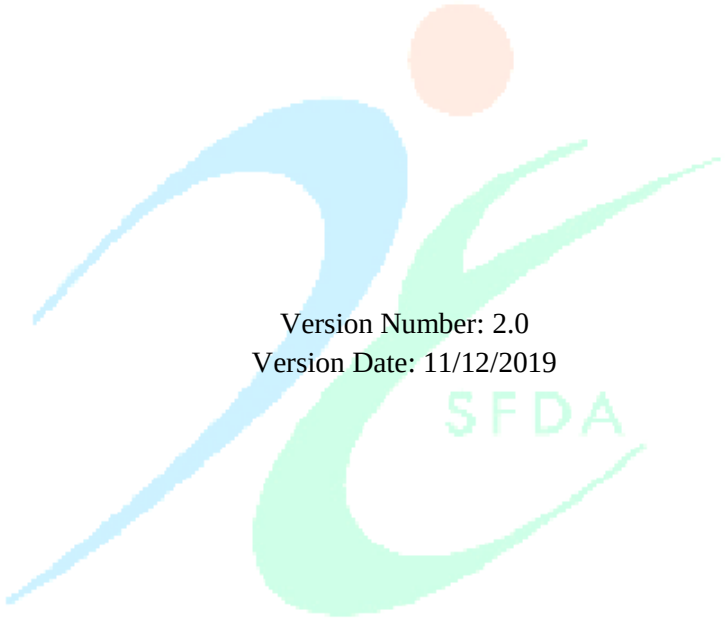
MDS-G34

Guidance on Requirements for Unique Device Identification (UDI) for Medical Devices



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Introduction

Purpose

The purpose of this guidance is to specify the SFDA requirements for UDI for medical devices.

Scope

This guidance applies to the following:

A. All medical devices and their accessories that will be supplied to the KSA market, except medical devices and IVDs for research use, or investigational, custom-made

B. Manufacturers, authorized representative, importers, distributors, and healthcare providers.

Background

SFDA/MDS has issued this guidance document in order to support SFDA's activities specified in Chapter Nine of the "Medical Devices Interim Regulation" issued by Saudi Food and Drug Authority Board of Directors decree No. (1-8-1429) dated 29/12/1429 H and amended by Saudi Food and Drug Authority Board of Directors decree No. (4-16-1439) dated 27/12/2017 that is in relation to safeguard activities.

The UDI system aims to increasing patient safety and optimizing patient care by facilitating the following:

- Identification and Control of medical devices during its life cycles.
- Identification & Traceability of medical devices in adverse events and field safety corrective actions.
- Safe and effective use of devices and reduction of medical errors.
- Documentation and longitudinal capture of data on medical devices.

The purpose of SFDA's UDI System is to provide standardized identification of medical devices (and their accessories) and associated device-specific meta-data to support numerous and varied public-health and safety initiatives. These include device traceability, identification of counterfeits, recalls, adverse event reporting (both the specific identification of devices in individual reports – as well as the ability to aggregate reports), the inclusion of specific devices in various types of clinical information systems (such as patient records), as well as the inclusion of device information in population-based data sets, such as insurance data.

