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182 **Body: Ministry of Health/National Health Surveillance Agency/Collegiate Board**

RESOLUTION - RDC No. 591, OF DECEMBER 21, 2021

Provides for the identification of medical devices regularized at Anvisa, through the Unique Identification of Medical Devices (UDI) system.

The Collegiate Board of the National Health Surveillance Agency, using the powers conferred on it by art. 15, III and IV, combined with art. 7th, III, and IV, of Law No. 9,782, of January 26, 1999, and art. 187, VI, §§ 1 and 3 of the Internal Regulations approved by Collegiate Board Resolution - RDC No. 585, of December 10, 2021, resolves to adopt the following Collegiate Board Resolution, as resolved in a meeting held on December 21, 2021, and I, Deputy CEO, determine your

Publication.

CHAPTER I

INITIAL PROVISIONS

Section I

goal

Art. 1 This Resolution establishes the identification of medical devices regularized at Anvisa, through the Unique Identification of Medical Devices (UDI) system, which allows the identification of devices in the country.

Single paragraph. For the purposes of this Resolution, medical devices are considered to be: medical products and in vitro diagnostic products regulated by Collegiate Board Resolution - RDC nº 185, of October 22, 2001, Collegiate Board Resolution - RDC nº 36 , of August 26, 2015, and Collegiate Board Resolution - RDC nº 40, of August 26, 2015, or subsequent regulations.

Section II

Coverage

Art. 2 This Resolution applies to all medical devices regulated by Anvisa, except custom-made medical devices and medical devices in clinical investigation.

Section III

Definitions

Art. 3 For the purposes of this Resolution, the following definitions are adopted:

I - UDI Database: Electronic system that contains information and other elements of identification associated with a particular medical device;

II - Configuration: A combination, specified by the manufacturer, of medical device items that function together as a device to achieve the anticipated intended use. The combination of items can be modified, adapted or personalized to satisfy specific needs, for example:

a) supports, tubes, tables, consoles and other elements of equipment that can be configured/combined to perform an intended use in computed tomography; It is,

b) ventilators, breathing circuits, vaporizers combined to perform a function intended in anesthesia.

III - Transport container: Packaging whose traceability is controlled by a specific process of the logistics systems. Example: maritime container used exclusively for logistical purposes;

IV - Notification or registration holder: legal entity, public or private, manufacturer or importer, responsible for the medical device in the national territory, which holds the concession to commercialize the medical device, issued by the health authority;

V - Configurable device: Medical device that consists of several components that the manufacturer can assemble in multiple configurations. Each of these components may or may not itself be a medical device. Configurable devices include computed tomography systems, ultrasound systems, anesthesia systems, physiological monitoring systems and radiology information systems;

VI - Medical device for lay use: medical device for personal use that does not depend on professional assistance for its use, according to the specification defined in the registration or notification of the product with Anvisa;

VII - Base packaging: lowest level of packaging that contains a UDI. The base package can contain multiple devices;

VIII - Issuing entity: An organization accredited by Anvisa to operate a UDI generation;

IX - Manufacturer: refers to the legal manufacturer, that is, any legal entity, public or private, with responsibility for the design, manufacture, packaging and labeling of a medical device, with the intention of making it available for use under its name, these operations being carried out by the company itself or by third parties on its behalf;

X - Automatic identification and data capture, in English Automatic identification and data capture (AIDC): Technology used for automatic data capture. AIDC technologies include barcodes, smart cards, biometrics and RFID;

XI - Radio Frequency Identification (RFID, English acronym for Radio Frequency Identification): 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 identification purposes;

XII - Unique device identification, in English Unique Device Identification (UDI): Sequence of numeric or alphanumeric characters created through worldwide accepted device identification and coding standards. Allows unambiguous identification of a specific device on the market. The UDI is made up of the UDI-DI and the UDI-PI. The term "single" does not imply the serialization of individual production units;

