IMDRF International Medical Device Regulators Forum

Proposed Draft

International Medical Device Regulators Forum

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Contents

1. Preamble

This document is inscribed in the framework of the International Medical Device Regulators Forum (IMDRF). It replaces the "Guidance on a Unique Device Identification System (UDI) for Medical Devices" adopted by the Global Harmonization Task Force (GHTF) on 16 September 2011.

The IMDRF Guidance on a "Unique Device Identification System (UDI) for Medical Devices" clarifies and supplements the above mentioned GHTF Guidance by providing non-binding rules for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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2. Introduction

This guidance provides a framework for those regulatory authorities that intend to develop their own UDI Systems – such that, when implemented, it achieves a globally harmonized approach to UDI. It is expected that the regulatory authorities will follow the guidance when developing their own UDI requirements. The framework can be used at a local, national, or global level. In order to reach the goal of a globally harmonized UDI System, it is critical that these systems are implemented **without** regional or national differences. This guidance is intended to provide a high-level conceptual view of how a global UDI System should work. It is recognized that further additional guidance may be needed once these core concepts are implemented.

The fundamental concepts of a globally harmonized UDI System include:

a. the UDI and UDI Carrier are based on global standards,
b. a UDI applied to a medical device anywhere in the world should be able to be used globally to meet the UDI requirements of any regulatory authority,
c. national or local identification numbers should NOT be a substitute for UDI,
d. regulatory Authorities should not specify how to modify these standards
e. the UDI Database (UDID) core elements should not be modified,
f. the UDID should use the HL7 SPL for data submission,
g. each medical device needs to be identified by a UDI.

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 additional information. It is critical to note that the benefits of UDI can only accrue if all stakeholders, from the manufacturer to healthcare providers and patients, use UDI throughout their systems. Therefore, it is imperative that all stakeholders be educated about the development and use of a UDI System.

A globally harmonized and consistent approach to UDI is expected to increase patient safety and help optimize patient care by facilitating the:

a. traceability of medical devices, especially for recalls and other field safety corrective actions,
b. adequate identification of medical devices through distribution and use,
c. identification of medical devices in adverse events,
d. reduction of medical errors,
e. documenting and longitudinal capture of data on medical devices.

2.1 Traceability

The global use of a Unique Device Identifier (UDI) will facilitate traceability throughout distribution.
In order to achieve traceability, it is necessary to require all stakeholders to capture and store the UDI (Device Identifier + Production Identifier) throughout distribution and use.
This is especially important for recalls and other field safety corrective actions.
Though the UDI Database (UDID) does not capture Production Identifiers (UDI-PI), it is expected that supply chain operators will capture and use these identifiers. This is critical during recalls and other field safety corrective actions. In addition, the foundational use of UDI can help fight counterfeiting and secure the supply chain for all stakeholders.
Traceability includes:

a. recording medical devices from manufacturer to healthcare provider throughout the supply chain,
b. recording medical device use in patients,
c. implementation of medical device recalls,
d. a standardized way to input medical device identification into registries.

2.2 Identification

UDI will facilitate the adequate identification of the medical device through distribution and use by providing a single global identifier that can be used to link and integrate existing government, clinical, hospital, and industry databases. UDI should allow for improved procurement, inventory management, and accounting. The existence of a single device identifier (UDI-DI) to link disparate data bases should allow creative new medical and business applications, and synergy among those applications.

2.3 Adverse Event Reporting

UDI will allow industry and regulatory authorities to more rapidly identify medical devices involved in adverse events. UDI will be available for inclusion in adverse event reports, allowing greater accuracy in reporting, and more rapid aggregation of related reports. Using this information, Health Authorities can more rapidly collate and analyze problem reports and identify the most-appropriate solution for a particular concern. UDI will allow more targeted

safety alerts, recalls, and other corrective actions on the specific medical devices that are of concern.

2.4 Medical Errors

By providing rapid and electronic access to critical patient safety information relating to a medical device, the UDI system may help clinicians more safely select and use the proper medical device for a patient. UDID data could be downloaded by healthcare providers to be used for internal reference of safety related information.

