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Preface

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world. The document has been subject to consultation throughout its development.

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Introduction

The IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) provides a framework for the regulatory authorities that intend to develop their UDI systems in a globally harmonized approach. This UDI system Application Guide is to be used as a supplement to the IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) which was developed as a high-level conceptual framework containing the basic core concepts of a UDI system. The document further acknowledges that additional guidance may be necessary.

This UDI system Application Guide, together with the IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013), provide a harmonized approach to UDI system implementation. Each is primarily intended for medical device regulatory authorities and manufacturers that plan to develop and implement UDI systems.

However, the benefit and purpose of a UDI system will only be realized, if healthcare stakeholders integrate and obtain value in their systems from UDIs and data in associated Unique Device Identification Databases (UDIDs). This guide is therefore also intended to assist all relevant stakeholders within the healthcare supply chain and clinical care systems to gain a better understanding of their role and impact on the UDI system.

1.0 Scope

This Application Guide is intended to provide the details and specifications necessary to ensure consistency for enabling a harmonized approach in the application of the requirements set forth in the IMDRF UDI Guidance Document (IMDRF/UDI WG/N7Final:2013).

It is recognized that national regulation could differ in relation to certain specific aspects dealt with in the text.

2.0 References

- IMDRF/UDI WG/N7 Final: 2013 - UDI Guidance: Unique Device Identification (UDI) of Medical Devices
- IMDRF/RPS WG/N19 Final: 2016 - Common Data Elements for Medical Device Identification
- GS1 General Specification:
http://www.gs1.org/docs/gsmf/barcodes/GS1_General_Specifications.pdf
- Health Industry Business Communications Council (HIBCC) UDI and Labelling Resource Center: <http://www.hibcc.org/udi-resources/>
- International Council for Commonality in Blood Banking Automation (ICCBBA) - Technical Specification:
<https://www.iccbba.org/tech-library/iccbba-documents/technical-specification>

- ISO/IEC 646:1991, Information technology - ISO 7-bit coded character set for information interchange
- ISO/IEC 15415:2011, Information technology - Automatic identification and data capture techniques. Bar code symbol print quality test specification - Two-dimensional symbols
- ISO/IEC 15416:2016, Automatic identification and data capture techniques - Bar code print quality test specification - Linear symbols
- ISO/IEC 15417:2007, Information technology -- Automatic identification and data capture techniques -- Code 128 bar code symbology specification
- ISO/IEC 15420:2009, Information technology -- Automatic identification and data capture techniques -- EAN/UPC bar code symbology specification
- ISO/IEC 15426-1:2006, Information technology- Automatic identification and data capture Techniques - Bar code verifier conformance specification — Part 1: Linear symbols
- ISO/IEC 15426-2:2015, Information technology-Automatic identification and data capture techniques - Bar code verifier conformance specification — Part 2: Two-dimensional symbols
- ISO/IEC 15459-2:2015, Information technology - Automatic identification and data capture techniques - Unique identification, Part 2: Registration procedures
- ISO/IEC 15459-4:2014, Information technology - Automatic identification and data capture techniques - Unique identification, Part 4: Individual products and product packages
- ISO/IEC 15459-6:2014, Information technology - Automatic identification and data capture techniques - Unique identification, Part 6: Groupings
- ISO/IEC 16022:2006, Information technology- Automatic Identification and Data Capture Techniques-Data Matrix Bar Code Symbology Specification
- ISO/IEC 18000-6:2013, Information technology -- Radio frequency identification for item management -- Part 6: Parameters for air interface communications at 860 MHz to 960 MHz
- ISO/IEC 18004:2015, Information technology -- Automatic identification and data capture techniques -- QR Code bar code symbology specification
- ISO/IEC TR 24720:2008, Information technology -- Automatic identification and data capture techniques -- Guidelines for direct part marking (DPM)

- ISO 28219:2017, Packaging -- Labelling and direct product marking with linear bar code and two-dimensional symbols
- ISO/IEC TR 29158:2011, Information technology - Automatic identification and data capture techniques - Direct Part Mark (DPM) Quality Guideline

3.0 Definitions

The following terms are used throughout the text. Definitions are derived from GHTF, IMDRF or other authoritative sources. Special notes indicate when a definition is not consistent across all regulatory jurisdictions.

Accessory

Accessory means an article intended specifically by its manufacturer to be used together with a specific medical device(s), to enable the medical device to be used in accordance with its intended use [modified draft GHTF definition –GHTF/SG1/N071:2012].

Alphanumeric

Consisting of both letters and numbers and often other symbols (such as punctuation marks and mathematical symbols).

Automatic Identification and Data Capture (AIDC)

A technology used to automatically capture data. AIDC technologies include bar code, smart cards, biometrics and RFID.

Base Package

Lowest packaging level.

Checksum Digit

Digital calculated from data and appearing as part of the data string to ensure that the data is correctly composed and transmitted.

Configurable medical device system

A configurable medical device system consists of several components which can be assembled in multiple configurations. Those individual components may be medical devices themselves 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.

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/combined to deliver an intended function.

Data delimiter

Within a UDI, a defined character or set of characters that identifies specific data elements.

Device Identifier (UDI-DI)

The UDI-DI is a unique numeric or alphanumeric code specific to a model of medical device and that is also used as the "access key" to information stored in a UDID. Examples of the UDI-DI include GS1 GTIN (Global Trade Item Number), HIBC-UPN (Universal Product Number), or ICCBBA ISBT 128-PPIC (Processor Product Identification Code). GS1, HIBCC and ICCBBA are accredited issuing agencies/entities in some jurisdictions.

Direct marking

Direct marking, for purposes of UDI requirements, is affixing a UDI permanently on the device itself.

Human Readable Interpretation (HRI)

Human Readable Interpretation is a legible interpretation of the data characters encoded in the UDI Carrier.

Implantable device

Any device, including those that are partially or wholly absorbed, which is intended:

- to be totally introduced into the human body or,
- to replace an epithelial surface or the surface of the eye,

by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device. [GHTF SG1/N77:2012]

Issuing Agency/Entity:

An organization accredited by a regulatory authority to operate a system for the issuance of UDIs.

Kits

Kits are a collection of products, including medical devices, that are packaged together to achieve a common intended use and are being distributed as medical devices. These could also be called procedure packs or convenience kits.

Note: Jurisdictions may differ in their definition of kit.

Label

Written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices [GHTF/SG1/N070:2011].

Manufacturer

Manufacturer means any natural or legal person¹ with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s) [GHTF SG1/N55:2009]. This includes reproprocessors and remanufacturers that take responsibility for the device and reintroduce it into commercial distribution.

NOTE: Attention is drawn to the fact that the provisions of national or regional regulations can apply to the definition of manufacturer. For the specific purpose of compliance with UDI requirements, some jurisdictions might consider certain entities other than the manufacturers (e.g. labellers) in the same way as manufacturers.

Own Brand/Private Labelers

An Own Brand or Private Labeler relabels a device from a third party with his own name without making any further changes to the device thereby taking responsibility for it as the manufacturer.

Packaging

Product to be used for the containment, protection, handling, delivery, storage, transport and presentation of goods, from raw materials to processed goods, from the producer to the user or consumer, including processor, assembler or other intermediary. (ISO 21067-1:2016)

Packaging Levels

Packaging levels means the various levels of device packages that contain a fixed quantity of medical devices, e.g. each, carton, case.

Note: This does not include shipping containers.

Production Identifier (UDI-PI)

The Production Identifier is a numeric or alphanumeric code that identifies the unit of device production.

The different types of Production Identifier(s) include serial number, lot/batch number, Software as a Medical Device (SaMD) version and manufacturing and/or expiration date.

Radio Frequency Identification (RFID)

RFID is a technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object, for the purpose of identification.

Shipping containers

Shipping container is a container, where the traceability is controlled by a process specific to logistics systems.

Software as a Medical Device (SaMD)

¹ The term “person” that appears here includes legal entities such as a corporation, a partnership or an association.

The term SaMD is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. [IMDRF SaMD WG/N10R4FINAL:2013]

Standard

Document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. [GHTF/SG1/N044:2008]

Third party

A third party is referred to in this text as a company/individual, other than the original manufacturer of a device, that, based on a contract with that manufacturer, is authorized by the manufacturer to carry out certain operations on his behalf, such as submission of data to the UDI database and/or placing of the UDI carrier on the device label.

Unit of Use (UoU) UDI-DI

The UoU UDI-DI is an identifier assigned to an individual medical device. It is assigned in instances when a UDI is not labelled at the level of the device unit of use (e.g. several units contained in a plastic bag). Its purpose is to associate the use of a device to/on a patient.²

Unique Device Identification System (UDI system)

A system that is intended to provide single, globally harmonized positive identification of medical devices through distribution and use, requiring the label of devices to bear a globally unique device identifier (to be conveyed by using AIDC and, if applicable, its HRI) based upon standard, with the DI of that unique identifier being also linked to a jurisdiction-specific public UDI database. For more information on the fundamental concepts of the unique device identification system, see IMDRF/WG UDI/N7Final:2013

Unique Device Identifier (UDI):

The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI is comprised of the UDI-DI and UDI-PI. The unique identifier may include information on the lot or serial number, and be able to be applied anywhere in the world.

Note: The word "Unique" does not imply serialization of individual production units.

Unique Device Identifier Carrier (UDI carrier)

The UDI Carrier is the means to convey the UDI by using AIDC and, if applicable, its HRI.

Note: Carriers can include 1D/linear bar code, 2D/Matrix bar code, RFID, etc.

Unique Device Identification Database (UDID)

The UDID contains identifying information and other elements associated with the DI of the UDI specific to the model of a medical device.

² Because of their nature, the Unit of Use is not appropriate to *in vitro* diagnostic medical devices.

4.0 Fundamental Elements of a Harmonized UDI System

The fundamental elements of a UDI system can be summarized as follows:

- Development of a standardized system of Unique Device Identifiers (UDIs)
- Placement of UDIs in human readable and AIDC formats/forms on package labels and in some cases, on the device itself
- Submission of core UDI data elements to a UDID
- Setting of appropriate transitional and implementation arrangements to ensure a smooth UDI system implementation

Benefits of the UDI system strongly rely on effective integration of the UDI system to support various regulatory activities during the lifecycle of medical devices and uptake of the UDI system across the whole healthcare sector.

5.0 Guiding principles for UDI system design and operations

The UDI system is being developed to facilitate adequate device identification through distribution and use on patients. This system is newly forming across various regulatory jurisdictions at varying levels of system maturity.

When the UDI system is fully implemented, the label of most devices will include a UDI in human- and machine-readable form. In addition, globally harmonized meta-data about devices will be available in UDIDs as populated by regulated entities.

As the UDI system matures it will require ongoing process and data improvements driven by multi-stakeholder efforts to meet both submitter and user requirements. Foundational to UDI system adoption in the device ecosystem is recognition of the existence of legacy device identifiers and the need to match UDIs to these identifiers.

The UDI and metadata stored in UDIDs are intended to be the identifiers also used in the context of business and clinical transactions (e.g. purchase orders, invoices, inventory maintenance/management, clinical notes etc.).

6.0 The Unique Device Identifier (UDI)

6.1 Content, Structure and representation of a UDI

The UDI is composed of two parts: Device Identifier (DI) + Production Identifier (PI) = Unique Device Identifier (UDI). $DI + PI = UDI$.

- **Unique Device Identifier - Device Identifier (UDI-DI):** The Device Identifier of the UDI is a unique numeric or alphanumeric code specific to a model of medical device and that is also used as the "access key" to information stored in a UDID. This mandatory, fixed portion of a UDI identifies a manufacturer's specific product and package

configuration. Examples of the UDI-DI include GS1 GTIN (Global Trade Item Number), HIBC-UPN (Universal Product Number), or ICCBBA ISBT 128-PPIC (Processor Product Identification Code).