Chapter One: UDI Requirements

A. General UDI Requirements:

1. The manufacturer shall assign and manage the UDI following the chosen issuing agency's specifications, standards and guidelines.
2. The provisional UDI Issuing Agencies shall be GS1, HIBCC and ICCBBA. Maintenance of their accreditation is covered in Chapter One, Section (F).
3. The UDI shall contain two parts: the UDI-DI and the UDI-PI(s).
    - The UDI-DI is unique to a specific manufacturer's device and provides access to the information in the UDI database.
    - The UDI-DI shall be globally unique at all levels.
    - If a lot number, serial number, batch number, software identification, expiration (use by) date, or any other product's reference is on the label or package, it shall be included in the UDI-PI.
    - Manufacturing date may not be required to be included in the UDI-PI if there are other PIs in the UDI, however If the labeled manufacturing date is the only PI, then it shall be included in the UDI.
4. The UDI shall be placed on the label of the device and on all higher levels of packaging and be presented in two forms:
    - Easily readable plain-text (also known as HRI), and
    - AIDC technology.
5. The information encoded in the UDI (both AIDC and plain-text/HRI) may also include other data, such as quantity or internal reference number, which is not considered part of the UDI.
6. The HRI format shall follow the rules of the UDI issuing agency; it shall be the full, proper HRI, including AIs, and NOT a mix of HRI and non-HRI text.
7. If the AIDC technology is not evident upon visual examination of the label or package, the label or package shall disclose the presence of AIDC technology.
8. When there is AIDC carrier on the product labelling other than the UDI, the UDI shall be easily and readily identifiable.
9. If linear barcodes are used, the entire UDI shall be concatenated into a single barcode. However, If the UDI information is available through a 2D barcode as well, then either concatenated or stacked barcodes are acceptable.
10. If the manufacturer is using RFID technology, a linear or 2D barcode or other type of barcode shall also be provided on the label.

11. Barcodes shall be verified according to the appropriate ISO/IEC standard and they shall meet the issuing agency's grading standards.
12. The UDI shall be readable during normal use and throughout the intended life of the device.
13. The UDI shall be placed so that the AIDC can be accessed during normal operation, storage and transport.
14. If the UDI is readily readable and in the case of AIDC scannable through the device's package, then the placing of the UDI on the "outer" package shall not be required.
15. Other label or package Production Identifier (such as expiration, use by, date, lot number) shall not remove from the label or package even if it is being conveyed in the UDI.
16. A UDI is not required to be placed on any shipping container that not consider a package to be tracked.
17. Placing of the UDI on the label or device itself shall not negatively impact the risk and performance of the device.

B. Direct Marking (DM)

1. The marking of the UDI is an additional requirement – it does not replace any other marking or labeling requirements.
2. Reusable devices subject to the UDI requirements shall also bear a DM UDI on the device itself.
3. The DM UDI shall be permanent and readable during normal use and throughout the intended life of the device.
4. If the device's primary label is on the device itself and is permanent – a separate DM UDI is not required. However, the UDI label requirements will take precedent.
5. The UDI provided through the DM UDI may be:
   - Identical to the UDI that appears on the label of the device, or
   - A different UDI used to distinguish the unlabeled/unpackaged device.
6. Direct Marking UDI may be provided through either or both of the following:
   - Easily readable plain-text/HRI;
   - AIDC technology, or any alternative technology, that will provide the UDI of the device on demand.
7. A device is exempt from the DM requirement if the manufacturer can adequately demonstrate and document that:
   - Any type of DM would interfere with the safety, performance or effectiveness of the device;

- The device cannot be directly marked because it is not technically feasible;

C. The UDI-DI Lifecycle

1. A new, unique UDI-DI is required whenever there is a change made to a device or its attributes, and the change may include but not limited to the following

    - Results in a new DI record,
    - Results in a new variant such as version, model, etc.
    - Could lead to ambiguity in the identification of the device,
    - Could affect the traceability of the device,
    - Creates a new package, or

2. Change to any of these UDI database elements:
    a. Issuing Agency
    b. Primary UDI-DI Number
    c. Quantity
    d. Brand/Trade Name
    e. Version or Model
    f. Clinically Relevant Size
    g. Labeled as Single Use
    h. Device required to be labeled as containing natural rubber latex
    i. MRI safety information (if not already labeled as Safe, Unsafe, or Conditional)
    j. Device Packaged as Sterile
    k. Requires Sterilization Prior to Use
    l. Critical warnings or contraindications that appear on the device's label