2.5 Documentation

The use of UDI System will facilitate and simplify the documentation of medical device use in various patient records including traditional as well as electronic health records and registries. UDI should also enable linkages of medical device information across various systems and across geographies. These applications of UDI could help identifying medical device problems and enhance comparative effectiveness.

Other considerations essential for the successful development and implementation of a globally harmonized UDI System include:

a. a risk-based approach which is essential given the huge diversity of the medical devices,
b. kits, systems and other groups of devices which need to be managed appropriately,
c. requirements which should be phased in over a period of years based on risk classes, starting with the highest risk class, to reduce the burden of implementation,
d. the need for all supply chain stakeholders to have sufficient time to prepare their systems, processes and staff, for the proper use of the UDI system.

3. Rationale, purpose and scope

3.1 Rationale

There are currently no global definitions of what constitutes a UDI or UDI System. As a consequence, discrepancies between different national approaches do exist and will most likely increase. Common globally harmonized UDI System requirements would offer significant benefits to manufacturers, healthcare providers, patients, and regulatory authorities. In addition, eliminating or reducing differences between regulatory authorities decreases the cost of gaining regulatory compliance.

3.2 Purpose

A UDI unambiguously identifies a manufacturer's specific medical device. A standardized UDI is part of the label, documented in the UDID, and used consistently throughout distribution and use should facilitate a number of patient safety benefits, including:

a. traceability of medical devices,

b. the identification of medical devices in adverse events reports and other post-market safety surveillance activities,
c. field safety corrective actions, including recalls,
d. the reduction of medical errors,
e. establishing and maintaining registries.

This guidance intends to avoid country-specific requirements regarding the core elements of the UDI System by developing common guidance for:

a. creating, use and maintaining a UDI,
b. applying a UDI Carrier,
c. establishing the UDID model/structure, with a defined list of Data Elements,
d. establishing basic requirements for a data submission format based on a common standard,
e. establishing basic requirements for a common data exchange standard.

In order to facilitate global traceability, the UDI System should be promoted and used at all levels by all stakeholders, including regulatory authorities, medical device manufacturers, distributors, healthcare providers and patients.

This document does not address the use of the UDI System, e.g. by healthcare providers. Therefore it does not directly address issues associated with counterfeit medical devices or how to enable better control of purchasing which will depend on the use of the UDI System by healthcare providers.

3.3 Scope

This document applies to all products to be placed on the market that are regulated as medical devices. For a definition of a medical device, see the GHTF document "*Information Document Concerning the Definition of the Term "Medical Device*"".
This document is addressed to the regulatory authorities and affects medical device manufacturers.

4. References

- GHTF final documents;
- SG1/N071:2012 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device';
- SG1/N070:2011 Label and Instructions for Use for Medical Devices;
- SG1/N055:2009 Definitions of Terms Manufacturer, Authorized Representative, Distributor and Importer;
- SG1/N065:2010 Registration of Manufacturers and other Parties and Listing of Medical Devices;
- ISO/IEC 15459-2:2006 – IT Unique identifiers Part 2: Registration procedures;
- ISO/IEC 15459-4:2008 – IT Unique identifiers Part 4: Individual items;
- ISO/IEC 15459-6:2007 – IT Unique identifiers Part 6: Unique identifier for product groupings;

- ISO/IEC 16022:2006 – IT AIDC technics Data Matrix bar code symbology specification;
- ISO/IEC 18004:2006 – IT AIDC techniques QR Code 2005 bar code symbology specification.

5. Definitions

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 –SG1 N071:2012].

Automatic Identification and Data Capture (AIDC)
AIDC refers to the methods for automatic identification of objects, collecting data about them, and entering the data directly into computer systems.

Configurable medical device system
A configurable medical device system consists of several components which can be assembled in multiple configurations. Those components may be medical devices itself and/or non-medical devices.
Examples are Computed Tomography (CT) systems, Ultrasound systems, Anesthesia systems, Physiological Monitoring systems, Radiology Information System (RIS).

