MINISTRY OF HEALTH

NATIONAL HEALTH SURVEILLANCE AGENCY

BOARD

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

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

The Collegiate Board of Directors of the National Health Surveillance Agency, in the exercise of the powers conferred on it by article 15, III and IV, together with article 7, III, and IV, of Law No. 9,782, of January 26, 1999 , and article 187, VI, paragraphs 1 and 3 of the Internal Regulations approved by the Collegiate Board Resolution - RDC No. 585, of December 10, 2021 , resolves to adopt the following Resolution of the Collegiate Board of Directors, as resolved at a meeting held on December 21, 2021, and I, Deputy Chief Executive Officer, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Objective

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

Sole Paragraph. For the purposes of the provisions of this Resolution, medical devices are considered to be those regulated by the Resolution of the Collegiate Board of Directors - RDC No. 751, of September 15, 2022 , and medical devices for in vitro diagnosis regulated by the Resolution of the Collegiate Board of Directors - RDC No. 830, of December 6, 2023 , or subsequent regulations. *(Text given by the Resolution of the Collegiate Board of Directors - RDC No. 884, of 06/26/2024)*

Previous Drafts

Section II

Scope

Art. 2 This Resolution applies to all medical devices regularized by Anvisa, except for custom-made medical devices and medical devices under 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 the information and other identification elements associated with a given medical device;

Configuration: A combination, specified by the manufacturer, of medical device items that work together as a device to achieve its intended intended use. The combination of items can be modified, adapted or customized to meet specific needs, such as:

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

b) ventilators, breathing circuits, combined vaporizers to perform an intended function 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 – Holder of notification or registration: legal entity, public or private, manufacturer or importer, responsible for the medical device in the national territory, which holds the concession for the commercialization of medical devices, issued by the health authority;

V - Configurable device: Medical device consisting of several components that the manufacturer can assemble in multiple configurations. Each of these components can be itself a medical device or not. 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 system for generating UDI;

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 (AIDC): Technology used for automatic data capture. AIDC technologies include barcodes, smart cards, biometrics, and RFID;

XI – Radio Frequency Identification (RFID): Technology that uses communication through the use of radio waves for the exchange of data between a reader and an electronic tag attached to an object, for identification purposes;

XII - Unique Device Identification (UDI): A sequence of numeric or alphanumeric characters created through globally accepted device identification and coding standards. It allows the unambiguous identification of a specific device in 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 - 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 an ID to identify a device used on a patient when an ID is not present on the device label. The Device Unit of Use Identifier should be assigned when the lowest level package contains a number of devices greater than one. Example of UoU UDI-DI application: syringes packed with other syringes in multipack;

XIV - Human Readable Interpretation (HRI): Readable interpretation of the characters of the data encoded in the support of the UDI;

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 (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 exam, or a part thereof;

XVII - Packaging levels: Various levels of device packaging that contain a defined amount of devices, such as a package or a 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 labels to carry a unique device identifier (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: UDI transmission medium 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 (UDI-DI): Unique numerical 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 (UDI-PI): Numerical 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), date of manufacture, and expiration date.

CHAPTER II

GENERAL REQUIREMENTS

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

Article 5 - Manufacturers are obliged to comply with the determinations established in the caput of article 8 and article 9 of this Resolution, as provided for in Annex II.

Paragraph 1 - The manufacturer's quality management system must implement control mechanisms that ensure the correct attribution of the UDI to all devices manufactured by it or on its behalf, under the terms of the caput of article 8 of this Resolution.

Paragraph 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 for 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.

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

Sole Paragraph. It is also the responsibility of the holder of the notification or registration to ensure with the manufacturer the consistency and validity of the information presented and transferred to the UDI database, under the terms of the sole paragraph of article 8 of this Resolution. *(Text given by the Resolution of the Collegiate Board of Directors - RDC No. 884, of 06/26/2024)*

Previous Drafts

CHAPTER III

UNIQUE IDENTIFICATION OF MEDICAL DEVICES

Section I

Unique Medical Device Identification System

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

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

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

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

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

V - Storage of the IDU of implantable medical devices, of risk classes IV, by health services and health professionals, for a period equivalent to the period of storage of the patient's medical record, according to the applicable legislation; *(Text given by the Resolution of the Collegiate Board of Directors - RDC No. 884, of 06/26/2024)*

Previous Drafts

VI – Creation of a UDI database, under the terms of 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 Chapter III of this Resolution.

Paragraph 1 ***(Revoked by the Resolution of the Collegiate Board of Directors - RDC No. 884, of 06/26/2024)***

Previous Drafts

Sole Paragraph. 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. *(Text given by the Resolution of the Collegiate Board of Directors - RDC No. 884, of 06/26/2024)*

Previous Drafts

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

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

Sole Paragraph. For medical devices exempt from UDI-DI or UDI-PI, such as trays for orthopaedic procedures whose content is configured for a specific request, it is not necessary to send the respective exempt information in the notifications of adverse events, technical complaints and field

actions, without prejudice to the reporting requirements provided for in other regulations.

Section II

UDI Issuing Entities

Article 11. Issuing entities shall operate a UDI allocation system under the terms of this Resolution and that meet the following criteria.