3. If the new UDI-DI is a replace of previous DI, then it shall be entered and identify the relationship.

D. Saudi Arabia UDI Database

1. The manufacturer, or its authorized representative, shall submit and maintain the appropriate data to the UDI database for all devices subject to this guidance.
2. The manufacturer, or its authorized representative, shall validate UDI data during submission process also in annual bases
3. SFDA may request additional information, updates, or data confirmations at any time.
4. The data for new UDI-DI shall be available in UDI database at the time the device is placed on the market. For changes that not requiring a new UDI-DI, the manufacturer shall update the relevant record within 10 working days of making the change.
5. All specified (non-private) data in the UDI database will be made publicly available. Data relating to devices no longer on the market shall be retained in the UDI database.
6. The manufacturer, or authorized representative, shall provide in the UDI database the applicable data from the listed in articles 7 to 11 for each Primary UDI-DI (defined as the UDI-DI on the device's primary label), or for those situations where there is no device label or package containing the label, the DM UDI-DI, or the Unit of Use UDI-DI (as applicable).
7. All of the following device attribute information shall be provided in English, unless stated otherwise (all fields are required unless otherwise noted):

    7.1 The GTIN-14 (GS1) [and for those devices intended exclusively for retail Point of Sale (POS), the GTIN-12/13 provided in a 14-digit format], HIBC-LIC (HIBCC), or ISBT 128-PPIC (ICCBBA)

    7.2 The establishment national registry number of the authorized representative or local manufacturer

    7.3 The medical device national listing number

    7.4 Name and address of the manufacturer (as labeled)

    7.5 Name and address of the authorized representative (as labeled)

    7.6 Brand/Trade name (as labeled; if no formal brand or trade name is used or registered, enter device name that users are accustomed to using)

    7.7 Arabic version of Brand/Trade name – for Lay person/ home-use devices

    7.8 Variants such as version/model name/number identifier. Note that this is a manufacturer specified identifier – and is in addition to, and different from, the GMDN Preferred Term identified.

    7.9 Catalog number

    7.10 Device description – as labeled, in the labeling, or presented in marketing material, including a website.

    7.11 Arabic version of device description – for lay person / home-use devices

7.12 Quantity (for primary UDI-DI) – number of units in this device or package

7.13 Unit of use the primary DI number (when the number of units (quantity) >1) [can be used in multiple DI records]

7.14 Production identifier(s) included in the UDI [lot/batch number, serial number, expiration (use by) date, manufacturing date, and/or software version number]

7.15 The equivalent DIs to the primary DI If the same device can be provided to the KSA market with different DIs (separate DI records for the other DIs may, or may not, be in UDI database).

7.16 Previous DI (see Chapter One, section C) – the UDI-DI that was changed because there was a change made to a device or its attributes that resulted in a new DI record, a new version or model, or a new package.

7.17 If the configurable device UDI-DI is not physically on the label/device, but rather presented electronically, where/how it can be found

7.18 Labeled as a single-use device

7.19 Disposal/Scraping method – if the label or labeling specifies a disposal or scraping methods

7.20 Device packaged/labeled as sterile

7.21 For the devices that need sterilization prior to reuse, shall Identify sterilization method of the device.

7.22 The maximum number of reuses (where the label indicates the maximum number of reprocessing cycles)

7.23 Clinically Relevant Size

7.24 Device labeled as containing natural rubber latex or dry natural rubber

7.25 Device labeled as "Not made with natural rubber latex"

7.26 Home-use / lay person

7.27 MRI safety status (safe, unsafe, or conditional – or label does not contain)

7.28 Special storage conditions (if labeled)

7.29 Critical warnings or contra-indications (as indicated on the device label)

7.30 GMDN,

7.31 Risk class of the device

7.32 URL for additional information, such as electronic instructions for use (if applicable)

7.33 Customer service Contact – phone and email

8. For devices subject to Direct Marking and DM UDI is different than the primary label UDI, identify the following:

   8.1 List the DM-DI

   8.2 Determine PIs: lot number, serial number, expiration (use by) date, manufacturing date, if it's different than those used in the label UDI,