Configuration
Configuration is a combination of items of equipment, as specified by the manufacturer, that operate together to provide an intended use or purpose as a medical device. The combination of items may be modified, adjusted or customized to meet a customer need.
Examples:
1. CT: gantry, tube, table, console are items of equipment that can be configured/combined to deliver an intended function.
2. Anesthesia: ventilator, breathing circuit, vaporizer are items of equipment that can be configured/combine to deliver an intended function.

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, HIBC-LIC, ISBT product code.

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

Kits
Kits are a collection of products, including medical devices, that are packaged together to achieve a common intended use and is being distributed as a medical device. 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 person [1] 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 reprocessors and remanufacturers that take responsibility for the device and reintroduce it into commercial distribution.

Own Brand/Private Labelers
An Own Brand or Private Labeler relabels a device from a 3rd party with his own name without making any further changes to the device thereby taking responsibility for it as the manufacturer.

Packaging Levels
Packaging levels means the various levels of device packages that contain a fixed quantity of medical devices, e.g. each, carton, case. This does not include shipping containers such as pallets.

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, 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.

Standalone medical device software
Standalone Medical Device Software is software intended to be a medical device in its own right and which is not embedded in another device.
Examples:
Radiation planning software, surgical planning software, cardiac patient management software, picture archiving and communication systems (PACS).

Unit of Use (UoU) UDI-DI

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

The Unit of Use UDI-DI is an identifier assigned to an individual medical device when a UDI is not labelled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient.

UDI

UDI means Unique Device Identification. 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 comprises the UDI-DI and UDI-PI.

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

UDI System

The UDI System is the framework for the production of a UDI, its application on the label or directly on device, and the storage of the UDI-DI and additional device related information in a UDID.

UDI Carrier

The UDI Carrier is the means to convey the UDI by using Automatic Identification and Data Capture (AIDC) and, if applicable, its human readable interpretation (HRI).

Note: Carriers can include linear bar-codes, 2D bar-codes and RFID, etc…

UDI Database (UDID)

The UDID contains identifying information and other elements associated with the specific medical device.

6. Guidance for a UDI System

A UDI System comprises 3 parts:

1. the development of the UDI using globally accepted standards,
2. the application of that UDI on the label, and
3. the submission of appropriate information to a UDID.

In order to facilitate a globally harmonized approach to UDI, it is imperative that:

1. the marking of the UDI should be an additional requirement – it does not replace any other marking or labeling requirements;
2. the manufacturer should create and maintain globally unique UDIs on his medical devices;
3. the UDI on the device should not be changed, except in the cases of reprocessing, remanufacturing, or relabeling that lead to a regulated new medical device;
4. only the manufacturer can establish the UDI on the device or its packaging. Reprocessors of single use medical devices, remanufacturers, Own Brand/Private Labelers are considered the manufacturer of the reprocessed or remanufactured device – and as such are also subject to these requirements;

5. Manufacturer should provide UDI which can be readable at any user side and keep the appropriate marking based on the quality management, such as clear readable label, including uniqueness;
6. globally accepted coding standards managed 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. It is imperative that these coding systems be adopted and implemented, without national deviations or changes to these global coding systems; proliferation of coding systems must be discouraged;
7. national or regional regulatory requirements shall not restrict methods of AIDC as this will hinder the establishment of a globally harmonized UDI System;
8. the National/Regional regulation for UDI System shall include a robust process for evaluating and adjudicating applications for UDI exemptions that would exempt certain device types or package levels (including direct part marking) from being labeled with UDI or specific elements in the UDID;
9. common criteria for accreditation are:
    a. The employed UDI must meet the requirements of the globally harmonized UDI System to adequately identify a device through its distribution,
    b. The employed UDI is in compliance with international standards ISO 15459-2, ISO 15459-4 and ISO 15459-6,
    c. The employed UDI will be available to all users according to a single set of consistent fair and reasonable terms and conditions.

To meet the public health objectives of this guidance and to ensure that medical device user facilities, healthcare providers, regulatory authorities, and others will be able to make efficient and effective use of the UDI, there could be a need to limit the number of accredited global organizations and available coding systems.