- **Unique Device Identifier - Production Identifier (UDI-PI):** The Production Identifier of the UDI is a numeric or alphanumeric code that identifies the unit of device production when one or more of the following is included on the package label of the device. The different types of Production Identifier(s) include:
 - a) The Lot or Batch within which a device was manufactured;
 - b) The Serial Number of a specific device;
 - c) The Expiration Date of a specific device;
 - d) The date of manufacture (may not be required if other Production Identifiers are on the label);
 - e) Software as a Medical Device (SaMD), Version³
 - f) The Distinct Identification Code, when applicable⁴

6.2 The UDI carrier

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) stated that the UDI and UDI carrier should be based upon standards and are fundamental parts of UDI system requirements.

The UDI Carrier shall be on the label or on the device itself and on all higher levels of device packaging. Higher levels do not include shipping containers.

Direct marking is affixing the UDI and, potentially the full UDI carrier, permanently on the device itself.

The UDI contains the device identifier (DI) and the specific production identifiers (PI) specified in this document.

The UDI carrier may also contain other identifiers not considered part of the UDI but carried within the UDI carrier to support sharing of standardized non-UDI information between trading partners.

Figure 1 shows an example of fictitious medical device label that meets UDI requirements.

Figure 2 shows the different options for placing the UDI carrier.

³ SaMD version might be captured in the lot Production Identifier under certain national regulations.

⁴ The distinct identification code, generally referred to as a donation number or donor number, corresponds to the donation identification number in ISBT 128. This number is an essential identifier for medical products of human origin

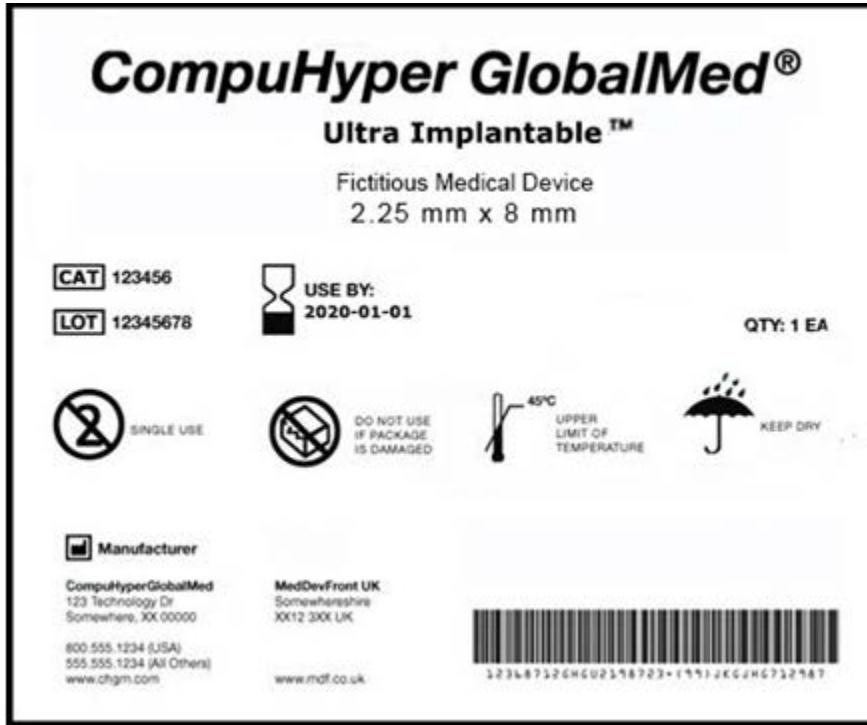


Figure 1: Example of medical device label

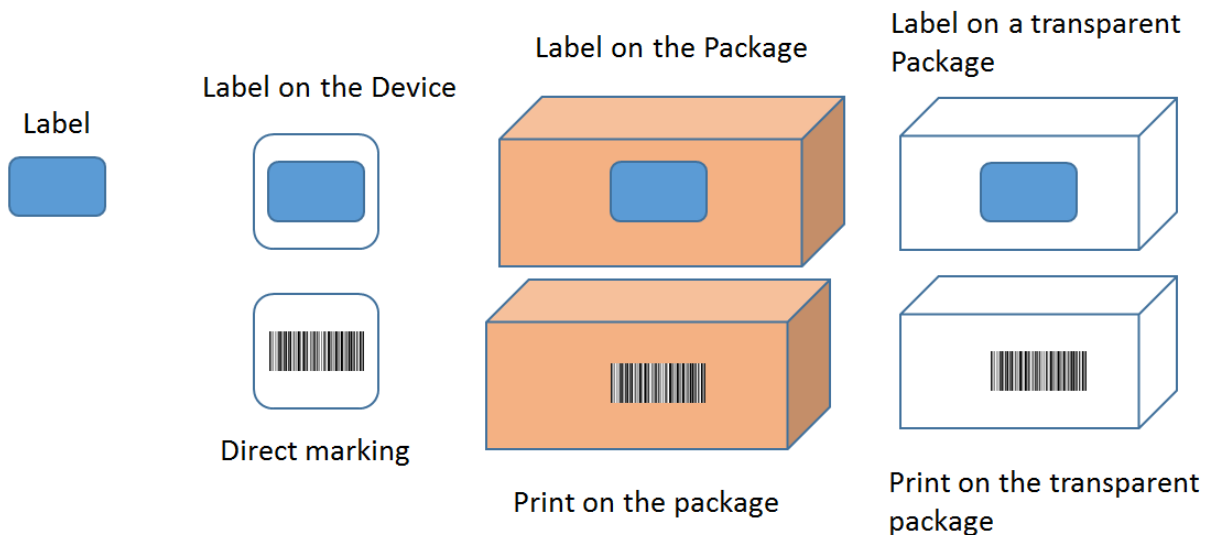


Figure 2: Option for placing the UDI carrier

6.3 UDI Human Readable Interpretation (HRI) Format, Structure and Content of Each Issuing Agency/Entity.

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) requires the HRI format to follow the specifications of the UDI issuing agency/entity as sanctioned by the regulatory authority. The tables in Appendix A contain the UDI HRI formats to be used for each of the issuing

agencies/entities with examples of the HRI alone, followed by a representation of the HRI combined with AIDC in linear and two-dimensional bar code.

The inclusion of the data delimiters is necessary in the HRI to determine what the identifiers are in the string of characters that follow the data delimiter.

6.4 Auto Identification Data Capture (AIDC) representation of UDI

There are a wide variety of AIDC carriers available; however, to meet the imperatives of the IMDRF UDI Guidance, the UDI should comply with the requirements of the global accredited issuing agencies/entities and the accepted AIDC standards, i.e., ISO/IEC 15459-2; ISO/IEC 15459-4; ISO/IEC 15459-6; ISO/IEC 646; ISO/IEC 15415; ISO/IEC 15416; ISO/IEC TR 29158.

Each issuing agency/entity has their own general technical specifications that include information on the carrier type, size, placement and quality in addition to recommendations about the human-readable presentation of the encoded data (for further information on issuing agencies/entities see Section 10.3 of this document).

Some carriers are only approved for specific applications (e.g. retail). Therefore it is imperative to understand the appropriate application of each carrier and allow the manufacturer to choose the appropriate carrier based upon the application for use.

For purpose of illustration, the images shown in Appendix B depict some of the most widely used AIDC carriers used in healthcare (medical devices and pharmaceuticals) today.

RFID may also be an acceptable AIDC technology. Examples of RFID are provided in Appendix C⁵.

6.5 Considerations on bar code readers

Bar code readers are designed and manufactured in many configurations (e.g. fixed mount, handheld, tethered, cordless, wearable, mobile phone etc.) and, like many electronic devices, can be acquired with a wide range of factory and/or user selectable features and capabilities.

Bar code readers are available as “linear” scanners for “linear” symbologies only (e.g. Code 128) and as “image scanners” for linear and 2-dimensional (2D)-symbologies (e.g. Code 128 and Data Matrix).

Since image scanners can scan linear and 2D symbologies, it is recommended for users to utilize image scanners for UDI applications.

There is no additional technical knowledge needed to use (i.e. to scan with) a 2D/matrix versus 1D/linear scanner. In fact, both the omnidirectional reading capability of a 2D/matrix “camera” or “area imager” scanner, and the 2D/matrix scanner’s inherent ability to read both 2D/matrix and 1D/linear types of barcodes will make them easier and in the long run more economical to use in many instances. The only additional technical consideration is that every scanner (whether

⁵ It should be noted that jurisdictions might choose to opt for certain AIDC systems only.

2D/matrix or 1D/linear) must be properly set up and/or configured for its intended use. This is generally easily done by ensuring that the firm the readers are purchased from sets them up (i.e. configures them) properly.

Readers for UDI applications need to support the Barcode symbologies in line with relevant international standard (including ISO/IEC 16022, ISO/IEC 18004, ISO/IEC 15417, ISO/IEC 15420).

Standard bar code symbology has a symbology identifier registered with ISO/IEC 15424. Scanners transmit the symbology identifier to differentiate between the data carriers of each issuing agency/entity.

Today, some RFID readers have the capability to read 1D/linear and 2D/matrix barcodes. However, bar code readers typically cannot read RFID tags without the addition of external / auxiliary RFID reading devices.

7.0 Application of UDI to packaging levels

7.1 Applying UDI to Medical Device Package Level Structures

One of the main principles of a UDI system is to apply a UDI to each packaging level of a medical device package structure. The DI of each package level requiring UDI must be unique to distinguish between package quantities at each package level.

The device package level structure is a key concept to understand in terms of UDI system. It is also important to note that, while most medical devices are contained within packages with labels, there are instances where the devices are no longer within the original packaging and therefore the label no longer exists.

Appendix D provides some examples of how packaging configurations are captured in the UDID.

7.2 UoU DI

The UoU DI is an unmarked 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 provide a DI to identify a device used on a patient when a DI does not appear on the label of the device.

The UoU DI should be assigned when the base package, i.e., the lowest packaging level with a UDI, has a Device Count greater than 1.

User education is key to assure proper assignment, entry and use of the unmarked UoU DI. The user education should include education of data submitters, data users and Electronic Health Record (EHR) system vendors.

Examples of packaging configurations (including UoU) are provided in Appendix D.

8.0 The Unique Device Identification Database (UDID)

Regulatory authorities are responsible for developing the UDID in their jurisdiction based upon local policy requirements and the principles developed in the IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) and this document.

Providing public access to each UDID will further allow healthcare stakeholders to access essential information to identify devices.

8.1 Expectations for a good UDID design

The IMDRF UDI Guidance (IMDRF/UDI WG /N7Final:2013) indicates in its introductory section that: "The UDI System is intended to provide a single, globally harmonized system for positive identification of medical devices. Healthcare professionals and patients will no longer have to access multiple, inconsistent, and incomplete sources in an attempt to identify a medical device and its key attributes". The UDID is a designated source for device identification information.

To ensure that all stakeholders, in particular the healthcare sector, are able to obtain value from the UDI system and the UDID, regulators should consider the following principles when developing regional UDIDs.