   8.3 The DM UDI is presented as:

   - Plain-text/human-readable interpretation (HRI)
   - AIDC

9. For devices packages (repeatable for multiple packages):

   9.1 The Package UDI-DI number

   9.2 Package type (e.g. case, carton, box)

   9.3 Quantity per package

   9.4 The UDI-DI of the next lower device/package contained within this package

   9.5 If the package contains PIs that are different than those used in the label, the PIs used in this package UDI [defaults to primary DI PIs]: lot number, serial number, expiration (use by) date, manufacturing date

10. For kits: The UDI-DIs of all devices assigned or labeled with a UDI-DI within the kit, whether marked or not.

11. For end of commercial distribution: Date no longer available on the market (that is, commercial distribution end date, date device is no longer offered for sale)

E. Request for an Exception from or Alternative to a UDI Requirement

1. A manufacturer or its authorized representative may submit a request for an exception from or alternative to any of the requirements of this guidance.

2. A written request for an exception or alternative shall:

4. Identify the device or devices that would be subject to the exception or alternative;

5. Identify the specific parts of this guidance for an exception or alternative;

6. If requesting an exception, explain why you believe the requirements are not feasible;

7. If requesting an alternative, describe the alternative and explain why it would provide for more accurate, precise, or rapid device identification than the requirements or how the alternative would better ensure the safety or effectiveness of the device that would be subject to the alternative.

F. Management of UDI Issuing Agencies

1. The provisional accredited issuing agencies, GS1, HIBCC, and ICCBBA, shall provide a point of contact for the SFDA – and other information deemed necessary by SFDA to maintain accreditation.

Chapter Two: Additional Requirements

1. Software as a Medical Device

1.1. Software as a Medical Device (SaMD) means software intended to be used for one or more medical purposes that performs this purpose without being part of a hardware medical device.

1.2. SaMD that is distributed in both a physical, packaged form and in a form that is not packaged (e.g., when downloaded) may use the same or a different UDI.

1.3. A UDI shall be applied to the physical media and label or package that containing SaMD.

1.4. A UDI shall be provided on a readily accessible screen for the user in an easily-readable plain-text format (e.g., in an about, help or start-up screen).

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

1.6. Only the plain-text/HRI portion of the UDI shall be required in the software display and shall include the relevant AIs.

1.7. In addition to the change rules outlined in Chapter One, section (C), a new UDI-DI shall be required whenever there is a modification that changes:

a. the original performance and effectiveness,
b. the safety or the intended use of the Software, or
c. the interpretation of data.

2. Implantable Devices

2.1. All active implantable devices shall be controlled by serial number.

2.2. Manufacturers of implantable devices shall provide an “implant card” to the patient with information allowing the identification of the device, including its UDI.

2.3. The following implants are exempted from the need to provide an implant card: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.

2.4. The full UDI (UDI-DI and UDI-PI) of an implantable device shall be readily available, either electronically or readable (scannable), at the point of implantation.

3. Configurable Devices

3.1. A UDI shall be allocated to the configurable device in its entirety and shall be called the configurable device UDI.

3.2. The configurable device UDI shall be placed on the assembly that will not be exchanged during the lifetime of the system and shall be identified as the Configurable device UDI.

3.3. Alternatively, the configurable device UDI can be presented electronically (e.g., through a computer interface) – and not physically located on the label. If so, then the location and how to access it shall be entered into UDI database.

3.4. Each component, sub-system or accessory that can be removed or separated from the configuration or is available and distributed on its own (placed on the market) shall have its own, separate UDI and meet all of the other UDI requirements.

4. Device constituent parts of "Combination Products"

When a device is placed on the market or put into service, incorporates a substance which, if used separately, would be considered to be a medicinal product, and as per SFDA classification and authorization the medical device(s), and/or its accessories, shall meet the UDI requirements.

5. Accessories

5.1. Each accessory that can be installed or removed by the end-user (regardless of whether it is commercially available and distributed on its own) and is available and distributed on its own (placed on the market), shall have its own, separate UDI and meet all of the other UDI requirements of this guidance

5.2. Accessories that significantly changes the intended purpose, safety or performance of the device shall, for the purposes of UDI, be considered a remanufacturing operation – and as such subject the entire device to a new UDI-DI.