XIII - Device use unit identifier, in English Unit of Use UDI-DI (UoU UDI-DI): It is an identifier assigned to the individual medical device in which the UDI is not labeled at the unit of use level. Its purpose is to provide a DI to identify a device used on a patient when a DI is not present on the device label. The Device Usage Unit Identifier must be assigned when the lowest level package contains a number of devices greater than one. Example of application of UoU UDI-DI: syringes packed with other syringes in a multipack;

XIV - Interpretation for human reading, in English Human Readable Interpretation (HRI): Legible interpretation of data characters encoded in the UDI support;

XV - Kit: is a collection of products, including medical devices, that are packaged together to achieve a common intended use and are being distributed as medical devices.
Examples: sets, sets or trays used for a specific medical procedure;

XVI - IVD Kit (English acronym for In Vitro Diagnostics): is a collection of products, including medical devices, that are packaged together and intended to be used to perform a specific in vitro diagnostic test, or a part thereof;

XVII - Packaging Levels: Various levels of device packaging that contain a defined quantity of devices, such as a package or box. This does not include shipping containers;

XVIII - Unique identification system for medical devices (UDI system): is a system intended to provide a unique, globally harmonized identification for the identification of medical devices during their distribution and use, which requires that labels bear a unique identifier of devices (to be converted using AIDC and, if applicable, HRI) based on standards, with the

UDI-DI of this unique identifier also being linked to a public UDI Database;

XIX - UDI Support: Means of transmitting the UDI using the AIDC and, if applicable, its HRI. UDI supports include but are not limited to linear identification/barcode, matrix/two-dimensional (2D) barcode, RFID etc;

XX - Device Identifier, in English Device Identifier (UDI-DI): Unique numeric or alphanumeric code, specific to a device model, and which is also used as an "access key" to information stored in a UDI database;

XXI - Production Identifier, in English Production Identifier (UDI-PI): Numeric or alphanumeric code that identifies the device's production unit. The different types of UDI-PI include one or more of the following information: serial number, batch number, version (for Software as a Medical Device - SaMD), manufacturing date and expiration date.

CHAPTER II

GENERAL REQUIREMENTS

Art. 4 The identification of medical devices regulated by Anvisa referred to in this Resolution requires compliance with the determinations related to the UDI system by manufacturers and holders of notification or registration.

Art. 5 Manufacturers are obliged to comply with the determinations established in the caput of art. 8 and in art. 9th of this Resolution, as set out in Annex II.

§ 1 The manufacturer's quality management system must implement control mechanisms that guarantee the correct attribution of the UDI to all devices manufactured by it or on its behalf in accordance with the caput of art. 8th of this Resolution.

§ 2 In the case of stents for coronary arteries, drug-eluting stents for coronary arteries, and implants for hip and knee arthroplasty, the manufacturer or holder of the regularization must ensure the provision of UDI support on the traceability label, in addition to the information provided in the Collegiate Board Resolution - RDC nº 59, of August 25, 2008, in the Collegiate Board Resolution - RDC nº 14, of April 5, 2011, and in subsequent regulations.

Art. 6 It is up to the notification or registration holders to verify whether the manufacturer has complied with the determinations established in Section I of Chapter III of this Resolution.

Single paragraph. The holder of the notification or registration is also responsible for ensuring the coherence and validity of the information presented and transferred to the UDI database with the manufacturer, in accordance with § 2 of art. 8th of this Resolution.

CHAPTER III

UNIQUE IDENTIFICATION OF MEDICAL DEVICES

Section I

Unique Identification System for Medical Devices

Art. 7 The UDI system described in Annex II consists of:

I - a specific UDI-DI for each medical device model from each manufacturer, which allows access to the information provided in Annex I;

II - a UDI-PI that identifies the device's production unit and, if applicable, the devices packaged as specified in Annex II;

III - Affixing the UDI on the label or on the device itself and on its upper packaging as specified in Annex II;

IV - Storage of UDI by manufacturers, notification or registration holders, importers and distributors for a period equivalent to the period in item 3.1.6.2 of the Collegiate Board Resolution - RDC no. 16, of March 28, 2013, or any standard that may be to replace it;

V - Storage of IDU by health services and health professionals for a period of time equivalent to the retention period for patient records, in accordance with applicable legislation;

VI - Creation of a UDI database, in accordance with Section III of Chapter III of this Resolution.

