is involved, it should conform to the coding standard of the issuing agency selected.

Note1: If some regulatory agencies allow other traceability information in the label, the manufacturing date may not be placed in the PI.

Note2: Software as a Medical Device (SaMD) version.

8) The UDI-PI characteristics (e.g. lot or serial number) shall be defined by the manufacturer according to the manufacturer's quality management. For medical devices controlled by batch production, considering the application scenario, if marking on a single product is required, a serial number should be included in addition to the combination of UDI-DI and production batch number, or other data delimiters should be included according to the coding standard of the issuing agency selected.

5 General Principles for UDI Placement

UDI placement should follow the general principles listed below.

1) The UDI placement requirements should not replace the requirements of existing marking or labelling regulations.

2) UDI placement should be done according to the criteria or specifications of the issuing agency, and the issuing agency should provide the data carrier rules for its criteria, including but not limited to the requirements for carrier type, size, placement and carrier quality, and the recommendation for the corresponding HRI representation form.

3) UDI data carriers include AIDC and HRI, and the HRI portion should include data delimiter. In case of space constraints or restrictions of use, the AIDC carrier form should be favored.

4) To facilitate all stakeholders throughout distribution and use to quickly search and locate UDI data carriers, the UDI graphic symbols (see Table 2) specified in 5.7.10 of ISO 15223-1:2021 should be used to identify data carriers containing UDI information. If used, it shall comply with the requirements of ISO 15223-1:2021. For the one-dimensional code and/or two-dimensional code data carrier identification using this symbol, see Figure 1.

Table 2 Symbols to convey medical device information

Reference number and graphic	Title	Description	Requirements	Notes	Restrictions of use	ISO/IEC symbol number and registration date
5.7.10 (ISO 15223-1:2021) 	Unique Device Identifier	Indicates a data carrier that contains Unique Device Identifier information	This symbol may be used when multiple data carriers are present on the label. If used, this symbol shall be placed adjacent to the Unique Device Identifier carrier.	This symbol identifies the UDI carrier, including the AIDC and HRI.	—	N/A

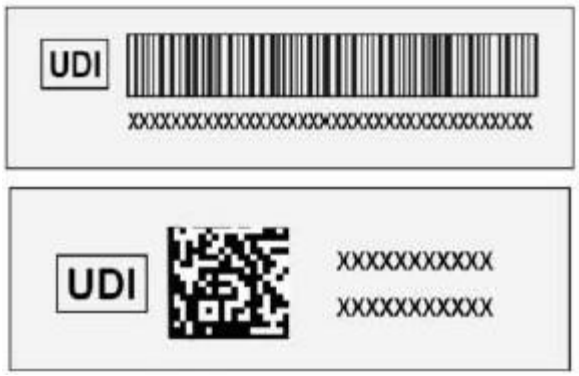


Figure 1 Schematic representation of 1D and/or 2D code using UDI graphic symbol

Note: This figure is for the purpose of illustration only to provide a reference for the use of UDI graphic symbols.

5) UDI data carriers should be placed in an easily visible position. If other types of AIDC representation other than UDI are placed on the relevant packaging, label or device, the placement of these other internal or proprietary AIDC markings should be done in such a way as to avoid causing confusing with UDI data carriers.

6) UDI data carriers should be readily readable throughout distribution and use of medical devices. Currently, the common forms of data carriers include: marking on the package, marking on the label and direct marking on the device itself, as shown in Figures 2 to 4.

Figure 2 Marking on the medical device package

Figure 3 Marking on the medical device label

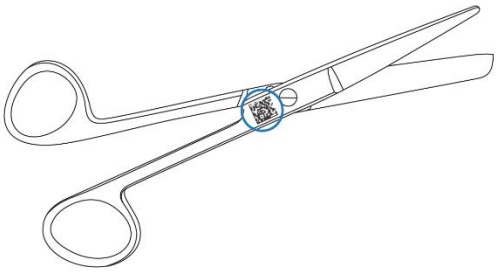


Figure 4 Direct marking

Note：The above figures are only the UDI representation.

7) The influence of transportation, storage and handling environment on the readability of UDI data carriers should be taken into consideration. The placement of UDI data carriers may refer to the relevant requirements of the national regulations and standards.