6. Single Use Device Exception

6.1. Individual single-use devices, which are labeled and packaged individually, are not required to have the UDI on the individual device label/package if all of the following conditions are thoroughly documented and met – the single-use devices are:

A. All of the same version or model,
B. Distributed together in a single package,
C. Stored in that package until removed for use,
D. Not intended for individual distribution, and
E. Not implantable devices.

6.2. The primary UDI will be on the package of these individual single-use devices.

6.3. When this exception is used, UDI database will require that a Unit of Use DI be assigned to the unmarked individually labeled and packaged device and entered into the database.

7. Kits and Procedure Pack (which includes other non-homogenous package configurations)

7.1. A kit shall have its own, unique UDI (DI and PI) – referencing this specific collection of devices.

7.2. The UDI-DIs of all devices within the kits/packs, whether marked or not, shall be entered into the UDI database. unless the device is:

7.2.1. An individual single-use disposable device, which cannot be used outside the context of the kit or procedure pack, or

7.2.2. Otherwise exempt from having a UDI on the label or package of the device that is in the kit or procedure pack.

8. Devices Sold at Retail

8.1. For devices intended exclusively for retail point of sale, it could include the UDI-PI(s) of the UDI's AIDC or other alternative data capture that appear on the point of sale package.

8.2. Higher levels of packaging, not intended for retail Point of Sale, shall contain the full UDI.

8.3. A device intended both for retail and use in clinical environments, e.g., hospitals, shall also contain the full UDI on the label and packaging, in addition to the retail data carrier.

9. Own Brand/Private Labelers

For the purposes of UDI, an Own Brand or Private Labeler, who labels a device from a third party under his own name and/or Trade/Brand name, is considered the manufacturer of the devices – and is responsible for the UDI of the labeled device.

10. Relabeled, Repackaged, Remanufactured, and Serviced Devices

10.1. Re-labelers, re-packagers, and re-manufacturers, shall create their own, new UDI for the relabeled, repackaged, or remanufactured medical device, which shall replace the OEM's UDI where it exists.

10.2. The new UDI shall meet all of the requirements of this guidance.

10.3. The re-processor, re-labeler, re-packager, re-furbisher, or re-manufacturer shall keep, where available, a record of the UDI of the original device.

10.4. The act of servicing a device, if returned to the original user, does not in and of itself subject the device to UDI. However, if the serviced device is not necessarily returned to the original user, the serviced device is subject to UDI.

Chapter Three: Device Import & Distribute Control

For each device identification (DI) being imported into the KSA market, Manufacturers or Authorized representatives or Importers shall provide :

- The applicable Production Identifiers (UDI-PIs)
- Destination (e.g., specific distributor, hospital).
- Quantity of lot-controlled devices,

Chapter Four: Compliance Dates

Devices Risk Classes	Enforcement Timeframe	DM Requirements	Existing Inventory Exception
Class D	(6) months after launching UDI database	(1) years after applicable class compliance date.	A device manufactured and labeled prior to the applicable compliance date may be distributed without being UDI compliant for an additional (1) year after the applicable compliance date. This exception does not apply to the DM requirement.
Class B & C	(1) year after launching UDI database		
Class A	(2) years after launching UDI database		

Chapter Five: UDI in Healthcare Delivery

The adoption, implementation and use of UDIs across and throughout the healthcare ecosystem by health systems, hospitals, healthcare providers, patients, insurance companies, and others will bring about significant cost, quality, safety, and efficiency improvements in the delivery and management of medical-device related healthcare.

The documentation and use of a device's UDI throughout healthcare will vastly improve the:

- Inventory management of devices,
- Identification of SFDA approved medical devices for procurement activities,
- Identification of medical devices at the point of use,
- Identification of medical devices in adverse events, and analyzing of relevant reports,
- Enable effective consumer-focused information,
- Traceability of medical devices, especially for field safety corrective actions,
- Documentation and longitudinal capture of data on medical devices.