Art. 8 Before placing a device on the market, the manufacturer must assign to the device and, when applicable, to all higher levels of packaging, a UDI created in accordance with the rules of the issuing entity designated by Anvisa under the terms of Section II of the Chapter III of this Resolution.

§ 1 For imported medical devices that are not classified as medical devices in the manufacturer's country, the notification or registration holder is entitled to assign the UDI under the terms established in the caput, as long as authorized by the manufacturer

§ 2 Before placing a device on the market, the holder of the notification or registration must ensure that the information referred to in Annex I of the device in question is correctly presented and transferred to the UDI database referred to in Section III of Chapter III of this Resolution .

Art. 9 UDI supports must be placed on the label or on the device itself and on all upper levels of packaging, except transport containers, in accordance with the rules established in ANNEX II of this Resolution.

Art. 10. The UDI, including UDI-DI and UDI-PI, must be informed when event notification adverse event, technical complaint and field action to the agency's information systems.

Single paragraph. For medical devices exempt from UDI-DI or UDI-PI, such as trays for orthopedic procedures whose contents are configured for a specific order, there is no need to send the respective exempt information in notifications of adverse events, technical complaints and field actions , without prejudice to the notification requirements provided for in other regulations.

Section II

UDI Issuing Entities

Art. 11. Issuing entities will operate a UDI allocation system in accordance with this Resolution and that meet the following criteria.

I - The issuing entity is an organization with legal personality;

II - Is your UDI assignment system suitable for identifying a device during the course of its distribution and use in accordance with the requirements of this Resolution;

III - Your UDI allocation system complies with relevant international standards;

IV - The issuing entity must provide access to its UDI allocation system to all interested users, in accordance with a set of predefined and transparent terms and conditions;

V - The issuing entity must:

a) operate its UDI allocation system for at least a period of 10 years after its designation,

b) make available to Anvisa, whenever requested, information relating to its system of UDI assignment; It is,

c) continue to comply with the designation criteria and the terms under which it was made.

Single paragraph. The issuing entities referred to in the caput are GS1, HIBCC (Health Industry Business Communications Council) and ICCBBA (International Council for Commonality in Blood Banking Automation).

Section III

UDI Database

Art. 12. Anvisa will establish a UDI database to validate, gather, process and make available the information referred to in Annex I to the public.

Art. 13. Anvisa will consider the general principles in the design of its UDI database established in Section IV of Annex II.

Art. 14. The essential data elements transmitted to the UDI database, referred to in the Annex I, will be made available free of charge to the public.

CHAPTER IV

OF THE FINAL AND TRANSITIONAL PROVISIONS

Art. 15. After the effective date of this Resolution, the deadlines for granting the UDI, as per the caput of art. 8th, apply the UDI supports, according to § 2nd of art. 5th and art. 9th, transmit information to the UDI database, according to the sole paragraph of art. 8th, as well as transmitting the UDI in notifications of adverse events, technical complaints and field actions, according to art. 10, will be:

I - 2.5 years for medical devices in risk class IV;

II - 3 years for risk class III medical devices;

III - 4 years for risk class II medical devices;

IV - 6 years for risk class I medical devices.

§ 1 For reusable devices in which the UDI support is placed on the device itself, art. 9th is applicable two years after the end of the deadlines referred to in the caput for the respective class of medical devices.

§ 2 The inclusion of UDI support in traceability labels for the unique identification of stents for coronary arteries, drug-eluting stents for coronary arteries and implants for hip and knee arthroplasty is mandatory from the beginning of this Resolution.

§ 3 The deadlines stipulated in the caput for transmitting information to the UDI database, referred to in the sole paragraph of art. 8th, will begin from the moment Anvisa publishes in a normative instruction that the Agency's UDI database is able to receive UDI information from Annex I, as well as the conditions for sending the data and the mechanisms available to meet to Item 4.10 of Annex II.