Jurisdictions are recommended that their UDID is designed:

1. as a central medical device master database containing all essential information to identify devices in the regulatory jurisdiction
2. to include the entire package level hierarchy of a medical device (e.g. unit-of-use, base package, higher package levels). The hierarchy should be linked to a specific device and provide a parent-child relationship structure
3. to be freely and effectively accessible to all stakeholders, in particular the healthcare sector
4. in a way that relevant available UDI-DI related information can be integrated through downloads and/or Application Programming Interfaces (APIs) into:
 - a. internal regulatory systems (such as adverse event reporting, recalls)
 - b. device registries
 - c. healthcare supply chain systems, clinical systems (e.g. electronic health records), and clinical engineering device maintenance systems
5. to ensure a high level of availability and reliability (e.g. multi-access automatic up- and downloads 24/7)
6. to ensure the integrity of data and data transmission processes using recognized data exchange standards, when possible
7. to connect the device UDI-DI information with codes and terms of a nomenclature⁶ which would enable other stakeholders to: use the UDID data for activities like purchasing, stock

⁶ According to Section 9.2 of the IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013), nomenclature is listed as one of the core UDID data elements

handling, reimbursement or search; find UDID information related to similar devices or to enable regulatory authorities to effectively assess the safety and performance of product groups in the field

8. to have a set of transparent rules on UDI-DI related information updates
9. to keep history of UDID entries and make information on changes publicly available
10. to ensure via security protocols that information provided by the manufacturer (or an authorized third-party acting on behalf of a manufacturer) is successfully submitted
11. to provide clearly defined data validation rules specific to a single data field or a combination of data fields to ensure data integrity, that including, to the extent possible, reasonable automatic plausibility “checks” so that data format requirements for all data elements required for submission to an UDID shall remain stable over a long time
12. to have multiple options for submission (e.g. HL7 SPL, Excel or CSV files, Structured input via a Web-interface to allow for manual UDI data entry)
13. for web submissions, to be based upon user interface design principles so that data entries is intuitive for an average user
14. to accommodate the submission of data from authorized third parties
15. to notify manufacturers about data quality issues and track response to the notifications
16. to have validation procedures to ensure that data submitted is consistent across internal regulatory systems
17. in relation to kits, to capture the UDI-DI of the kit as well as of each medical device in the kit that is marked with a UDI.

During the design and development of the UDID, feedback from all the stakeholders that are expected to be using the UDID should be sought.

8.2 UDID Data Specifications

Regulators should ensure that UDID data specifications for UDID data elements⁷ are available to relevant stakeholders as soon as practicable, in order to ensure that they have sufficient time for developing respective systems and procedures.

The following is a recommended data specification list at a data field level:

- field name
- field description
- field characteristics (numeric, alphanumeric)
- field length (number of digits, fixed length, variable length)
- indication whether field is a single value or multiple value field (maximum number of values allowed)

⁷ Section 9.2 of the IMDRF UDI Guidance (IMDRF/UDI WG /N7Final:2013) provides a list of core UDID data elements

- list of predefined values (remark: value 'blank' or 'null' should be avoided)
- field edit rules (e.g., value changes allowed, deletion, only new values to be added, value locked after grace period)
- indication whether the field is mandatory, optional, or conditional (include rules for conditional)
- indication whether a value change triggers a new UDI-DI

Ideally, the UDID data specifications would be constructed in a data reference table. An example of data reference table is provided in the IMDRF information document (this document is under preparation).

Certain harmonized specifications for some UDID data elements are already included in the IMDRF Common Data Elements⁸ document. They provide a controlled vocabulary, standardized nomenclature, structure and definition for those UDID data elements.

8.3 Submission of information to UDID by third-party submitter

As indicated in Section 10.2 of this guide, the manufacturer is ultimately held responsible for the information submitted to the UDID.

Regulators that allow a third-party submitter should establish a formal process to authorize those third-party solution providers to submit UDID data on behalf of a medical device manufacturer⁹. This process might include the following:

- the manufacturer provides third-party information, which is saved as part of the manufacturer's account
- the third-party submitter completes the relevant testing on behalf of the manufacturer
- during submission processing, the UDID validates that third-party is authorized to submit data on behalf of the manufacturer
- the third-party submitter performs data validation before submitting data to the UDID

8.4 UDI-DI triggers

UDI-DI triggers are data elements within a device's UDID entry that, if changed, would require a device to obtain a new DI.

The IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) provides that, at a minimum, a new UDI-DI is required whenever there is a change that could lead to misidentification of the

⁸ IMDRF/RPS WG/N19Final:2016

⁹ Some jurisdictions might not have a specific process in place to authorize third-party solution providers

medical device and/or ambiguity in its traceability. Specifically, any change of one of the following UDID data elements¹⁰ determines the need for a new UDI-DI:

- a. Brand Name,
- b. Device version or model,
- c. Clinical Size (including Volume, Length, Gauge, Diameter),
- d. Labeled as single use,
- e. Packaged sterile,
- f. Need for sterilization before use,
- g. Quantity of devices provided in a package,
- h. Critical warnings or contraindications: e.g. containing latex or Bis(2-ethylhexyl) phthalate (DEHP).

It shall be noted that new packaging configurations require a new UDI-DI.

To date, those with experience implementing a UDI system into regulatory and healthcare systems have identified a significant challenge with the assignment of multiple DIs to products which share essential design and manufacturing characteristics. Inconsistent applications of UDI-DI triggers by manufacturers as well as a lack of agreement among different jurisdictions on the full list of UDI-DI triggers are among the key factors causing the multiple DI issue.

To minimize that risk, regulators that implement UDI systems and issuing agencies/entities would improve the value of the UDI system by ensuring that UDI-DI triggers other than the ones provided in the IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) are kept to a minimum and that manufacturers implement those UDI-DI triggers consistently and in a way that promotes UDI as a global standard for device identification.

Jurisdictions that have started or plan to implement a UDI system should rely on learning UDI communities (on the issue of learning communities, see also Section 13) to look closely at the issue of multiple DIs.

9.0 UDI Format and Structure When Entered into Forms, Databases, Registries, etc.

While the data delimiters in the HRI are necessary to allow for a legible interpretation of the identifiers, the data delimiters themselves are not part of the parsed data set. Therefore, when the UDI is required to be reported in forms, or submitted in electronic data interchange (EDI) databases, the data delimiters should not be included or displayed as part of the data set itself.

¹⁰ Definitions of UDI data elements have been provided by IMDRF in the document IMDRF/RPS WG/N19Final:2016

To take advantage of the structured data embedded in a UDI it is recommended that the UDI be parsed into discrete fields in database entries and forms in order to have the UDI data properly catalogued.

Using scanners, that enter the information in a parsed manner at the initial entry stage, is the most efficient method for capturing UDI, as it will alleviate the need to manually record the full UDI and to manipulate the data for future analysis. A suggested example to capture the UDI is as follows:

- **Device Identifier:** 1022222333334
- **Product identification:**
 - **Expiration Date:** 091231
 - **Lot:** A1345B
 - **Serial Number:** 1234

The IMDRF information document (the document is under preparation) provides further information and recommended best practices for recording UDI in electronic health sources.

10.0 Establishing Responsibility for Creating and Maintaining a UDI System

Establishing the fundamental elements of a UDI system requires that all relevant parties have a clear understanding of their role to achieve the system goals.

Regulatory authorities that intend to establish a UDI system are responsible for establishing the basic regulatory requirements and vision for the UDI as a global standard. Issuing agencies/entities, accredited or recognized by regulatory authorities, are responsible to define the general UDI specifications based on relevant international standards. Manufacturers are responsible for creating and maintaining globally unique UDIs for their medical devices by following the issuing agency/entity's specifications. Distributors, importers, healthcare providers and users significantly contribute to enhance the potential of the UDI as a key standard to facilitate adequate device identification through distribution and use on patients.

10.1 Regulatory Authority

To avoid each regulatory authority implementing and managing local UDI systems differently, the participating IMDRF jurisdictions have developed the details and specifications outlined in this document to harmonize their unique device identification system requirements, and increase global consistency of implementation.

The regulatory authorities that establish a UDI system are responsible for establishing a standardized UDI system to meet local regulatory requirements and to develop and maintain a local publicly available UDID that is capable of linking to other regulatory authority UDIDs. It is recognized that local specificities and regulations could impact certain aspects of UDI implementation.

Regulatory authorities have the following key oversight roles:

- accrediting issuing agencies/entities and overseeing their operations to an extent which may vary depending on each jurisdiction;
- issuing operational guidance and specifications;
- laying down and enforcing obligations for manufacturers in relation to the UDI system in a particular jurisdiction;
- when they deem appropriate, providing instructions for the importers, distributors and healthcare providers to facilitate uptake of the UDI system in the supply chain and clinical systems.

Additionally, the regulatory authorities have shared responsibility with accredited issuing agencies/entities, manufacturers, and standards development organizations to strengthen the UDI as a global standard by committing to ongoing harmonization of UDID data elements, and development of common vocabularies and exchange standards used in UDI implementation.

10.2 Manufacturer

The IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) states: “The medical device manufacturer should create and maintain globally unique UDIs on his medical devices.”

To that purpose, manufacturers shall also keep any UDI related information in their device documentation.

Manufacturers are responsible for understanding both regulatory and issuing agency/entity requirements to accurately assign and place the UDI in human readable and AIDC format on the label or on the device itself and on all higher levels of device packaging. Based on a contract with a manufacturer, a third party may place the UDI carrier on the label or on the device itself and on all higher levels of device packaging on behalf of the manufacturer. However, under that scenario, the manufacturer is ultimately held responsible for the conformity of the UDI carrier¹¹.

Manufacturers are also responsible for the initial submission and updates to the information in the UDID. While manufacturers should also be allowed to engage with third parties who provide services to submit UDI data to the UDID (see Section 8.3 for additional information), the manufacturer is however ultimately held responsible for the information submitted¹².

10.2.1 Own brand or private labellers

Own-brand/private labelers shall be meant as companies/individuals, other than the original manufacturers of a device that make available on the market that device under their own brand name.

¹¹ It should be noted that certain jurisdictions might consider those third-parties as legally responsible for placing the UDI carrier on the label or on the device itself and on all higher levels of device packaging.

¹² It should be noted that certain jurisdictions might consider those third-parties as legally responsible for submission of data to the UDI database

The IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) indicates that own brand/private labelers assume all manufacturers' obligations, related to the UDI system, including obligations to place the UDI carrier on the label and to submit UDI information to the UDID.

However, when a company/individual that makes that make available on the market a device under its own brand name enters into an agreement with the original manufacturer of the device whereby that manufacturer is identified as such on the label, all relevant manufacturers' responsibilities for that device remain with the original manufacturer including all UDI related responsibilities.

10.3 Issuing Agency/Entity

The IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) document states that “globally accepted ISO/IEC coding standards implemented by global organizations, such as GS1, HIBCC and ICCBBA, meet the criteria of the UDI and manufacturers shall be permitted to choose which system to use. These organizations have responsibility for maintaining the global uniqueness of their coding systems.”

The main task of these agencies/entities is to operate a system to be used by the manufacturers for assignment of the UDIs to their devices.

Issuing agencies/entities are responsible for defining the UDI as a trade item standard. Regulatory requirements take precedence over issuing agency/entity requirements.

If the issuing agency/entity intends to update their standards or specifications that have an impact on the UDI system, they are expected to submit a request for authorization to the relevant jurisdictions. Given the global nature of those standards or specifications, it is recommended that IMDRF regulatory authorities consult each other about the impact of those changes.

Issuing agencies/entities shall develop initiatives and tools to educate manufacturers on the appropriate use and implementation of the agencies'/entities' systems for the issuance of UDIs. This includes training and development of educational material.

Conditions for designation of agencies/entities shall include that:

- the agency/entity operates a system for the issuance of UDIs which conforms to the relevant international standards;
- the agency/entity undertakes to operate its system for the assignment of UDIs for a period which should be no less than 3 years;
- the agency/entity undertakes to make available to the relevant national authorities, upon request, any information concerning its system for the assignment of UDIs;

Jurisdictions may opt for setting additional agencies/entities' responsibilities. In this case, those jurisdictions might consider establishing agreements with the issuing agencies/entities, upon their designation, under which these entities would be required:

- to make available to regulators their tools that validate that the UDI-DI is meeting the issuing agency/entity's specification for a valid UDI-DI
- to work in cooperation with regulators and manufacturers to avoid problems listed below and correct, if needed:
 1. deficiencies in UDI creation (e.g. tests for validity, uniqueness, check digit)
 2. deficiencies in UDI placement and use (e.g. print quality, scannability, types of UDI carriers, surface and substrate impact)
- to have procedures in place to take necessary follow-up actions up to and including revoking the use of their system for the issuance of UDIs, whenever they become aware that manufacturers or labellers do not meet their requirements related to UDI
- to maintain a maximum level of stability regarding their requirements for data formats on UDI-DI and UDI-PI and their encoding in an AIDC
- to involve regulators when planning additions or changes to their specifications, particularly when those specifications have an impact on the construct of a UDI and the way it is captured
- to have the relevant global standards implemented consistently across their regional members
- to continuously supply to regulators educational materials, application forms, and access to other materials the issuing agency/entity provides for its members

It is recommended that regulatory authorities duly consider the impact of their agreements on global harmonization.