Health systems shall take the critical steps necessary to facilitate and leverage the implementation of UDI throughout KSA by putting systems and processes in place to capture and use UDI in real time. This includes the documentation of the use or implementation of a device's UDI in patient's electronic health records, the inclusion of UDI in inventory management and billing systems, the use of UDI in the communication of device safety concerns, and leveraging UDI for easily accessible clinician and patient information.

Annexes

Annex (1): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
AI(s)	Application Identifier(s)
API	Application Program Interface
DI	Device Identifier
DM	Direct Marking
GHTF/IMDRF	Global Harmonization Task Force/International Medical Device Regulators Forum
GMDN	Global Medical Device Nomenclature
GTIN-14	Global Trade Item Number-14
HIBC	Health Industry Bar Code
HRI	Human Readable Interpretation
IVD	InVitro Diagnostic
OEM	Original Equipment Manufacturer
PI(s)	Production Identifier(s)
RFID	Radio-Frequency Identification
SaMD	Software as a Medical Device
UDI database	Saudi Arabia UDI – Database
UDI	Unique Device Identifier
UPC/EAN	Universal Product Code/European Article Number
URL	Uniform Resource Locator (also known as a web address)
XML	Extensible Markup Language
Placing on the Market	means the first making available in return for payment or free of charge of a medical device, with a view to distribution and/or use within the KSA
Putting into Service	means the stage at which a device has been made available to the final user as being ready for use for the first time in the KSA for its intended purpose.
Manufacturer	means any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it

	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.
Establishment	means any place of business within the KSA that is involved in the manufacture and/or placing on the market and/or distribution of medical devices or acting on behalf of the manufacturer.
Authorized Representative (AR)	means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.
Importer	means any natural or legal person in the supply chain who is the first to make a medical device, manufactured in another jurisdiction, available in the KSA.
Distributor	means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.
User	means the health care institution, professional or patient using and /or maintaining medical devices.
Supply Chain	means different elements of the distribution activities of a medical device occurring between it being available for importation into the KSA and it being put into service.
Medical Device Marketing Authorization (MDMA) Number	means the code assigned by the SFDA to one or more medical devices, that have been included in a single marketing authorization application, to indicate these devices are authorized to be placed on the KSA market.
National Registry Number	means the number issued to a person by the SFDA under the establishment registration provisions of the Medical Devices Interim Regulation.
Medical Device National Listing Number	means the code assigned by the SFDA to a single medical device to indicate the device is authorized to be placed on the KSA market and facilitate traceability.
Medical Device	means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article: A. Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: – Diagnosis, prevention, monitoring, treatment or alleviation of disease; – Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

	– Investigation, replacement, modification, or support of the anatomy or of a physiological process; – Supporting or sustaining life; – Control of conception; – Disinfection of medical devices; – Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and B. Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
In-Vitro Medical Device	means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles.
Accessory	means a product specifically intended by its manufacturer to be used together with one or several particular medical device(s) or in vitro diagnostic medical device(s) to enable the device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in view of its/their intended purpose(s).
Implantable Device	means 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
Active Implantable Medical Device	means any implantable device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient,