§ 4 The deadlines stipulated in the caput for transmitting the UDI in notifications of adverse events, technical complaints and field actions, according to art. 10, will begin from the moment Anvisa publishes in a normative instruction that the Agency's electronic systems that receive those notifications are able to include UDI information, as well as the conditions for sending the data.

Art. 16. Compliance with the provisions of this Resolution is optional for the medical device manufactured before the deadline established in art. 15.

Single paragraph. In the cases of medical devices listed in § 2 of art. 15 of this Resolution, the affixing of UDI support to traceability labels applies to devices manufactured after June 20, 2020.

Art. 17. Failure to comply with the provisions contained in this Resolution constitutes a health infraction, under the terms of Law No. 6,437, of August 20, 1977, without prejudice to applicable civil, administrative and criminal responsibilities.

Single paragraph. Anvisa may suspend the sale, import and/or use of the medical device until compliance with the provisions contained in this Resolution in the event of non-compliance with current legislation or inconsistency that justifies such sanitary measure.

Art. 18. Collegiate Board Resolution - RDC No. 232, of June 20, 2018, published in the Official Gazette of the Union No. 120, of June 25, 2018, Section 1, page 120, is revoked. 36.

Art. 19. This Resolution comes into force from January 10, 2022.

MEIRUZE SOUSA FREITAS
Deputy CEO

ANNEX I

ESSENTIAL DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE ALONG WITH THE UDI-DI UNDER THE TERMS OF THIS RESOLUTION

The notification or registration holder must provide the UDI-DI to the UDI database and all the following information regarding the manufacturer and the device, and this responsibility may be delegated to the manufacturer:

1- Quantity per packaging configuration,

2- The UDI-DI of the device and its issuing entity, as well as the UDI-DI and its issuing entity for each level of packaging as specified in Annex II,

3- How the device production is controlled: serial number, batch number, and/or expiration date (or manufacturing date) or software version or SaMD release date (y/n),

4- If applicable, UoU UDI-DI (if there is no UDI indication on the device label at the level of its unit of use, a device use unit identifier is assigned to associate the use of the device with a specific patient),

5- Name and address of the manufacturer, as well as customer service information Consumer (as indicated on the label),

6- The GMDN code, English acronym for Global Medical Device Nomenclature, of the medical device,

7- Trade name (as indicated by the manufacturer),

8- Commercial model of the device,

9- Catalog number (optional),

10- If applicable, clinically relevant dimensional characteristics (including volume, length, caliber, diameter),

11- Complementary description of the product (optional),

12- If applicable, storage and/or handling conditions (as indicated on the label),

13- Labeled as a single-use device (y/n),

14- If applicable, maximum number of reuses,

15- Device labeled as in sterile state (y/n),

16- Need for sterilization before use (y/n),

17-If applicable, sterilization method,

18- If applicable, information related to the presence of carcinogenic substances, mutagenic or toxic to reproduction and/or endocrine disruptors,

19- URL for supplementary information, such as electronic instructions for use (optional),

20- If applicable, warnings or critical contraindications (as indicated on the label), which include:

The. Contains latex (y/n),

B. Compatible with Magnetic Resonance environment (y/n),

w. Other critical warnings or contraindications.

21- Device discontinuation date (referring to devices that are no longer placed in the market)

ANNEX II

Medical Device Unique Identification System

Section I

1-General requirements

1- The UDI marking is a supplementary requirement - it does not replace any of the other marking or labeling requirements established in RDC 185/2001, RDC 36/2015 and RDC 40/2015, subsequent regulations or those that succeed them.

2- The manufacturer must assign and maintain unique UDIs for their devices. For imported medical devices, the holder of the notification or registration is entitled to assign the UDI, as long as it is authorized by the manufacturer and it is proven that the device is not classified as a medical device in the manufacturer's country.

3- Only the manufacturer or holder of notification or registration with authorization from the manufacturer and proof that the device is not classified as a medical device in the manufacturer's country can assign the UDI to the device or its packaging.

4- Only the coding standards provided by the issuing entities designated by Anvisa can be used, as per art. 11 of this Resolution.