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

II - Its UDI allocation system is adequate to identify a device in the course of its distribution and use in accordance with the requirements of this Resolution;

III - Its UDI allocation system is in accordance with the relevant international standards;

IV - The issuing entity shall 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 shall:

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

b) to make available to Anvisa, whenever requested, the information related to its system for assigning UDI; and

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

Sole 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

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

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

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

CHAPTER IV

FINAL AND TRANSITORY PROVISIONS

Article 15. After the effective date of this Resolution, the deadlines for assigning the UDI, according to the caput of article 8, applying the supports of the UDI, according to § 2 of article 5 and article 9, transmitting information to the UDI database, according to the sole paragraph of article 8, as well as transmitting the UDI in the notifications of adverse events, Technical complaints and field actions, according to art. 10, will be:

I - 3.5 years for medical devices of risk class IV; *(Text given by the Resolution of the Collegiate Board of Directors - RDC No. 884, of 06/26/2024)*

Previous Drafts

Original wording:

~~I - 2.5 years for medical devices of risk class IV;~~

II - 4 years for risk class III medical devices; *(Text given by the Resolution of the Collegiate Board - RDC No. 884, of 06/26/2024)*

Previous Drafts

Original wording:

~~II - 3 years for risk class III medical devices;~~

III - 5 years for risk class II medical devices; *(Text given by the Resolution of the Collegiate Board - RDC No. 884, of 06/26/2024)*

Previous Drafts

Original wording:

~~III - 4 years for medical devices of risk class II;~~

IV - 6 years for medical devices of risk class I. *(Text given by the Resolution of the Collegiate Board - RDC No. 884, of 06/26/2024)*

Previous Drafts

Original wording:

~~IV - 6 years for medical devices of risk class I.~~

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

Paragraph 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 as of the beginning of the effectiveness of this Resolution.

Paragraph 3 - The deadlines stipulated in the caput for transmitting the information to the UDI database, referred to in the sole paragraph of article 8, shall begin from the moment Anvisa publishes in a normative instruction that the Agency's UDI database is able to receive the UDI information in

Annex I, as well as the conditions for sending the data and the mechanisms made available to comply with Item 4.10 of Annex II.

Paragraph 4 - The deadlines stipulated in the caput for transmitting the UDI in the notifications of adverse events, technical complaints and field actions, according to article 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 the information from the UDI, as well as the conditions for sending the data.

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

Sole Paragraph. In the case of medical devices listed in paragraph 2 of article 15 of this Resolution, the affixing of the UDI support on traceability labels applies to devices manufactured after June 20, 2020.

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

Sole Paragraph. Anvisa may suspend the commercialization, importation 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.

Article 18. The Resolution of the Collegiate Board of Directors - RDC No. 232, of June 20, 2018 , published in the Federal Official Gazette No. 120, of June 25, 2018, Section 1, page 36, is hereby revoked.

Article 19. This Resolution enters into force as of January 10, 2022.

MEIRUZE SOUSA FREITAS
Deputy Chief Executive
Officer

ANNEX I

ESSENTIAL DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI UNDER THIS RESOLUTION

(Text given by the Resolution of the Collegiate Board of Directors - RDC No. 884, of 06/26/2024)

Previous Drafts

The holder of the notification or registration shall provide the UDI-DI to the UDI database and all of the following information relating to 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 packaging level as specified in Annex II,

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

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

5. Name and address of the manufacturer, as well as Customer Service information (as indicated on the label),

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

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

8. Device Business Model,

9. Catalogue number (optional),

10. Where applicable, clinically relevant dimensional characteristics (including volume, length, caliber, diameter),

11. Supplementary product description (optional),

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

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

14. If applicable, maximum number of reuses,

15. Device labeled as sterile (y/n),

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

17. If applicable, sterilization method,

18. URL for supplementary information, such as electronic instructions for use (optional),

19. Where applicable, critical warnings or contraindications (as indicated on the label), which include:

a. Contains latex (y/n),

b. Compatible with Magnetic Resonance Imaging (s/n) environment,

c. Other critical warnings or contraindications.

20. Device Discontinuation Date (referring to devices that are no longer placed on the market).

ANNEX II

UDI SYSTEM

(Text given by the Resolution of the Collegiate Board of Directors - RDC No. 884, of 06/26/2024)

Previous Drafts

Section I

1. General requirements

1.1. UDI marking is a supplementary requirement - it does not replace any of the other marking or labeling requirements established in RDC 751/2022 , RDC 830/2023 , subsequent regulations or those that succeed them.

1.2. Only the coding standards allowed by the issuing entities designated by Anvisa, according to article 11 of this Resolution, may be used.

Section II

2. UDI

2.1 The UDI must be assigned to the device itself or its packaging. The higher levels of packaging must have their own UDI.

Shipping containers are exempt from this requirement. As an example, UDI is not required in a logistics unit; when a healthcare facility orders multiple devices using the UDI or the model number of each device and the manufacturer places these devices in a container for transport or to protect the individually packaged devices, the container (logistic unit) is not subject to the requirements of the UDI.