10.4 Expectations from stakeholders related to UDI

10.4.1 Distributors and importers

Distributors and importers are expected to control that, where applicable, a UDI carrier has been affixed to devices they receive, prior to further making available of the device.

Distributors and importers should assure that all device records they maintain include the UDI as an essential component to allow traceability of devices along the distribution chain. National regulators may consider legal or regulatory measures required for this purpose.

10.4.2 Healthcare providers

Jurisdictions might require that healthcare providers assure that all device records they maintain include the UDI as an essential component to allow traceability of devices along the distribution chain.

Healthcare providers can play a crucial role in signalling lack of compliance related to UDI requirements, as they receive and use most of the medical devices available on the market.

National regulators should consider legal or regulatory measures required for this purpose.

10.4.3 Other stakeholders

Providing specific fields for the UDI-DI and UDI-PI and key fields in UDIDs allows for the capture of structured standardized data.

Regulatory reviewers, epidemiologists, clinical researchers and members of professional societies rely on clinical trial and real world data sources (Electronic health records, registries, reimbursement data, and medical device registries) to evaluate the patient and device safety.

Currently, the device identification information collected in clinical care and device registries is not structured or standardized. Often, it is captured in text fields and narrative that cannot easily be used for device evaluation.

Integrating UDI into device evaluation methodologies likewise improves the accuracy of clinical and research data. Researchers will easily see the value of the UDI to improve the quality of research data.

Both device industry and jurisdictions should encourage interdisciplinary participation within their own organizations between those who design and maintain UDIDs and their own internal users of this data in order to provide value to their internal customers and support UDI adoption within their own organizations.

10.4.4 International standards and terminology development organizations

Standards and terminology development organisations (such as ISO/IEC, AIM, SNOMED, and HL7) are crucial to global harmonization in the UDI field, as they set detailed technical specifications on aspects such as UDI allocation rules, structure and placement of UDI carrier, and relevant data exchange.

Regulators, manufacturers and healthcare providers, who plan to adopt and implement a UDI system, are recommended to actively engage with those organizations.

11.0 General Considerations to Facilitate an effective UDI Implementation

11.1 Transitional period

The considerations listed in the IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) include a risk-based approach to UDI implementation and the “need for all supply chain stakeholders to have sufficient time to prepare their systems, process and staff, for the proper use of the UDI systems.”

The following is an example of an effective implementation schedule of a UDI system that jurisdictions could consider:

- Initial implementation period in jurisdictions should begin no less than two years from the publishing of the National UDI system requirements for the highest risk devices,

followed by 2 year incremental implementations for each risk category of medical devices.

- Direct Marking timelines should provide an additional two years for implementation at each risk level.

Regulators shall ensure that relevant technical specifications are adopted and published. In particular, technical specification for UDI data elements and for data exchange protocols should be available well ahead of the date of application of the relevant National UDI requirements.

When setting the timelines for adoption of those specifications, regulators shall consult the relevant stakeholders.

11.2 UDI implementation arrangements

The following implementation arrangements should be considered by regulators for a successful UDI implementation:

- Public forums for UDI system education and public comment on the UDI system
- Engagement with national medical device trade associations
- UDI system conferences to allow industry stakeholders to learn and help educate on UDI implementation
- Help Desk service to assist industry with implementation questions
- Guidance documents to address issues or challenges that arise
- Process for manufacturers to apply for exceptions and/or alternative methods for marking a UDI
- UDID data submission training and education webinars
- UDID user group sessions to obtain feedback from both UDID submitters and UDID users
- Promoting a better understanding of UDI user requirements by forming regional UDI expert clinical and supply chain groups or learning communities to identify and specify best practices for UDI implementation that can be shared globally

12.0 Special cases

This Section intends to complement or, where necessary, clarify some of the requirements set in Section 10 of the IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013), based on learning experience with certain specific device types in the course of the last few years.

12.1 Implantable devices

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) indicates that:

"Implantable devices should follow the rules listed below:

1. All unit packs of implantable devices (lowest level of packaging) need to be identified/AIDC marked with an UDI (UDI-DI + UDI-PI);
2. PI should have the following characteristics:
 - a. serial number for active implantable devices,
 - b. serial number for other implantable devices or lot number according to the manufacturer's quality management system;
3. The UDI of the implantable device must be identifiable prior to implantation."

In relation to those requirements, it must be noted that:

- Implantable devices are not always required to have a UDI carrier on the device itself (direct marking)
- The rationale of requirements in 3. ("The UDI of the implantable device must be identifiable prior to implantation") is to minimise the risks of misidentification of the implanted device
- It shall be ensured that the UDI can be scanned prior to implantation and linked to any electronic system, this implying that an AIDC is present.

12.2 Reusable devices requiring reprocessing between uses

The IMDRF UDI Guidance (IMDRF/WG/N7Final:2013) states: "Medical devices that are reusable should have a UDI Carrier on the device itself. The UDI Carrier of reusable medical devices that require reprocessing between patient uses should be permanent and readable after reprocessing cycles for the intended life of the device. Manufacturers may determine that this may not be possible or warranted on some devices due to size, design, materials, processing, or performance issues."

The determination of whether a device is reusable or not is to be made by the manufacturer. That determination should be reflected in the instructions of use, together with any relevant appropriate information on appropriate processes for allowing reuse.

Direct marking is the preferred solution for placing the UDI Carrier on the device itself. There are a variety of methods for applying direct marking, including both intrusive methods (e.g., dot pin; etching; direct laser marking; etc.) and non-intrusive methods (e.g., cast/forge/mold; laser bonding; stencil; permanent adhesive label; etc.).

The standard ISO/IEC TR 24720 provides guidelines for direct marking, namely in relation to selection of methods of marking based on material. Other useful standards in this context include ISO 28219, ISO/IEC TR 29158. Issuing agencies/entities (see References in Section 2) might have recommendations on key aspects of direct marking, including substrate requirements, symbol dimensions, symbol quality, and symbol placement.

Direct marking supports accurate identification and capture of a UDI (and when marked with an AIDC carrier, allows auto-capture) when the device is no longer accompanied by its label or package containing the UDI. The figure below shows examples of direct marking on surgical instruments.



Figure 3: Example of direct marking

An exemption to the direct marking obligation shall be foreseen under the following circumstances:

- a. any type of direct marking would interfere with the safety or performance of the device;
- b. the device cannot be directly marked because it is not technologically feasible.

The applicability of those exemptions shall be based on evaluations of the size, design, materials, processing, or performance issues related to the device in question.

Examples of usability issues linked to direct marking are provided in Appendix F.

12.3 Non-IVD kits

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) states that "The manufacturer of the Kit is responsible for identifying the Kit with a UDI including both UDI-DI and UDI-PI."

12.3.1 Placement of UDI carrier on the medical device contents of kits

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) states that

"Medical device contents of Kits should have a UDI Carrier on their packaging or on the device itself".

Where applicable and practicable, the UDI of the medical device contents of kits should be readable and scannable from the outside of the kit. In this context, it should be noted that there

are situations where the presence of multiple bar code could lead to confusion scanning and the ability to read and scan the UDI of the contents of the kit from the outside of the kit does not provide any value or benefit to users.

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) indicates the following exemption to the requirement whereby medical device contents of Kits should have a UDI Carrier on their packaging or on the device itself:

- a. Individual single-use disposable medical devices within a Kit, whose uses are generally known to the persons by whom they are intended to be used, and which are not intended for individual use outside the context of the Kit do not require their own UDI Carrier.

Example: An unpackaged sterile syringe within a sterile Kit cannot be used for another procedure, due to the lack of a sterile barrier once removed from the Kit;

- b. Medical devices that are normally exempted from having a UDI Carrier on the relevant level of packaging do not need to have a UDI Carrier when placed within a Kit."

For the example provided under b), it must be noted that this does not apply to devices that are being broken down from bulk packaging for use in a kit when the bulk package manufacturer intends them to remain in the box until the point of use.

Appendix G provides useful example of UDI assignment for non-IVD kits in relation to issues explored under Sections 12.3.1 and 12.3.2.

12.3.2 Exemption for non-IVD kits

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) states that

"Orthopedic procedure trays whose contents are configured for a specific order are exempted from this UDI requirement"¹³

Figure 4 represents an example of this kind of orthopedic procedure tray. These trays are often delivered to a hospital in a stainless-steel box, then stored and sterilized by the hospital for use in a procedure. After the procedure, the hospital will normally replace used parts and re-sterilize the box with its original and replaced contents.

¹³ Jurisdictions may differ in relation to the qualification of these trays as medical devices.



Figure 4: Example of orthopedic trays used in trauma and spine surgeries

It is important to note that these trays are made up of registered and approved medical devices, including instruments and/or implants, in their own right, and are distributed together in non-sterile metal containers strictly for healthcare provider convenience, the convenience of sterilization processing and to accommodate set replenishment in the field or the hospital. The medical devices included in the trays shall be identified individually and are subject to UDI rules at the individual level.

The original exemption provided by the IMDRF Guidance (IMDRF/UDI WG/N7Final:2013) does not address the needs of clinical users and patients for identifying the devices in those trays.

12.4 IVD kits

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) states that:

"The manufacturer of the IVD Kit is responsible for identifying it with a UDI including both UDI-DI and UDI-PI"

12.4.1 Medical device contents of IVD kits

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) states that:

1. "Medical device contents of IVD Kits should have a UDI Carrier on their packaging or on the device itself,
 - a. The IVD Kit is a device and all aspects of this guidance that is relevant apply to it. If an IVD Kit does not include any components which on their own are considered medical devices the only UDI is the UDI of the kit itself;
 - b. Reagents used in automated systems bear bar codes necessary for their handling and identification by the automated systems. This does not constitute a UDI;
 - c. Individual single-use medical devices packaged within an IVD Kit, whose uses are generally known to the persons by whom they are intended to be used, and which are not intended for individual use outside the context of the IVD Kit do not require their own UDI Carrier;

- d. Medical devices that are normally exempted from having a UDI Carrier on the relevant level of packaging do not need to have a UDI Carrier when placed within an IVD Kit."

In relation to those requirements, some additional considerations can be made:

- IVD kits contain at least one item which on its own can be considered a medical device.
- It must be highlighted that, for individual single-use medical devices packaged within an IVD Kit, whose uses are generally known to the persons by whom they are intended to be used, they do need a UDI when distributed as replacement parts for the kit.

12.4.2 Placement of UDI on IVD kits

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) states that:

“Placement of UDI on IVD Kits:

- a. The IVD Kit UDI is generally affixed to the outside of the packaging;
- b. The UDI must be readable or in the case of AIDC scan able, whether placed on the outside of the IVD Kit package or inside a transparent package”

Appendix G provides a useful example of a UDI assignment for IVD kits in relation to issues explored under Sections 12.4.1 and 12.4.2.

12.5 Configurable medical devices

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) indicates that:

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

1. A UDI is allocated to the entire, configurable medical device system and is called the System UDI.
2. A system UDI-DI is allocated to defined groups of configurations, not per configuration within the group. A group of configurations is defined as the collection of possible configurations for a given product line as described in a regulatory file.
3. A system UDI-PI is allocated to each individual system. A later change of a component, sub-systems or accessory of the system does not change the UDI-PI of the system.
4. The carrier of the System UDI should be put on the assembly that most likely does not get exchanged in its lifetime and should be identified as the System UDI.
5. Each component, sub-system or accessory that is considered a medical device and a distributed or supplied unit needs a separate UDI.