8) Avoiding scanning obstacles

Anything that will obscure or damage a barcode will reduce scanning performance and shall be avoided. For example:

i. Never position the barcode on the item in an area with inadequate space. Do not let the other graphics encroach on the space for the barcode.

ii. Never place barcodes, including Quiet Zones, on perforations, die-cuts, seams, ridges, edges, tight curves, folds, flaps, overlaps and rough textures.

iii. Never put staples through a barcode or its Quiet Zones.

iv. Never fold a barcode around a corner.

v. Never place a barcode under a package flap.

vi. Barcodes used for production control purposes SHOULD be obstructed wherever possible before entering general distribution.

Obscuring the barcodes on individual units inside the multipack is necessary so they are not confused with the outer multipack barcode, which shall have different DIs.

1) If the space permits, considering the management and use needs of medical devices, it is encouraged to assign UDI data carriers at the level of device unit of use.
2) Reusable medical devices should be assigned with UDI data carriers via direct marking. If direct marking is used, the UDI data carrier should be readable after each reprocessing cycle for the intended life of the product.
3) Direct marking should not compromise the safety and effectiveness of the medical device.

6 UDI Creation and Placement General Principles for Specific Device Types

6.1 Medical Device Kits

UDI creation and placement for medical device kits should follow the general principles listed below:

1) Individually sold and used medical device kits should have their own UDI;
2) Individually sold and used medical devices within a medical device kit should have their own UDI;
3) Single-use disposable medical devices within a medical device kit which are not intended for use outside the context of the kit do not require their own UDI.

6.2 Software as a Medical Device (SaMD)

UDI creation and placement for SaMD should follow the general principles listed below.

1) The UDI should be assigned at the level of the device.
2) The full version of the software is considered an important tool to achieve SaMD traceability and should be displayed in the UDI-PI.
3) A major software update for SaMD would require a new UDI-DI, and only a minor software update would require a new UDI-PI (not a new UDI-DI).

Major software update whenever there is a modification that changes:

(i) the original performance;

(ii) the safety or the intended use of the software;

(iii) interpretation of data.

Minor software update are generally associated with bug fixes, usability enhancements that

are not for safety purposes, security patches or operating efficiency.

Minor software update shall be identified by a manufacturer-specific form of identification.

4) Typically, the software version can be represented by the data delimiter of the production batch number. If the issuing agency assigns a specific data delimiter for the software version, such specification can also be followed.

5) When the SaMD is delivered on a physical medium, e.g. CD or DVD, each package level shall bear the human readable and AIDC representation of the complete UDI. The UDI that is applied to the physical medium containing the SaMD and its packaging must be identical to the UDI assigned to the system level SaMD.

6) UDI should be provided on a readily accessible screen by the user in an easily-readable plain-text format (e.g. an "about" file or included on the startup screen).

7) The SaMD lacking a user interface must be capable of transmitting the UDI through an Application Programming Interface (API).

Note: The cybersecurity of the UDI data transfer requires integrity of all incoming data, ensuring that it is not modified in transit or at rest. Also, it requires all data originating from external sources is well-formed and compliant with the expected protocol or specification.

8) Only the human readable portion of the UDI is required in electronic displays of the SaMD. (including data delimiter).

The UDI AIDC marking needs not be used in the electronic displays, e.g. about menu, splash screen, etc…; i.e. SaMD not being distributed by the use of physical data carriers (CDs, DVDs or similar) will not carry an AIDC.

6.3 Implantable Devices

UDI creation and placement for implantable devices should follow the general principles listed below:

1) The lowest level of device packaging of implantable devices shall be identified with an UDI;

2) The UDI-PI of active implantable devices shall contain at least the serial number, and the UDI-PI of other implantable devices shall contain at least the production batch number and/or serial number;

3) The UDI of the implantable device must be identifiable prior to implantation;

4) If the implantable device is affixed with an identification used to record medical device-related information in the medical record, UDI information should be included.