7. The UDI

1. A UDI shall be assigned to the device itself or its package. Higher levels of packaging shall have their own UDI.
2. Shipping containers should be exempted. As an example, UDI is not required on a logistics unit; when a healthcare provider orders multiple medical devices using the UDI or model number of individual devices and the manufacturer places these devices in a container for shipping or to protect the individually packaged devices, the container (logistics unit) is not subject to UDI requirements.
3. The UDI contains two parts: a Device Identifier (UDI-DI) and a Production Identifier (UDI-PI).
4. The UDI-DI (e.g., GS1 GTIN, HIBC-LIC, ISBT product code) should be globally unique at all levels of packaging.
5. If a lot number, serial number, software version number or expiration date appears on the label, they should be part of the UDI-PI. If there is ALSO a manufacturing date on the label, it does NOT need to be included in the UDI-PI. If there is only a manufacturing date on the label, this should be used as the UDI-PI.

6. When a UDI is not assigned to the device at the level of its unit of use, then a Unit of Use (UoU) UDI-DI should be assigned, to associate the use of a device with a patient. [for example, a UoU UDI-DI would be assigned to an individual electrode when the electrode is distributed in a package of 10 – and lowest level UDI is assigned to that package of 10]
7. Each component, sub-system or accessory that is regulated as a medical device needs a separate UDI.
8. Kits should have their own UDI.
9. The manufacturer assigns the UDI to a device following the relevant coding standard.
10. Any change of one of the following UDID data elements determines the need for a new UDI-DI:
    a. Brand Name,
    b. Device version/ model,
    c. Reference and/or catalogue number,
    d. Clinical Size (including Volume, Length, Gauge, Diameter),
    e. Labelled as single use,
    f. Packaged sterile,
    g. Need for sterilization before use.
11. At a minimum, a new UDI-DI is required whenever there is a change that could lead to misidentification of the medical device and/or ambiguity in its traceability.
12. Reprocessors of single use medical devices, remanufacturers, Own Brand/Private Labelers should create their own, new UDI for the reprocessed, remanufactured, or relabeled medical device which will replace the OEM's UDI where it exists.
13. Reprocessors of single use medical devices, remanufacturers, Private (Own Brand) Labelers shall retain record of the Original Equipment Manufacturer's (OEM) UDI.
14. A change of the label to display or modify a UDI-DI should not (in and of itself) require a premarket submission and/or re-registration. Manufacturers may be requested to notify/inform the Regulator.

8. UDI Carrier

1. The UDI Carrier (AIDC and HRI representation of the UDI) shall be on the label of the device, its package, or on the device itself, and on all higher levels of packaging.
2. The UDI Carrier for low risk devices packaged and labeled individually does not need to be on its package but rather on a higher level of packaging, e.g. carton. However, when the healthcare provider is not expected to have access (e.g., home user) to the higher level of packaging (e.g., carton), the UDI should be on its package.
3. Non-prescription medical devices exclusively for retail Point of Sale (POS) do not need to encode Production Identifiers in AIDC on the point of sale package.
4. No particular AIDC methods should be required by a regulatory authority. Globally accepted AIDC methods based on ISO standards that have been approved by the global organization (e.g., GS1, HIBCC or ICCBBA) shall be used.
5. RFID should comply with open, commercially acceptable, industry standards such as EPC (Electronic Product Code) and be vendor neutral.
6. When AIDC carriers other than the UDI Carrier are part of the product labeling, the UDI Carrier shall be readily identifiable.

7. If linear bar codes are used, the UDI-DI and UDI-PI can be concatenated or non-concatenated in two or more bar codes. All parts and elements of the linear bar code shall be distinguishable and identifiable.
8. If there are significant constraints limiting the use of both AIDC and HRI on the label, the AIDC format shall be favored. However, certain environments or use situations, such as home care, may warrant the use of HRI over AIDC.
9. In case of RFID, a linear or 2D bar code shall also be provided on the label.
10. Medical devices that are reusable should have a UDI Carrier on the device itself.
    a. The UDI Carrier of reusable medical devices that require reprocessing or sterilization between patient uses should be permanent and readable after reprocessing or sterilization cycles for the whole 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.
11. The UDI Carrier should be readable during normal use and throughout intended life of the medical device.
12. If the UDI Carrier is readily readable through the medical device's package, then the UDI Carrier does not also need to be on the package.
13. A single finished medical device made up of multiple parts that have to be assembled may have the UDI Carrier only on one part.
14. The placement of the UDI Carrier should be done in a way that AIDC method can be accessed during normal operation or storage.