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.
7. A new UDI-DI is not required when the activities performed do not result in a change/modification in performance, safety and/or intended use, of a previously marketed device intended for resale. The activities shall be performed in accordance with the manufacturer's instructions."

In relation to 3, if a later change of component results in a new model/version of the configurable device, then that would trigger a new system UDI-DI (as well as new system UDI-PI). If that change did not result in a new version/model, there would be no change in system UDI-DI (or system UDI-PI). Appendix H provides useful examples on this specific issue.

12.6 Software as a medical device

12.6.1 UDI Assignment Criteria

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) indicates that:

"The UDI should be assigned at the system level of the Software as a Medical Device (SaMD).

The version number of the SaMD is considered the manufacturing control mechanism and should be displayed in the UDI-PI.

The following change of a SaMD would require a new UDI-DI:

- Major SaMD revisions shall be identified with a new UDI-DI;

Major SaMD revisions are meant as complex or significant changes affecting:

- 1) the original performance and effectiveness,
- 2) the safety or the intended use of the SaMD,

These changes may include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.

The following change of a SaMD would require a new UDI-PI (not a new UDI-DI),

- Minor SaMD revisions shall be identified with a new UDI-PI;

Minor SaMD revisions are generally associated with bug fixes, usability enhancements (not for safety purpose), security patches or operating efficiency.

Minor revisions shall be identified by manufacturer-specific identification methods (e.g. version, revision number, serial number, etc.)"

12.6.2 UDI Placement Criteria

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) states that:

“

- a. 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.
- b. 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).
- c. The SaMD lacking a user interface (e.g. middleware for image conversion) must be capable of transmitting the UDI through an API.
- d. Only the human readable portion of the UDI is required in electronic displays of the SaMD. 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 carriers (CDs, DVDs or similar) will not carry an AIDC.
- e. The human readable format of the UDI for the SaMD should include the Application Identifiers (AI) for GS1, and Flag Characters for HIBC, to assist the end user in identifying the UDI and determining which standard is being used to create the UDI.”

In relation to those requirements, it shall be noted that:

- 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 first packaging level of the physical medium should be identical to the UDI assigned to the system level SaMD. This UDI information – HRI and AIDC - can be placed in a booklet or inlay that accompanies the physical medium. The physical medium itself is not a medical device and therefore does not require a separate UDI. The physical medium may be controlled by its own lot, batch or serial number or by another means of production control”.
- In relation to point d), "will not carry" shall be read as "will not be required to", as manufacturers will always be in a position to opt for those SaMD to carry an AIDC.

Appendix I provides useful example of UDI assignment for software in relation to issues explored under Sections 12.6.1 and 12.6.2.

12.7 Contact lenses

UDI -DIs are assigned by manufacturers for a given version or model of a device.

However, contact lenses are currently assigned UDI-DIs for a given version or model, prescription level, and (for gas permeable lenses) material resulting in the assignment of multiple UDI-DIs for each model/version of contacts lens.

There are three types of contact lenses addressed in this guide: rigid gas permeable, intraocular lenses and soft contact lenses. For soft contact lenses, entering these data might constitute a burden to manufacturers and could affect the IT infrastructure of authorities.

The following is the current thinking for addressing this issue by lens type:

- **Rigid Gas Permeable Lenses**

These are made-to-order lenses and conventional type contact lenses.¹⁴ Assignment rules for UDI-DI for these specific devices are to be based upon the material/color, so that only a change of material would trigger a new UDI-DI.^{15 16}

- **Intraocular Contact Lens**

This type of contact lens is high risk implantable (Class III in US) and the overall number of device records for this category is relatively low compared to other contact lens types. These devices have multiple DIs.

- **Soft Contact Lenses**

For this type of lenses, the following options can be considered:

- Allow entry of submissions based on current industry practice and under the same rules as intraocular lenses
- Capture key soft contact lens attributes as part of the device record to help users distinguish multiple device records for a given version or model. For example – Base Curve, Diameter, Thickness, Power, Cyl, Axis etc.
- If necessary, allow ability to capture range for prescription, i.e., -6 to +6

However, regulatory authorities should cooperate to find a consistent, effective way to deal with those products.

¹⁴ Conventional type contact lenses are those lenses which are usually intended to be worn from six months to a year.

¹⁵ Please note that in some jurisdictions, in the case of Rigid Gas Permeable Lenses, the specification holder might be held responsible for UDI regulatory compliance.

¹⁶ It should be noted that certain jurisdictions might require Rigid Gas Permeable Lenses to be subject to the same requirements as soft contact lenses.

13.0 Update of application guide and issues for future consideration

The IMDRF Management Committee might consider ways to systematically review this application guide, in order to incorporate learning from implementation of UDI in different jurisdictions as well as to ensure that the document is accurate and complete with respect to ISO versions, UDI formats, data standards, vocabulary, and relevant guidance and user community activities.

IMDRF jurisdictions will explore ways of mobilizing local learning UDI Communities with global governance to allow for Global Community of Practice that, based on the framework provided by this guide, share best practices on emerging issues including (but not limited to):

- contact lens attributes
- assignment of other multiple UDI-DI use cases
- software versioning
- identification of kits
- tools and device categorization nomenclature for grouping similar devices
- clinically relevant size dimensions by device type
- low unit of measures.

Those issues might also be considered under future IMDRF work items.

Appendices

Appendix A: UDI HRI formats to be used for each of the issuing agencies/entities

1. GS1 Standards

Issuing Agency/Entity	Data Delimiter	Identifier	Data type	Human Readable Field Size	Database Field Size
GS1	(01)	DI	Numeric	16	14
GS1	(11)	Manufacturing/ Production Date	numeric [YYMMDD]	8	6
GS1	(17)	Expiration Date	numeric [YYMMDD]	8	6
GS1	(10)	Batch/Lot Number	alphanumeric	22 (max)	20 (max)
GS1	(21)	Serial Number	alphanumeric	22 (max)	20 (max)
<i>GS1</i>		Maximum Base UDI	<i>alphanumeric</i>	76	66
ex: 01)09506000117843(11)141231(17)201231(10)1234AB(21)5678CD					

GS1 Sample UDI labels:

http://www.gs1.org/sites/default/files/docs/healthcare/udi_label_samples_-_20150317.pdf

2. HIBCC Standards

Issuing Agency /Entity	Data Delimiter	Identifier	Data type	Human Readable Field Size	Database Field size
HIBCC	+	DI	Alphanumeric	7 to 24	6 to 23
HIBCC	\$	Lot Number Only	Alphanumeric	19	18
HIBCC	\$\$7	Lot Number Only (alternative option)	Alphanumeric	21	18
HIBCC	\$\$	Expiration Date followed by Lot Number	Exp. Date: numeric [MMYY]	6	4
			Lot Number: alphanumeric	18	18
HIBCC	\$\$2	Expiration Date followed by Lot Number	Exp. Date: numeric [MMDDYY]	9	6
			Lot Number: alphanumeric	18	18
HIBCC	\$\$3	Expiration Date followed by Lot Number	Exp. Date: numeric [YYMMDD]	9	6
			Lot Number:	18	18

Issuing Agency /Entity	Data Delimiter	Identifier	Data type	Human Readable Field Size	Database Field size
			alphanumeric		
HIBCC	\$\$4	Expiration Date followed by Lot Number	Exp. Date: numeric [YYMMDDHH]	11	8
			Lot Number: alphanumeric	18	18
HIBCC	\$\$5	Expiration Date followed by Lot Number	Exp. Date: numeric [YYJJJ] – Julian Date format	8	5
			Lot Number: alphanumeric	18	18
HIBCC	\$\$6	Expiration Date followed by Lot Number	Exp. Date: numeric [YYJJJHH] – Julian Date format with Hour option	10	7
			Lot Number: alphanumeric	18	18
HIBCC	\$+	Serial Number only	Alphanumeric	20	18
HIBCC	\$\$+7	Serial Number only (alternative option)	Alphanumeric	22	18
HIBCC	\$\$+	Expiration Date followed by Serial Number	Exp. Date: numeric [MMYY]	7	4
			Serial Number: alphanumeric	18	18
HIBCC	\$\$+2	Expiration Date followed by Serial Number	Exp. Date: numeric [MMDDYY]	10	6
			Serial Number: alphanumeric	18	18
HIBCC	\$\$+3	Expiration Date followed by Serial Number	Exp. Date: numeric [YYMMDD]	10	6
			Serial Number: alphanumeric	18	18
HIBCC	\$\$+4	Expiration Date followed by Serial Number	Exp. Date: numeric [YYMMDDHH]	12	8
			Serial Number: alphanumeric	18	18
HIBCC	\$\$+5	Expiration Date followed by Serial Number	Exp. Date: numeric [YYJJJ]	9	5
			Serial Number: alphanumeric	18	18
HIBCC	\$\$+6	Expiration Date followed by Serial Number	Exp. Date: numeric [YYJJJHH]	11	7
			Serial Number: alphanumeric	18	18

Issuing Agency /Entity	Data Delimiter	Identifier	Data type	Human Readable Field Size	Database Field size
			alphanumeric		
HIBCC	/S	Supplemental Serial Number, where lot number <u>also</u> required and included in main secondary data string	Alphanumeric	20	18
HIBCC	/16D	Manufacturing Date (supplemental to secondary barcode)	numeric [YYYYMMDD]	12	8
HIBCC	/14D	Expiration Date (supplemental to secondary barcode as optional format)	numeric [YYYYMMDD]	12	8
<i>HIBCC</i>		<i>Maximum Base UDI</i>	<i>Alphanumeric</i>	<i>70 to 87</i>	<i>58 to 75</i>
Ex of Human Readable Barcode: +H123PARTNO1234567890120/\$\$420020216LOT123456789012345/SXYZ456789012345678/16D20130202C					

HIBCC Sample UDI labels:

<http://www.hibcc.org/wp-content/uploads/2016/02/HIBCC-UDI-Label-Examples.pdf>

3. ICCBBA Standards

Issuing Agency/Entity	Data Delimiters	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
ICCBBA	=/	DI	Alphanumeric	18	16
ICCBBA	=,	Serial Number	Alphanumeric	8	6
ICCBBA	=	Donation Identification Number	Alphanumeric	16	15
ICCBBA	=>	Expiration Date	numeric [YYYJJJ]	8	6
ICCBBA	=}	Manufacturing Date	numeric [YYYJJJ]	8	6
ICCBBA	&,1	MPHO Lot Number	Alphanumeric	21	18
ICCBBA		<i>Maximum Base UDI for</i>	<i>Alphanumeric</i>	79	67

		<i>HCT/Ps</i>			
Ex of Human Readable Barcode: =/A9999XYZ100T0944=,000025=A99971312345600=>014032=}013032&,100000000000XYZ123					

<i>Blood Bags Only</i>	Identifying Symbol	Identifier	Data type	Eye Readable Barcode Field Size	Database Field Size
ICCBBA	=)	DI for blood containers (bags)	Alphanumeric	12	10
ICCBBA	&)	Lot Number for blood containers (bags)	Alphanumeric	12	10
<i>ICCBBA</i>		<i>Maximum Base UDI for Blood Bags</i>	<i>Alphanumeric</i>	<i>24</i>	<i>20</i>
Ex of Human Readable Barcode: =)1TE123456A&)RZ12345678					

ICCBBA Sample UDI labels:

<https://www.iccbba.org/subject-area/medical-devices/label-examples>

Appendix B: AIDC carriers most widely used in healthcare

1. GS1 Standards

- GS1 Data Matrix with DI and PI's (Expiration Date + Lot/Batch Number)



(01)09506000117843
 (17)201231
 (10)1234AB

- GS1 Data Matrix with DI and PI's (Expiration Date + Lot/Batch Number + Serial Number)



(01)09506000117843
 (17)201231
 (10)1234AB
 (21)5678CD

- GS1-128 concatenated with DI and PI's (Expiration Date + Lot/Batch Number)



(01)09506000117843(17)201231(10)1234AB

- GS1-128 non-concatenated (shared in 2 parts)

a) DI only

b) PI's (Expiration Date + Lot/Batch Number)



(01)09506000117843



(17)201231(10)1234AB

- EAN13 with DI only

2. HIBCC Standards

- Data Matrix with DI and PI (Expiration Date + Lot/Batch Number)



+A999ABC123DE1/\$\$3221231LOT876S

- Code128 non-concatenated with DI and PIs (Expiration Date + Lot/Batch Number)



+A999ABC123DE1G



+\$\$3221231LOT876GT

- QR-Code with DI and PI (Expiration Date + Lot/Batch Number)



+A999ABC123DE1/\$\$3221231LOT876S

3. ICCBBA Standards

- ISBT128 with DI and PI's (Donation Identification Number, Serial Number, and Expiration Date)



=/A9999004344T0480



=A99971712345600



=,000005



=>018020

Data Matrix with DI and PI's (Serial Number + Donation Identification Number + Expiration Date)



=/A9999XYZ100T0479

=,000025=A99971412345600=>016008

Appendix C: Examples of RFID carriers

1. GS1 Standards

The data encoded in a GS1 barcode can also be encoded in a RFID tag, provided that a serial number is part of the data elements.