Section II

2-UDI

1- The UDI must be assigned to the device itself or its packaging. Higher levels of packaging must have their own UDI. Shipping containers are exempt from this requirement. As an example, UDI is not necessary in a logistics unit; When a healthcare facility orders multiple devices using the UDI or model number of each device and the manufacturer places those devices in a container for transportation or to protect the individually packaged devices, the container (logistical unit) is not subject to the requirements of the UDI.

2-The UDI must contain two parts: the UDI-DI and the UDI-PI.

3-The UDI-DI must be unique for each of the device's packaging levels.

4-If a batch number, serial number, software version such as a medical device or expiration date appear on the label, they must be part of the UDI-PI. If the label also indicates the date of manufacture, it is not necessary to include it in the UDI-PI. If only the date of manufacture appears on the label, this must be used as UDI-PI.

5-When the UDI is not assigned to the level of the unit of use of a device and the lowest level packaging contains a number of devices greater than one, then a UoU UDI-DI must be assigned, to associate the use of the device with a patient. For example, a UoU UDI-DI must be assigned to an individual electrode when the electrode is distributed in a package of 10. In this case, the lowest UDI level is assigned to the pack of 10 units (base pack).

6-Each component that is considered a device and that is available on the market on its own must be assigned a separate UDI, unless the components are part of a medical device marked with its own UDI.

7-Kits, including IVD kits, must have their own UDI.

8-The manufacturer or holder of the notification or registration, when applicable, must assign the UDI to the device in accordance with the relevant coding standard.

9-A new UDI-DI must be required whenever there is a change that could lead to error in the identification of the device and/or cause ambiguity in its traceability. In particular, for any change to one of the following elements of the UDI database, a new UDI-DI is required:

The. Trade name (as indicated by the manufacturer);

B. Commercial model of the device;

w. Clinically relevant dimensional characteristics (including volume, length, gauge, diameter);

d. Labeled as a single-use device;

It is. Labeled as sterile device;

f. Need for sterilization before use;

g. Number of devices supplied in one package;

H. Critical warnings or contraindications: for example, contains latex or DEHP.

10. The reprocessed single-use product cannot use the UDI assigned by the manufacturer to the original product. Companies and healthcare services that reprocess these devices under their own label must create their own unique UDI that will replace the UDI provided by the manufacturer. These companies and health services must keep the UDI record from the manufacturer of the originating device

11. The refurbished product cannot use the same UDI assigned before the refurbishment. The manufacturer or the company qualified and authorized by the original manufacturer that reconditions the product must create its own unique UDI that will replace the UDI assigned prior to reconditioning. The company that reconditions the product must keep a record of the UDI before and after reconditioning.

12. A labeling change to display or modify a UDI-DI should not (in itself) require a submission to change the health regularization of a product, this being a non-reportable change.

Section III

3-UDI Support

1- The UDI support (AIDC and HRI representation of the UDI) must be placed on the label or on the device itself and on all upper levels of packaging. Upper levels of packaging do not include shipping containers.

2- In case of important space constraints in the packaging of the unit of use,
the UDI support can be placed on the next top level of packaging.

3- For Class I and Class II devices, for single use, which are packaged and labeled individually, the UDI support does not need to appear on the packaging, but rather on a higher level of packaging, such as a box that contains several individually packaged devices.
However, at the time of device use, when access to the upper level of device packaging is not possible, such as in the context of home healthcare, the UDI must be placed in the individual device packaging.

4- For medical devices sold without prescription and intended exclusively for
lay public, it is not necessary for the UDI-PI in AIDC to appear on the packaging at the point of sale.

5- When AIDC supports, other than the UDI support, are part of the product labeling, the UDI support must be easily identifiable.

6- If linear barcodes are used, the UDI-DI and UDI-PI may or may not be concatenated into two or more barcodes. All elements and parts of the linear barcode must be distinguishable and identifiable.

7- If there are important conditions that restrict the use of both AIDC and HRI on the label, only the AIDC format should be required to appear on the label. For devices that are intended to be used outside healthcare facilities, such as devices for home healthcare, the HRI must still appear on the label, even if it means that there will be no space for AIDC.

8- The HRI format must follow the rules of the entity issuing the UDI code.