9. The UDID

9.1 General principles of the UDID

1. No product commercial confidential information shall be included in the UDID.
2. The manufacturer is responsible for the initial submission and updates to the identifying information and other medical device data elements in the UDID.
3. Appropriate methods/procedures for validation of the provided data shall be implemented.
4. The manufacturer shall periodically reconfirm all the data relevant to their medical devices, except for discontinued medical devices.
5. The core data elements in the UDID shall be accessible to the public free of charge.
6. The presence of the medical device UDI-DI in the UDID does not mean that the medical device is authorized in all jurisdictions.
7. The database should allow for the linking of all the packaging levels of the medical device.
8. Manufacturers should update the UDID within 30 days when a change is made to an element that does NOT require a new UDI-DI.
9. The UDID shall use HL7 Structured Product Labeling (SPL) standard for data submission and updates. Additional submission means could also be accommodated.
10. The core elements are the minimum elements needed to identify a medical device through distribution and use. Regional or National UDID may contain additional elements; however, these additional elements should be kept to a minimum.
11. The design of the UDID should support the official languages required in the jurisdictions where the medical device is put on the market.
12. Data relating to discontinued medical devices shall be maintained in the UDID.

13. The UDID shall support the use of all the core UDID data elements.

9.2 The core UDID data elements

All the core UDID data elements are mandatory, unless marked optional. “If applicable” means the information is mandatory to be in the UDID if it is on the label. Data elements and their definitions for the UDID are listed below.

The core UDID data elements are the following:

1. For every packaging level – the following shall be provided in a related way (for entire packaging hierarchy):
   - ü UDI-DI (UDI type, e.g. GS1 GTIN, HIBC-LIC, ISBT product code),
   - ü Quantity per package configuration: (e.g., each, 10 each, 5 shelf packs),
   - ü Additional device identifier(s) (if applicable) e.g. GS1, HIBC, or ISBT-128;
2. The Unit of Use UDI-DI (see section 7.6) code;
3. The data for new UDI-DI must be available at the time the medical device is put on the market.
4. Manufacturer’s name (as required on the label);
5. Manufacturer’s address (as required on the label);
6. Manufacturer's customer service contact information (country specific, could be multiple);
7. Authorized Representative's name (regional representatives responsible for the medical device) (country specific, could be multiple) (if required by the local/regional regulatory authority) (see GHTF SG1 N55);
8. Authorized Representative's contact information (country specific, could be multiple);
9. Global Medical Device Nomenclature (GMDN) preferred code/term;
10. Brand Name (if applicable);
11. Device software major version (if applicable);
12. Reference and/or catalogue number (if applicable);
13. How the device is controlled: serial, lot/batch number, and/or expiration date (or manufacturing date) or software version or software released date or ISBT-128 – check boxes (if applicable);
14. Clinical Size (including Volume, Length, Gauge, Diameter) (if applicable) (e.g. 8F catheter);
15. Additional product Description (optional) – Additional clinically relevant information, e.g. radio-opaque;
16. Storage conditions, as labeled on the product and/or in the IFU (if applicable) – to include temperature range, needs to be refrigerated, relative humidity range, pressure range, avoid direct sunlight;
17. Handling conditions (if different than storage conditions), as labeled on the product and/or in the IFU (if applicable) – to include temperature range, needs to be refrigerated, relative humidity range, pressure range, avoid direct sunlight;
18. Labeled as single use? (Yes/No);
19. Packaged sterile? (Yes/No);
20. Need for sterilization before use? (Yes/No) – *if yes, then the method of sterilization should be indicated*;
21. Restricted number of reuses (if applicable);

22. License and/or marketing authorization or registration number (if required by the local regulatory authority);
23. URL for additional information, e.g. electronic IFU (optional);
24. Critical warnings or contraindications (if applicable) – if a particular regulation requires that the label of the device contains a critical warning or contraindication associated with the use of the device [e.g.:
    a) Labeled as containing latex? (Yes/No),
    b) Labeled as containing DEHP? (Yes/No), etc…,];
25. Discontinuance information (Information referring to products no longer placed on the market – Date of discontinuance).