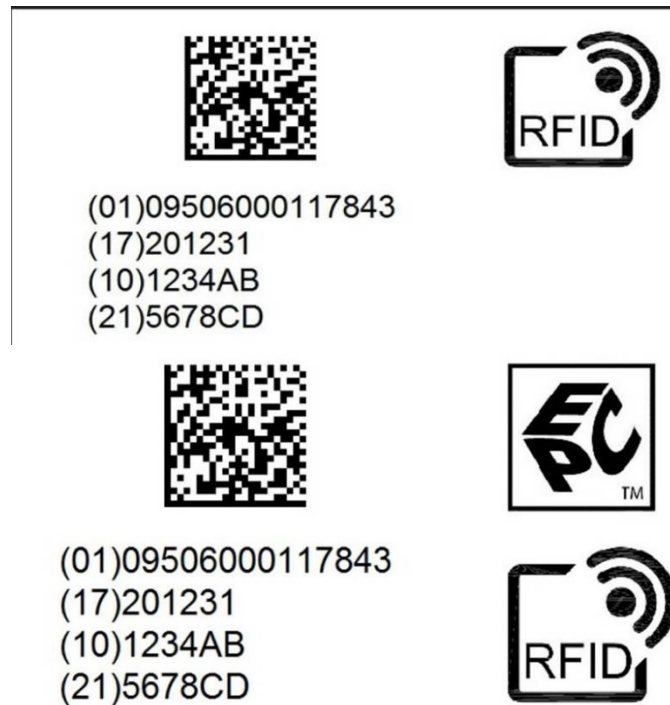
The use of an RFID tag requires that a specific RFID emblem is applied on the label/packaging/device to indicate the presence of radio frequency identification (RFID). The ISO/IEC standard 29160 specifies the design and use of the RFID Emblem.

In Europe, the standard EN 16656 on RFID Emblem is similar to ISO/IEC 29160 except that it requires that only the generic RFID Emblem shall be used as the RFID notification sign.

Both standards allow using optionally other signs, such as the EPC (Electronic Product Code) seal, in addition to the required generic RFID Emblem.

The EPC seal is the sign used to notify when unique EPCs are encoded onto RFID tags. GS1's EPC Tag Data Standard (TDS) specifies the data format of the EPC, and provides encodings for numbering schemes -- including the GS1 keys -- within an EPC/RFID.

Note: today, the relevant GS1 application standards on RFID do not yet address specific location/placement of the RFID Emblem on a label. Relevant CEN standards do state that in the absence of an appropriate application standard, the RFID Emblem shall be placed such that it is easily visible to those trying to read the RFID tag or label. To improve readability, the RFID Emblem should be located near the actual transponder. The visuals below are for example only.





2. HIBCC Standards

A HIBC UDI data string for the Barcode will be encoded with an RFID tag in a 1:1 relation; therefore scanning a Data Matrix with HIBC will yield the same result as scanning a RFID tag.

For RFID applications for UDI the appropriate standards for the product and packaging levels are

- ISO ISO 17367, Supply chain applications of RFID – Product tagging
- ISO ISO 17366, Supply chain applications of RFID – Product packaging

The AIDC and HRI formats are required under the UDI regulation. Therefore, the HRI is not required to be repeated for RFID again, if already present for another type of AIDC format. The ISO/IEC 29160 RFID Emblem is required to be shown as a visible indicator that an RFID is

present by a generic RFID Emblem or optional by a RFID Emblem showing frequency and application by a two character code. This optical visible indicator for frequency and application is helpful in areas where different RFID systems are in use and for diagnostic if a RFID Tag is not read.

The generic RFID Emblem according to ISO/IEC 29160 figure 2:

Fig. Generic RFID Emblem  telling “RFID inside”

Table A.1 (below) of ISO/IEC 29160 shows the appropriate RFID emblems for UDI, using a two character code assignmentment.

Table A.1 — Two-character code assignments for the RFID Emblem (excerpt)

Emblem “B5”: 860-960 MHz (UHF) ISO/IEC 18000-63 ISO 17366 Product packaging

Fig. 1b) RFID Emblem “B5” 

Emblem “B7”: 860-960 MHz (UHF) ISO/IEC 18000-63 ISO 17367 Product tagging

Fig. 2) RFID Emblem “B7” 

Examples of serialized UDI HIBC to be encoded in Barcode and optional RFID

a) on a product +A999ABC123DE0/\$+1234567Y



Fig. 3) UDI applied on a product package with Data Matrix and RFID



Fig. 4) UDI applied on a product with Data Matrix and RFID

Note to Fig. 3 and 4: Human Readable Interpretation (HRI) contains the UDI data within an envelope of two Stars ()*

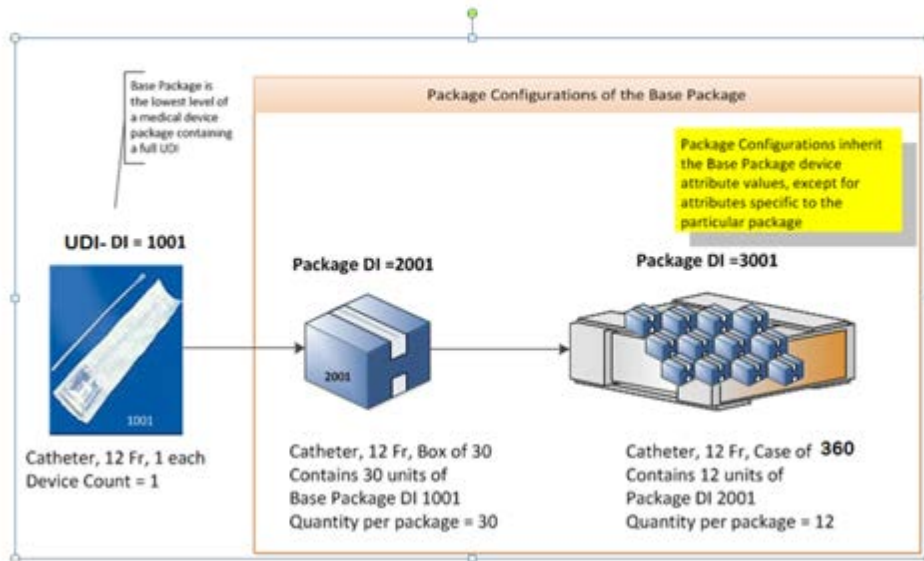
3. ICCBBA Standards

RFID tags are not currently used to carry identification information for medical products of human origin (MPHO), although some organizations are starting to add an RFID tag as a ‘license

plate' based on the unique tag identifier. This is in addition to the barcoded information and would not carry UDI information.

Appendix D: Examples of registration of packaging configurations

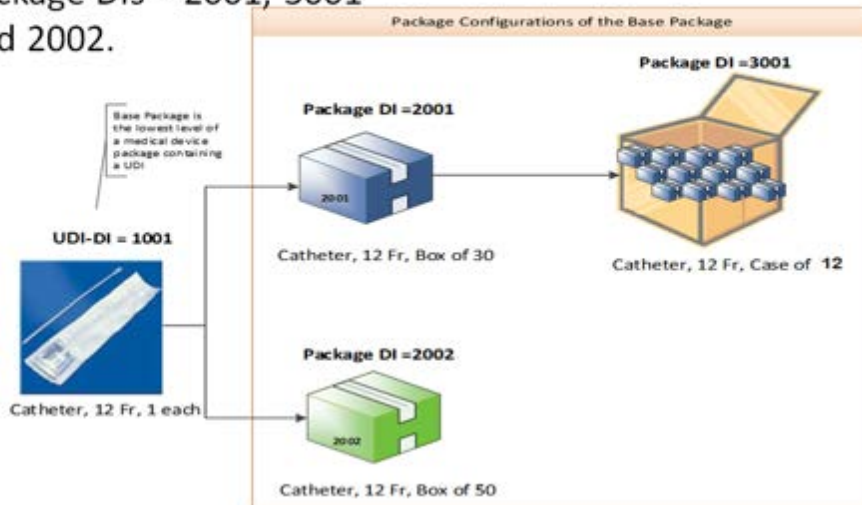
Package Configuration Example 1



Package Configuration Example 2

UDID Entry: UDI-DI = 1001

Package DIs = 2001, 3001 and 2002.



NB: Package configurations of a device are part of the same DI record.

Appendix E: Examples of UoU and packaging configurations

UOU Package Example



Unit of Measure (Package Level)	ANSI UOM	Device Identifier (DI)	Qty	Units at Next pkg level	Contains DI Package
Single Item	-	UOU DI (Unmarked)	1	-	-
Tray <small>(Lowest Pkg Level with DI)</small>	TY	Lowest Pkg Level DI (Full UDI Marked)	25	-	No
Case	CA	Case Level DI (Full UDI Marked)	1000	40	Tray

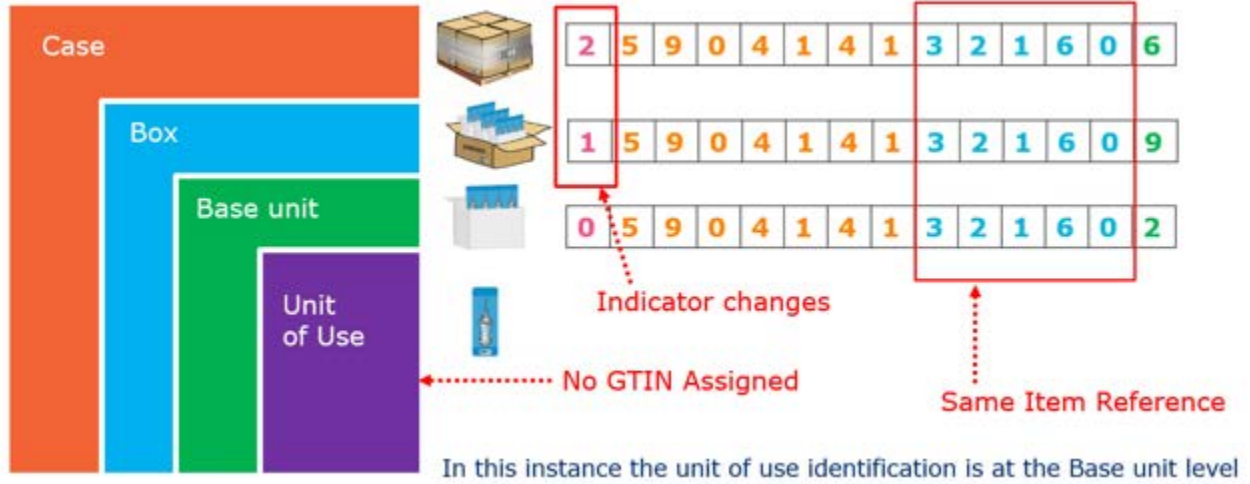
Lowest packaged level ≠ UOU

- Many products used on patients have multiple items in the lowest packaging level
- This concept is not generally used in industries outside healthcare
- There may be **clinical** reasons why we would like to track individual items within these specific packages
- From a **supply chain** perspective, the item cannot be replenished at any level lower than the lowest packaged level