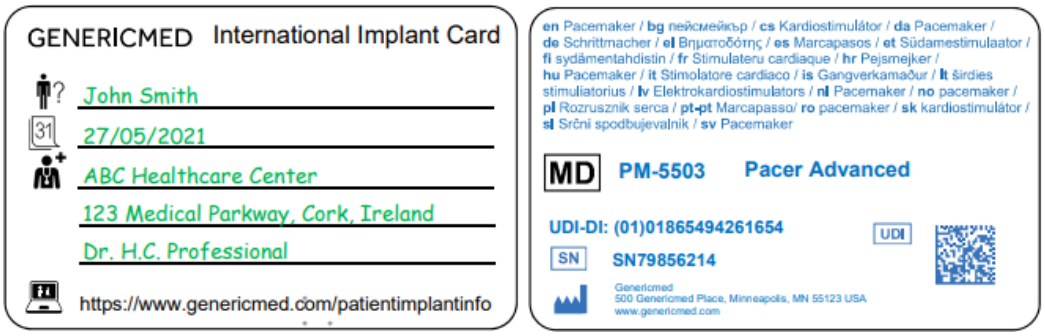


Figure 5 Patient Implant Card Representation

6.4 Configurable Medical Device

A configurable medical device system consists of several components which can be assembled in multiple configurations. Those individual components may be medical devices itself and/or non-medical devices.

Examples are Computed Tomography (CT) systems, Ultrasound systems, Anesthesia systems, Physiological Monitoring systems, Radiology Information System (RIS).

Configuration

Configuration is a combination of items of equipment, as specified by the manufacturer, that operate together to provide an intended use or purpose as a medical device. The combination of items may be modified, adjusted or customized to meet a customer need. The configuration may take place before a device is purchased or after the device has been placed on the market.

Examples:

1. CT: gantry, tube, table, console are items of equipment that can be configured/combined to deliver an intended function.
2. Anesthesia: ventilator, breathing circuit, vaporizer are items of equipment that can be configured/combine to deliver an intended function.

For configurable medical device systems, the rules listed below should be followed:

1. A UDI-DI is allocated to the entire, configurable medical device system and may be referred to as a “Configurable Device UDI” or “System UDI”. The Configurable Device UDI or System UDI is used on device labels, device registrations, UDI databases, and for various processes where UDI is utilized.

2. A Configurable Device UDI-DI is allocated to defined groups of configurations, not per configuration within the group. While generally UDI-DI assignments are applied to medical devices models with entirely homogeneous features, a Configurable device by definition has different variations, and the UDI-DI is therefore defined by the collection of possible configurations for a given product model as described in a regulatory file.

3. The UDI-PI for a Configurable device is generally a serial number and is allocated to each individual system. Since there is expected to be known variability for the possible variations of configurations for this model, the UDI-PI is essential to distinguishing between specific variations of the device. Note that a given Configurable Device or System UDI may have additional UDI-PI indicators including manufacturing date, etc. Additionally, a later change or addition of a component, sub-systems, or accessory of the system that has already been placed on the market does not change the original UDI-DI or UDI-PI of the system. It is necessary to be able to uniquely identify the changed device configurations in the field and the applicable records may now include more than one UDI for the device.

4. The carrier of the System UDI should be placed on the assembly or portion of the device that most likely does not get exchanged in its lifetime.

5. Each component, sub-system or accessory that is considered a medical device and is distributed or supplied independently from the original device needs a separate UDI. Some Configurable Devices may have multiple UDI assignments.

6. A new UDI-DI is required when the activities performed results in modifications to a previously marketed device intended for resale leads to a new medical device.

Note1: If a change of a device in the field would significantly change the safety, performance or the intended purpose (and these changes are not within the limits of the original configuration), those changed devices should be identifiable. To make the changed device identifiable a manufacturer should provide an upgrade kit (which, itself, is considered a medical device) with a correspondent UDI which meets all UDI requirement (e.g. labelling, publication to UDI database(s), etc.). The UDI of the

upgrade kit together with the original System UDI will be used to identify the changed device. A UDI label should accompany the upgrade kit and be permanently attached to the System UDI and captured in the record of the specific device.

Note2: An “upgrade kit” (to be distinguished from the term “kit” defined in this document) is a term commonly used in industry to denote a packaged medical device used to upgrade an installed medical device (after this latter has been sold and first use or installation is completed). The “upgrade kit” includes all of the components or constituents required for the medical device upgrade and may also include installation instructions, service manuals and user manuals.

Alternate Process

An alternate process would be that a manufacturer might perform this change as new installation (comparable with a resale of a modified device as described in point 6) the new installed device would need to be marked with a corresponding new System UDI. If this alternate process is utilized, the device manufacturer is responsible for updating the UDI labeling for devices that have been placed on the market and making the associated change in the applicable regulatory databases.

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