10. Rules for specific device types

10.1 Implants

Implants should follow the rules listed below:

1. All unit packs of implants (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 implants,
    b. serial number for other implants or lot number according to the manufacturer's quality management system;
3. The UDI of the implant must be identifiable prior to implantation.

10.2 Reusable devices requiring sterilization or high level disinfection between uses

These devices should follow the rules listed below:

1. The UDI of these products must be on the device and must be readable after each sterilization or high level disinfection;
2. PI characteristics (e.g. lot or serial number) should be defined by the manufacturer according to the manufacturer's quality management system;

10.3 Non IVD kits

1. The manufacturer of the Kit is responsible for identifying the Kit with a UDI including both UDI-DI and UDI-PI;
    a. Orthopedic procedure trays whose contents are configured for a specific order are exempted from this UDI requirement.
    Example: a hospital orders 30 different orthopedic devices for total joint replacement surgery. The 30 devices are delivered to the hospital in a stainless steel box where the devices can be stored and sterilized by the hospital when needed. After a procedure the hospital may replace used parts and re-sterilize the box with its contents;

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

   Exemptions:
   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.

3. Placement of the UDI Carrier on Kits:

   a. The Kit UDI Carrier 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 Kit package or inside a transparent package.

10.4 IVD Kits

IVD kits should follow the rules listed below:

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

2. 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 barcodes necessary for their handling and identification by the automated systems. This does not constitute a UDI;
   c. Individual single-use disposable medical devices 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.

3. 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.

10.5 Configurable medical device systems

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. The 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;

10.6 Standalone Medical Device Software

1. **UDI Assignment Criteria**

The UDI should be assigned at the system level of the Standalone Medical Device Software.

The following changes would require a new UDI-DI for Standalone Medical Device Software:

1. Changes to the Model Number or Part Number of the Standalone Medical Device Software (not revision);

2. Major Standalone Medical Device Software revisions shall be identified with a new UDI-DI;
   - Major Standalone Medical Device Software revisions are meant as complex or significant changes affecting the original performance and effectiveness, the efficacy of the safety or the intended use of the Standalone Medical Device Software. These changes may include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.

3. Minor Standalone Medical Device Software revisions shall be identified with a new UDI-PI;
   - Minor Standalone Medical Device Software revisions are generally associated with bug fixes, aesthetics, usability enhancements, security patches or operating efficiency.

Note: Minor Standalone Medical Device Software revisions shall not require a new UDI-DI. Minor revisions shall be identified by manufacturer-specific identification methods (e.g. version, revision number, serial number, etc…)

4. The version number of the Standalone Medical Device Software is considered the manufacturing control mechanism and should be displayed in the UDI-PI.

2. **UDI Placement Criteria**

a. When the Standalone Medical Device Software 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 software and its packaging must be identical to the UDI assigned to the system level software.

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. Software lacking a user interface (e.g. middleware for image conversion) must be capable of transmitting the UDI through an Application Programming Interface (API).

d. Only the human readable portion of the UDI is required in electronic displays of the Standalone Medical Device Software. The UDI AIDC marking needs not be used in the electronic displays, e.g. about menu, splash screen, etc…; i.e. software not being distributed by the use of physical data carriers (CDs, DVDs or similar) will not carry an AIDC.

e. The human readable format of the UDI for Standalone Medical Device Software should include the Application Identifiers (AI) for GS1, and Flag Characters for HIBCC, to assist the end user in identifying the UDI and determining which standard is being used to create the UDI.