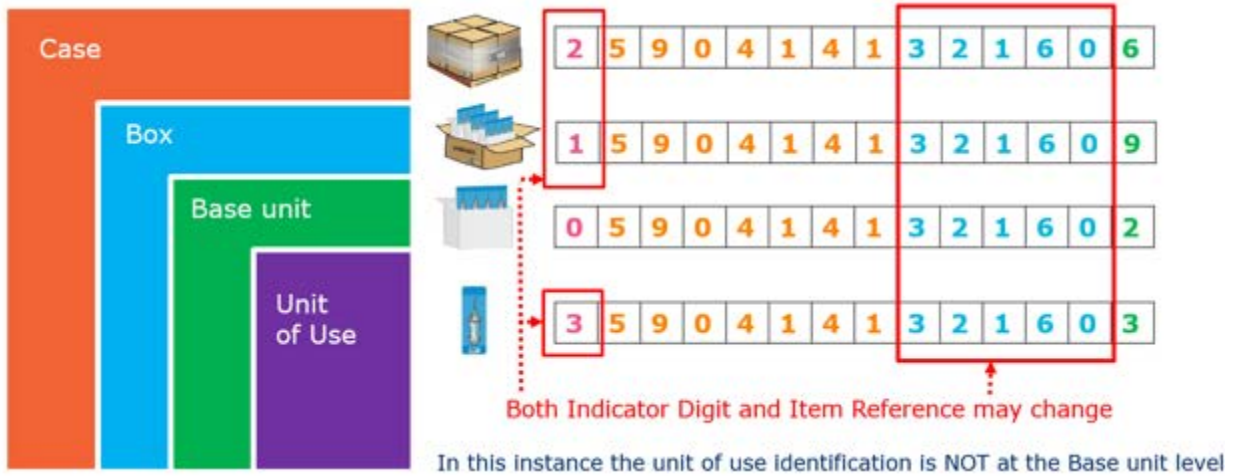
1. GS1 Standards

The examples below are using GTIN-13 and GTIN-14.

- GTIN (i.e. UDI-DI) Assignment Methods where the GTIN (i.e. UDI-DI) has a Device Count = 1.

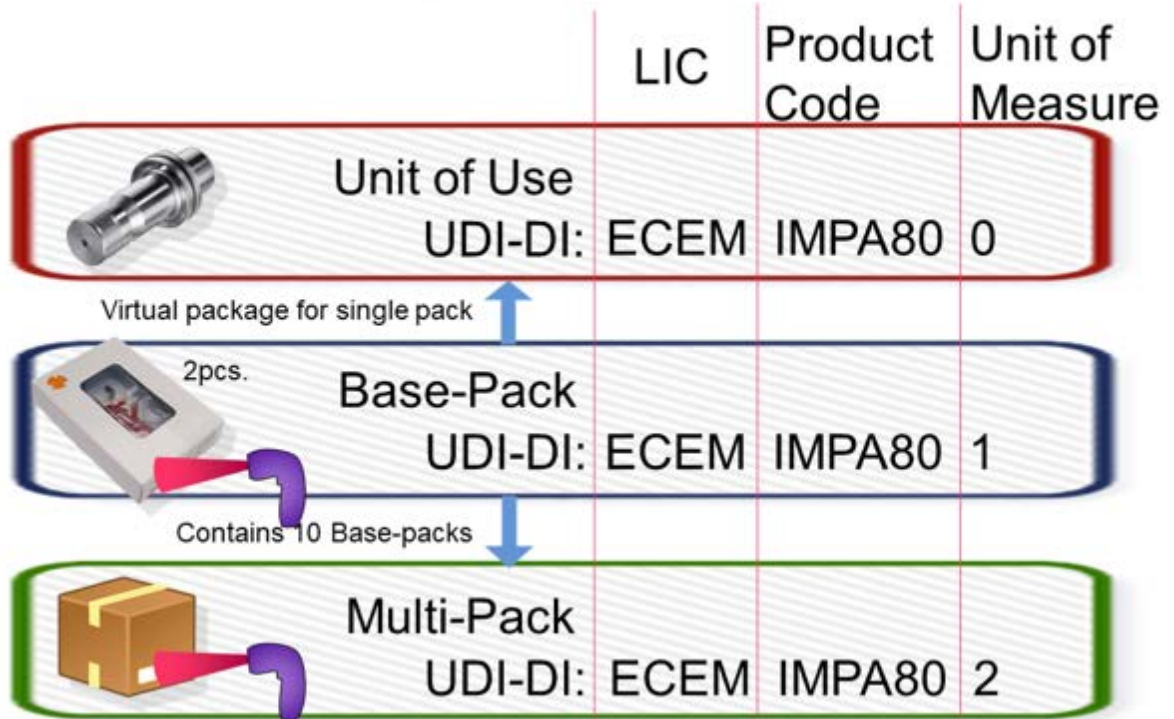


- GTIN (i.e. UDI-DI) Assignment Methods where the GTIN (i.e. UDI-DI) has a Device Count >1.



2. HIBCC Standards

HIBC Example for UDI-DI Levels



The last field of the HIBC UDI-DI is the "Unit of Measure". The Unit of Measure is a number (0-9) assigned by the manufacturer to indicate package level. The Unit of Measure is always located directly after the Product Code. Units of Measure 1-8 are used by the labeler to identify all remaining package levels in ranking order from smallest to largest.

A "Unit of Use UDI-DI" can be created from the UDI-DI of the base pack by using the Unit of Measure "0".

2. ICCBBA Standards

Medical devices containing Medical Products of Human Origin are distributed as single units due the unique nature of each item and its associated donation identification number. Thus, the Unit of Use will be the base pack DI for products labelled with ISBT 128.

Appendix F: Usability issues linked to direct marking

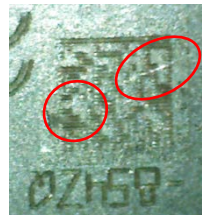
Surface wear / treatment

Due to mechanical influences during use and preparation, surface abrasion occurs. Directly marked products can thereby lose readability. When reprocessing instruments, regionally different re-processing cycles and in particular cleaners are used (North America - neutral cleaners, Europe - alkaline cleaners). With highly alkaline cleaners, marking fades faster over the entire life cycle.

Scratches



Abrasion on tempering inscription



Abrasion



Damage to the DM due to scratches or inclusions limits the readability of the carrier.

Corrosion



Thermal and deforming influences changes material properties, which lead to corrosion in CoCr alloys. Corrosion causes the code to become unreadable. Corrosion holes can be interpreted by the scanner as marked modules.



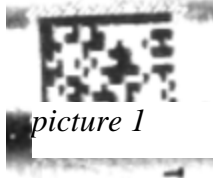
Material



Thermal melting influences on plastics

Reflection / Contrast

Picture 1 - The surface is disturbed by inappropriate lighting (e.g. reflection, resolution, contrast).



picture 1

Picture 2 - With dark materials, there is a lower

contrast ratio to the marking, which affects the readability.



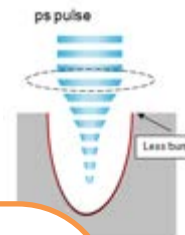
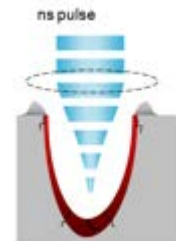
picture 2

Laser Marking

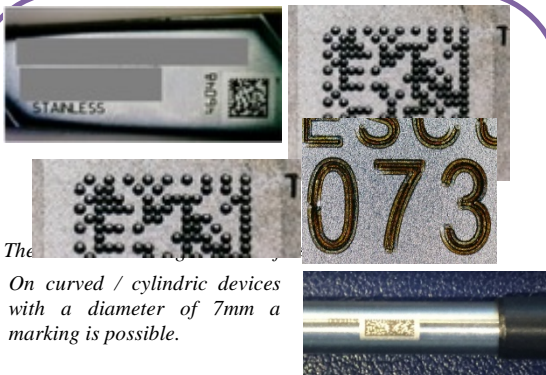
Stainless steel or titanium alloys are marked with conventional systems based on an ns-laser (nanosecond laser) via the engraving effect. Too little engraving (tempering inscription) leads to faster fading.

Passivation of stainless steel with this technique is a mandatory step to avoid corrosion. Passivation is usually done before and/or after the marking.

When marking with a ps-laser (picosecond laser), the material does not get warm due to a very short pulse duration. The surface is slightly roughened, the mark appears jet black and this regardless of the viewing direction. The passivation layer on reusable instruments is not attacked which limits the possibility to corrosion.

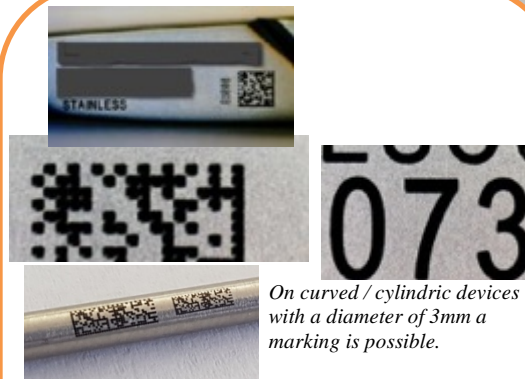


Marking with ns-Laser



The
On curved / cylindric devices with a diameter of 7mm a marking is possible.

Marking with ps-Laser



On curved / cylindric devices with a diameter of 3mm a marking is possible.

Marking 1,25 x 4mm
Marking 1,75 x 5,5mm

The readability of the plain text is independent of the marking method. Because of space reasons a marking of that, the plain text from of the UDI might not be always possible.



1:1



1:1

When used properly, the readability of a validated laser marking with a data-matrix is still given after at least 500 cycles.

(based on experiences made by individual device manufacturers)¹⁷



¹⁷ Users should discard using a reusable instrument, if damage (e.g. corrosion, chipping, discoloration, etc.) is seen.
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Appendix G: Kit Examples

• **Non-IVD kit examples**

Example 1: A sterile, disposable laparotomy kit contains a Mayo stand drape, 4 standard drapes, a laparotomy drape, table cover, 2 hand towels, 2 gowns, and a paper suture bag in a single package.

This kit contains two or more different medical devices packaged together for the convenience of the user where they are intended to remain packaged together and not replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user.

This kit should be identified with one UDI.



Example 2: It follows the same principles of Example 1 except the kit is customizable to meet health provider preferences.

Best practice recommendation: While it is the manufacturer that determines when a change to a device constitutes a new model/version of the device, unless there is a relatively small number of potential customizations, using DIs to differentiate between customized variations is not recommended because it can produce a very large number of DI records. Instead, differences in customized variation can be accounted for using UDI-PIs.

This kit should be identified with one UDI.

Example 3: Several implant components (including inflatable band, access port and tubing) and multiple sterile accessories (calibration assembly, end plug, closure tool, needles) are together in one package under one label. All the contents of the package are used or disposed of in a single procedure.

None of the devices in the kit are replaced, substituted, repackaged, sterilized, processed or modified before the devices are used by an end user.

This kit should be identified with one UDI.