	without any significant change, shall not be deemed to be active devices. Software shall also be deemed to be an active device.
Configurable Device	means a device that consists of several components which can be assembled by the manufacturer in multiple configurations. The individual components may be medical devices themselves.
Reusable Devices	means those devices that require cleaning, disinfection, sterilization or refurbishing between uses on different patients.
Single Use Medical Device	means a medical device intended for use once, on an individual patient for a single procedure, and then should be discarded.
Kit	means any combination of two or more different devices (UDI-DIs), regardless of whether they are finished devices, labeled, intended to be used together, created for the convenience of the user, subject to UDI, or marked with UDI, that are packaged together to achieve a common intended use and are being distributed as a medical device.
Generic Device Group	means a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.
Custom-Made Medical Device	a medical device that, at a minimum, meets the following requirements: – It is intended for the sole use of a particular individual; and – It is specifically made in accordance with a written request of an authorized healthcare professional, which gives, under their responsibility, specific design characteristics; and – It is intended to address the specific anatomo-physiological features or pathological condition of the individual for whom it is intended. Note 1: patient-specific medical devices, adaptable medical devices and mass-produced medical devices made by means of industrial manufacturing processes in accordance with the written request of an authorized healthcare provider, shall not be considered to be custom-made. Note 2: 'Specific design characteristics' means unique design specifications that are based on an individual's specific anatomo-physiological features or pathological condition, and that cannot be proposed by a manufacturer without the involvement of a healthcare professional during the conception phase. (For example, transmitting only dimensions/geometric parameters (such as DICOM files from CT scans) to a manufacturer prior to the production of a medical device is not sufficient to be considered as giving specific design characteristics.)

Primary UDI-DI	The UDI-DI on the device's primary label, which consider a primary key in the database and other DIs are linked to it (e.g., packages, Direct Mark) for those situations where there is no device label or package containing the label, the DM UDI-DI, or the Unit of Use UDI-DI (as applicable).
Investigational Medical Device	medical device being assessed for safety or performance in a clinical investigation.
Investigational IVD Medical Device	in vitro diagnostic medical device that are being assessed for safety or performance in a performance evaluation study.
Home Use Medical Device	a medical device labelled for use by users in any environment outside of healthcare facility. This includes but not limited to office environments, schools, and vehicles. If the medical device is intended to be used in healthcare facilities and outside those facilities, it meets this definition
Unit of Use DI	means a way to associate the use of a device to/on a patient to data related to that patient in instances when a UDI is not labelled at the level of the device unit of use (e.g. several device units contained in a plastic bag).
Unique Device Identification (UDI)	means 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 device on the market. The UDI is comprised of the UDI-DI and the UDI-PI. Note: The word "Unique" does not imply serialization of individual production units.
Device Identifier (UDI-DI)	means a unique numeric or alphanumeric code specific to a device and that is also used as the "access key" to information stored in a UDI database.
Direct Marked/Marking UDI (DM UDI)	means a permanent marking providing the UDI on the device itself.
Production Identifier (UDI-PI)	means a numeric or alphanumeric code that identifies the unit of device production. The different types of Production Identifier(s) include, but are not limited to, serial number, lot/batch number, software version number, manufacturing date and expiration (use by) date.
Human Readable Interpretation (HRI)	a legible interpretation of the data characters as encoded in the UDI.

Automatic Identification and Data Capture (AIDC)	means a technology used to automatically capture data. AIDC technologies include, but are not limited to, bar codes, smart cards, biometrics and RFID.
Labeling	means written, printed or graphic matter, – Affixed to a medical device or any of its containers or wrappers, – Information accompanying a medical device related to its identification and/or technical description, – Information accompanying a medical device related to its use, but excluding shipping documents.
Label	means written, printed, or graphic information that is: – affixed to or appearing on the medical device itself (including electronic display), or if there is none, – on the packaging of each unit (wrapper) or multiple devices (containers), and if none of that exists, – on a package insert (is used where it is impractical or inappropriate to affix a label directly on the medical device itself or its packaging. Impractical means where physical constrains prevent this happening). Among other information, the label contains that name of the device, the name and address of the manufacturer, the control information (e.g., lot number, serial number, manufacturing date, expiration (use by) date), if the device is intended for single use, and whether the device is an IVD medical device.
Primary Label	means the label on the device itself, or, if there is no label on the device itself, on the package containing the device.
Package	means the various levels of homogenous packages that contain a defined quantity of a single type (a single UDI-DI) of devices, e.g. each carton or case.
Shipping Container	means a container used during the shipment or transportation of devices, such as a pallet or tote, and whose contents vary both within the container and from one shipment to another. Shipping container's traceability is controlled by a process specific to the applicable logistics systems.
Radio Frequency Identification (RFID)	means an AIDC 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.