9- If the manufacturer uses RFID technology, an identification code must also appear on the label. linear or two-dimensional bars in accordance with the standard established by the issuing entities.

10- Reusable devices must have UDI support on the device itself. The UDI support for reusable devices that require processing between uses on patients must be permanent and legible after each processing carried out so that the device is ready for the next use during its expected useful life. The requirement in this section
does not apply to devices in the following circumstances:

a) Any type of direct marking that interferes with the safety or performance of the device;

b) The device cannot be marked directly because it is not feasible from the point of view technological;

c) Determined by the manufacturer that the product cannot be directly marked due to issues related to its size, design, materials, processing or device performance.

11- The UDI support must be readable during normal use and throughout the expected useful life of the device.

12- If the UDI support is easily readable and, in the case of AIDC, scannable, through the device packaging, it is not necessary to place the UDI support in the packaging.

13- In the case of single finished devices made up of multiple parts that must be assembled before their first use, it is sufficient to affix the UDI support to just one of the parts of the device.

14- The UDI support must be placed so that the AIDC can be accessed during the normal use or storage of the device.

15- Barcode supports that display both UDI-DI and UDI-PI can also present data essential for the operation of the device or other data.

Section IV

4-General principles of the UDI database

1- The UDI database must support the use of all essential data elements referred to in Annex I.

2- The inclusion of confidential commercial information in the database cannot be required.

3- The holder of the notification or registration must be responsible for the initial submission and updating of identification information and other elements of medical device data contained in the UDI database, and this responsibility may be delegated to the manufacturer by the holder.

4- Adequate methods/procedures must be used to validate the data provided.

5- The holder of the notification or registration must periodically verify that all important data for the medical devices it has placed on the market are correct, except for discontinued medical devices, and this responsibility may be delegated to the manufacturer by the holder.

6- It should not be assumed, because the UDI-DI is included in the UDI database, that the device is regularized at Anvisa.

7- The database must allow the linking of all device packaging levels.

8- Data relating to a new UDI-DI must be available when the device is placed on the market.

9- Notification or registration holders must update the UDI database record within 30 days after making a change to an element that does not require a new UDI-DI, and this responsibility may be delegated to the manufacturer by the holder.

10- The UDI database must use internationally accepted standards for data transmission and updating.

11- The user interface of the UDI database must be available in the official language of Brazil. The use of free text fields should be minimized in order to reduce the overhead caused by possible translations.

12- Data relating to discontinued devices must be kept in the database UDI data.

Section V

5-Rules applicable to specific types of devices

1-Implantable devices

1- Implantable devices must, at the base packaging level, be identified, or marked using AIDC, with a UDI (UDI-DI + UDI-PI).

2- The UDI-PI must present at least the following characteristics:

The. The serial number in the case of active implantable devices;

B. The serial number or batch number for other implantable devices.

3- The UDI of the implantable device must be identifiable before implantation.

2-Reusable devices that require processing between uses

1- The UDI of such devices must be placed on the device and be readable after each processing.

2- The UDI-PI must present at least the following characteristics: the batch or number of series.

3- Kits (not IVD).

1- The kit manufacturer must be responsible for identifying the kit with a UDI that includes both the UDI-DI and the UDI-PI; For imported kits, the notification or registration holder may assign the UDI, as long as it is authorized by the manufacturer and it is proven that the kit is not classified as a medical device in the manufacturer's country.

Exception:

a) Trays for orthopedic procedures whose contents are configured for an order specific data do not require the application of UDI-DI or UDI-PI.

2- The content of the kit device must have UDI support on the respective packaging or on the device itself.

Exceptions:

a) Individual single-use disposable devices whose use is generally known to the people by whom they are intended to be used, which form part of a kit and which are not intended for individual use outside the context of the kit do not require the its own UDI support; for example, a non-individually packaged sterile syringe provided in a kit cannot be used in another procedure due to the lack of a sterile barrier once it is removed from the kit.

b) Devices that are exempt from having UDI support at the packaging level relevant do not require such support when included in a kit.