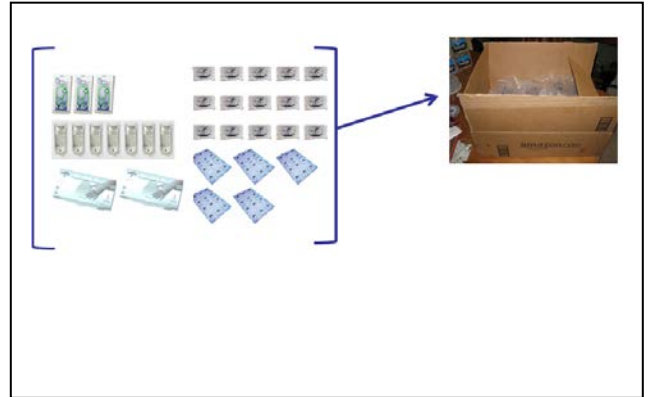


- **Collection of items not defined as kits examples**



Example 1: A collection of finished and labeled devices that are not necessarily intended to be used together and placed in a box for delivery to the hospital. The content of the box changes from day to day depending on what the hospital orders. In the case, the box contains 3

stethoscopes, 6 saline bags, 10 packages of IV tubing, 2 boxes of gloves and 4 cartons of EKG electrodes.



This is an example of a shipping container and no UDI is required on the shipping container. The collection is not itself a medical device (a “kit”) because the collection is not based on an intended use, but includes a continually varying collection based on what a customer ordered today. Note that each individual item should bear a UDI.

Example 2: A manufacturer manufactures two versions/models of a device. Model A is more popular than Model B. To sell more of Model B, the two models, when sent to retailers and distributors, are packaged in an assorted case that always includes 5 of Model A and 3 of Model B, i.e. a standard configuration.

Although both devices may have similar indications for use, Model A and Model B were not combined in a device package with the intent they are used together to achieve a common intended use. Rather, these two or more different models/versions of devices were packaged together for business reasons.



This package configuration itself is not a device (not a kit). However, to adequately identify this fixed configuration through distribution and use, packages require UDI.

Recommended best practice: place a UDI on each device in the packaging configuration and place a UDI on the package that contains the devices.

- **Example of an IVD kit (Microbial identification tests)**



Contents of kit includes various items (e.g. swabs, reagents, control materials) intended to be used together to detect specific organisms per the device indication.

The kit is a medical device and requires a UDI. Any items distributed separately require a UDI.

Recommended best practice: if items in this IVD kit are also in other IVD kits, then those individual items should also be identified by a UDI.

- **Examples from issuing entities¹⁸**

1. **GS1 Kit Examples**

Example 1:



This is self-adherent wrap (class I medical device) that comes in multiple colors.

The “each” is a pouched roll of self-adherent wrap.

Six (6) rolls of each color (6 colors) are packaged together in a 36-roll hospital kit.

Each color has a different Catalog code/REF, internal SKU, and GTIN.

¹⁸ Please note these examples represent current thinking and are open to feedback

The multi-color kit has a different Catalog code/REF, internal SKU and DI than would a case composed of a single color product.

The kit has a UDI and each item in the kit has a UDI.

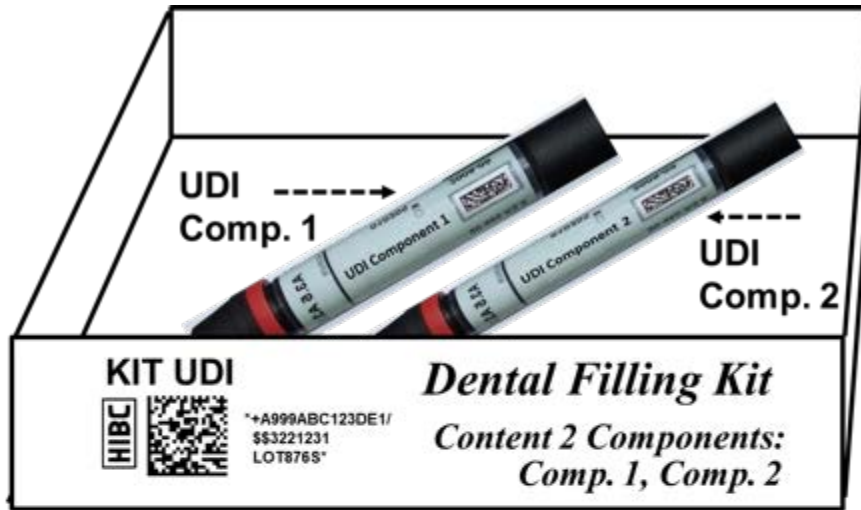
Example 2:






This is a 2-jar impression material. One jar contains a catalyst and the other jar a base, when combined the material cures and captures a dental impression. Products like this are a single medical device, the two components share the same conformity assessment, technical file and registration in every country of the world. Depending on the product, sometimes refills of a single component are sold, sometimes not.

The kit should be identified with one UDI.

2. HIBCC Example



HIBCC CODE DATA								
	Flag	LIC	REF	UoM	De- limiter	LOT	Check	HIBCC
KIT UDI	+	A999	KIT1X	1	/S	LOT1X	N	 *+A999KIT1X1/\$LOT1XN*
UDI Comp.1	+	A999	COMPO1	1	/S	LOT1	/	 *+A999COMPO11/\$LOT1/*
UDI Comp.2	+	A999	COMPO2	1	/S	LOT2	%	 *+A999COMPO21/\$LOT2%*

The kit should be identified with a UDI and each item in the kit should be identified with one UDI.

Appendix H: Examples of changes to configurable medical devices

- **Changes where UDI-DI and UDI- PI remain unchanged**

Example 1:

An installed CT system has an x-ray tube which has reached the end of its life and is replaced with a newer model tube by the original manufacturer without other changes to the device or its labeling. The manufacturer has determined that this does not constitute a new version/model of the system, according to their documented procedures for assessing device changes (e.g. the safety profile, the performance of the system and the intended use are unchanged). Because the change in the component does not result in a new model/version of the system, the system UDI-DI and UDI-PI remain unchanged.

Example 2:

For an x-ray system that is a configurable device where both the 50 kV generator and the 100 kV generator is an option (covered by what is specified for the defined groups of configurations), the 50 kV generator is replaced by 100kV generator or vice versa. The manufacturer has determined that this does not constitute a new version/model, according to their documented procedures for assessing device changes, and therefore the system UDI-DI and UDI-PI remain unchanged. Because the change in the voltage of the generator does not result in a new model/version, the system UDI-DI and UDI-PI remain unchanged.

Example 3:

The addition of an accessory, (e.g. adding a coil to an installed MRI system where coils are part of the configurable system) that is covered by what is specified for the defined groups of configurations does not result in a new model/version of the system. Because the addition of the accessory does not result in a new model/version, the system UDI-DI and UDI-PI remain unchanged. Because the accessory is being distributed separately from the system, the coil should have its own UDI.

- **Changes that induce a change of both UDI-DI and UDI-PI**

Example 1:

An installed MRI System ‘Model A’ is upgraded in a way that it becomes ‘Model B’ which is not covered by the defined groups of configurations for Model A, as the safety profile, the performance of the system or the intended use are changed. The manufacturer has determined that this upgrade/model change does result in a new model according to their documented procedures for assessing device changes. Because the upgrade results in a new model/version, a new UDI-DI and UDI-PI is required for the system.

Example 2:

A X-Ray system with a 50 kV generator is changed to a 100 kV generator. These generator options are not specified for the defined groups of configurations, and the performance of the system is changed. The manufacturer has determined that this constitutes a new version/model of the system because the change in the generator of the X-ray system results in a new model/version of the system, a new UDI-DI and UDI-PI is required for the system. .

Example 3:

An interventional x-ray system introduces a new stabilizing mechanism designed to prevent patient head movement during operating and imaging procedures. Although the imaging capabilities are unchanged, this represents a new safety profile for the patient and changes the specifications of the system, and therefore the manufacturer has determined that this upgrade/model change does result in a new model/version according to their documented procedures for assessing device changes. Because this design change to the system results in a new version/model of the system, a new UDI-DI and UDI-PI is required for the system.

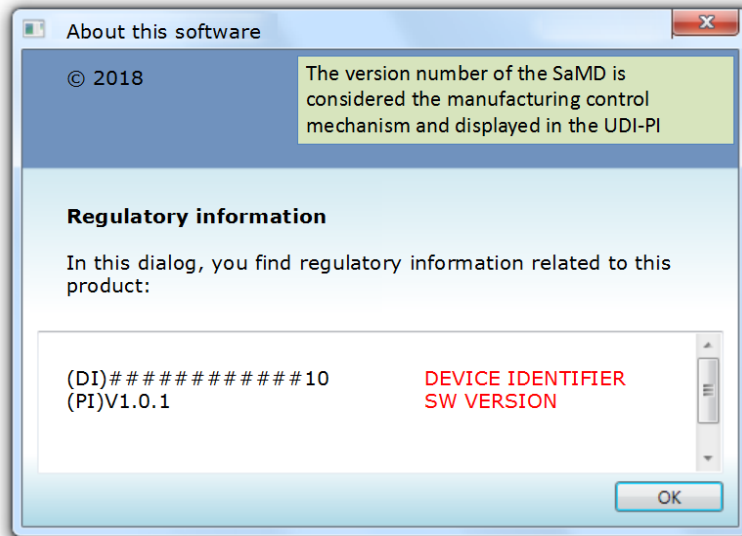
NB: If the stabilizing mechanism is an accessory, and not considered part of the defined configurable system, then no new UDI is required for the x-ray system. A UDI is required, however, for the stabilizing accessory.

Example 4:

A new diagnostic algorithm is introduced on a cardiac ultrasound system allowing new data calculations and imaging options. The algorithm introduces new indications for use and changes the performance of the system, and therefore the manufacturer has determined that this upgrade/model change does result in a new model/version of the cardiac ultrasound system according to their documented procedures for assessing device changes. Because the change results in a new version/model of the system, a new UDI-DI and UDI-PI is required for the system.

Appendix I: Example of UDI assignment for software

Example for UDI assignment to SaMD (Software as a Medical Device)
According to IMDRF/UDI WG/N7FINAL:2013



Example for UDI assignment to SaMD (Software as a Medical Device)
According to IMDRF/UDI WG/N7FINAL:2013

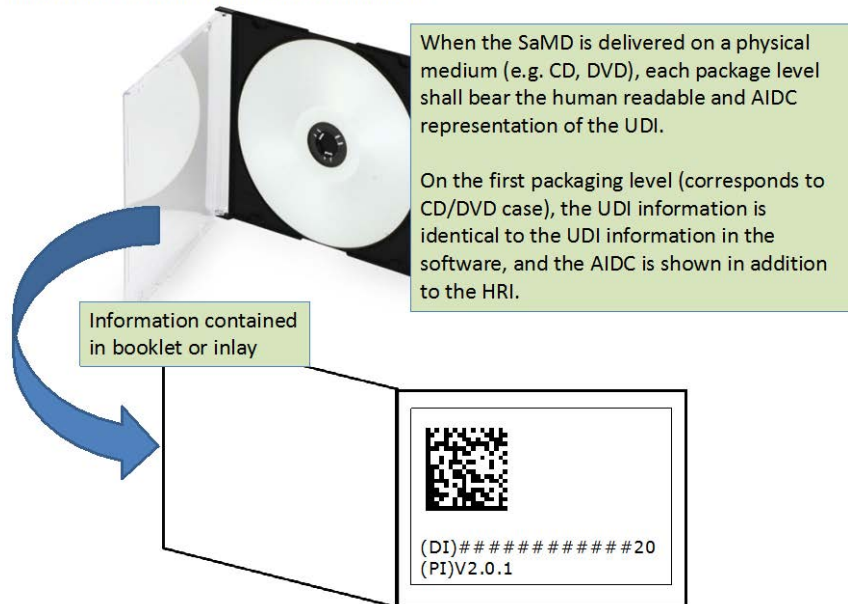


NB: SaMD version might be captured in the lot UDI-PI in certain national regulations.

Example for UDI assignment to SaMD (Software as a Medical Device)
According to IMDRF/UDI WG/N7FINAL:2013



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NB: SaMD version might be captured in the lot UDI-PI in certain national regulations.