3- Placing the UDI support in kits:

a) As a rule, the UDI support in kits must be affixed to the outside of the packaging.

b) The UDI support must be legible or, in the case of AIDC, scannable, whether placed on the outside of the kit packaging or inside a transparent packaging.

4- VD Kits.

1- The kit manufacturer must be responsible for identifying the kit with a UDI that includes both the UDI-DI and the UDI-PI; For imported IVD kits, the holder of the notification or registration is entitled to assign the UDI under the terms of this item, as long as it is authorized by the manufacturer and it is proven that the device is not classified as a medical device in the manufacturer's country.

a) The IVD kit is a medical device and all aspects of this regulation apply to it. If an IVD kit does not include any component that itself qualifies as a medical device, the only UDI required is the UDI of the IVD kit itself.

b) Reagents used in automated systems carry barcodes that are necessary for use and identification by automated systems. This does not constitute a UDI.

c) Single-use medical devices packaged together with an IVD kit, whose use is generally known to the users intended to use them and which are not intended for use outside the context of the IVD kit do not require the application of a specific UDI support.

d) Medical devices that do not require the application of a UDI carrier at the relevant packaging level do not require the application of a UDI carrier when packaged together with an IVD kit.

2- Placing the UDI support in IVD kits:

a) As a rule, the UDI support in kits must be affixed to the outside of the packaging.

b) The UDI support must be legible or, in the case of AIDC, scannable, whether placed on the outside of the kit packaging or inside a transparent packaging

5-Configurable devices:

1- The configurable device in its entirety must be assigned a UDI which must be designated as "UDIof the configurable device".

2- The "UDI-DI of configurable devices" must be assigned to groups of configurations and not to each of the configurations within the group. A configuration group is defined as the set of possible configurations for a given device as described in the technical documentation.

3- Each configurable device must be assigned its respective UDI-PI. A subsequent change to a component, part, or accessory of a configurable device does not require a change to the UDI-DI of the configurable device.

4- The UDI support of the configurable device must be placed in the set that is least likely to be changed during the lifetime of the system and must be identified as the "UDI of the configurable device".

5- Each component that is framed as a device and is available by itself only in the market should a separate UDI be assigned.

6- Software as a Medical Device (SaMD)

1-UDI attribution criteria

a) The UDI must be assigned to the system level of the software as a medical device. This requirement only applies to software that is available on the market by itself and to software that itself constitutes a device.

b) The version of the software as a medical device must be considered the manufacturing control mechanism and must be part of the UDI-PI.

2-A new UDI-DI must be required whenever there is a major modification of the software such as medical device. Major modifications are complex or significant changes that affect:

a) The original performance and effectiveness;

b) The safety or intended use of the software as a medical device.

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

3- Small software revisions require a new UDI-PI and not a new UDI-DI.

Minor software revisions are generally associated with bug fixes, ease of use improvements other than for security purposes, security patches, or operational efficiency.

Minor software revisions must be identified using a manufacturer-specific identification method, such as version, revision number, serial number,
between others.

4- UI placement criteria for software as a medical device

a) When software as a medical device is delivered on a physical medium, for example on CD or DVD, each packaging level must contain the AIDC and HRI representation of the complete UDI assigned to the software as a medical device. In the UDI applied to the physical media containing the software as a medical device and its packaging, it is optional to include additional production identifiers that allow greater traceability, such as the recording date or recording batch of the physical media;

b) The UDI must be provided on a screen easily accessible to the user in a text format simple to read, as an "about" file or included on the home screen;

c) Software such as a medical device that does not have a user interface, such as intermediary software for image conversion, must be capable of transmitting the UDI through the application programming interface (API);

d) Only the readable part (for human reading) of the UDI on the electronic displays of the software as a medical device should be required. It is not necessary to mark the UDI using AIDC on electronic displays, such as the "about" menu, the startup screen, etc.;

e) Software such as medical devices that are not distributed on physical media (CD, DVD or similar) do not require the affixation of an AIDC.

f) The human readable format of the UDI for software as a medical device must include the standard application identifiers of the issuing entities that were used to help the user identify the UDI and determine the standard used to create it.