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

2.3. The UDI-DI must be unique in each of the packaging levels of the device.

2.4. If a batch number, serial number, version of the software 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 for it to be included in the UDI-PI. If the label only contains the date of manufacture, it must be used as UDI-PI.

2.5. When the UDI is not assigned to the level of the unit of use of a device and the lowest level package contains a quantity 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 dispensed in a 10-pack. In this case, the lowest UDI level is assigned to the pack with 10 pieces (base pack).

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

2.7. Kits, including IVD kits, must have their own UDI.

2.8. The manufacturer or the holder of the notification or registration, where applicable, shall assign the UDI to the device in accordance with the relevant coding standard.

2.9. A new UDI-DI shall be required where there is a change that may mislead in the identification of the device and/or lead to 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:

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

b. Device business model;

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

d. Labeled as a single-use device;

and. Labeled as sterile device;

f. Need for sterilization before use;

g. Number of devices supplied in a package;

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

2.10 Health companies and services that carry out the reprocessing of single-use medical devices, according to specific regulations, and without prejudice to the prohibitions imposed by Resolution - RE No. 2605 of 08/11/2006 or another that may replace it, must keep the UDI record of the manufacturer of the original device, together with the records of the reprocessing process.

2.11. The refurbished product may not use the same UDI assigned before reconditioning. The manufacturer or the company qualified and authorized by the original manufacturer that refurbishes the product must create its own unique UDI that will replace the UDI assigned prior to reconditioning. The company that refurbishes the product must keep the record of the UDI before and after the reconditioning.

2.12. A labeling change to display or modify a UDI-DI should not (by itself) require a submission to change the health regularization of a product, which is a non-reportable change.

Section III

3. UDI Support

3.1 UDI support (AIDC and HRI representation of UDI) must be placed on the label or on the device itself and on all higher levels of packaging. Higher levels of packaging do not include shipping containers.

3.2. In case of significant space constraints in the packaging of the unit of use, the UDI holder may be placed on the next upper level of packaging.

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

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

3.5. Where AIDC media, other than UDI media, are part of the product labelling, the UDI media must be easily identifiable.

3.6. 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.

3.7. If there are important constraints restricting the use of both the AIDC and the HRI on the label, only the AIDC format should be required to appear on the label. For devices that are intended for use outside healthcare facilities, such as home health care devices, HRI should still appear on the label, even if it means that there will be no room for AIDC.

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

3.9. If the manufacturer uses RFID technology, a linear or two-dimensional barcode must also appear on the label in accordance with the standard established by the issuing entities.

3.10. Reusable devices must have UDI support on the device itself. The UDI support of reusable devices that require inter-use processing on patients must be permanent and readable after each processing performed for the device to be ready for the next use during its intended lifetime. 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 directly marked because it is not feasible from a technological point of view;

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.

3.11. The UDI media shall be legible during normal use and throughout the intended life of the device.

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

3.13.No the case of single finished devices consisting of multiple parts that have to be assembled before their first use, it is sufficient to affix the UDI support to only one of the parts of the device.

3.14.The UDI holder shall be placed so that access to the AIDC can be accessed during normal use or storage of the device.

3.15.Barcode media displaying both UDI-DI and UDI-PI may also display data essential for the operation of the device or other data.

Section IV

4. General principles of the UDI database

4.1. The UDI database shall support the use of all the essential data elements referred to in Annex I.

4.2. The inclusion of commercially confidential information in the database cannot be required.

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

4.4. Appropriate methods/procedures for validating the data provided shall be used.

4.5. The holder of the notification or registration shall periodically verify that all important data for the medical devices which 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.

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

4.7. The database shall allow linking of all packaging levels of the device.

4.8. Data for a new UDI-DI shall be available at the time the device is placed on the market.

4.9. Holders of the notification or registration must update the UDI database registration within 30 days of 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.

4.10. The UDI database shall use internationally accepted standards for the transmission and updating of data.

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

4.12.Data relating to discontinued devices shall be stored in the UDI database.

Section V

5. Rules applicable to specific types of devices

5.1. Implantable devices

5.1.1. Implantable devices shall, at the base packaging level, be identified, or tagged using the AIDC, with a UDI (UDI-DI + UDI-PI).

5.1.2 The UDI-PI shall have at least the following characteristics:

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

b. The serial number or lot number for other implantable devices.

5.1.3. The UDI of the implantable device must be identifiable prior to implantation.

5.2. Reusable devices that need processing between uses

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

5.2.2. The UDI-PI shall have at least the following characteristics: the batch or the serial number.

5.3. Kits (non-IVD).

5.3.1. The kit manufacturer shall be responsible for identifying the kit with a UDI that includes both the UDI-DI and the UDI-PI.

Exception:

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

5.3.2. The contents of the kit device must have the UDI support in its packaging or on the device itself.

Exceptions:

a. Individual single-use disposable devices whose use is generally known to the persons by whom they are intended to be used, which are part of a kit and which are not intended for individual use outside the context of the kit shall not require their own support from the IDU; For example, an unpackaged 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 set.

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

5.3.3. Fitting the UDI bracket into kits:

a. As a rule, the UDI bracket in kits should be affixed to the outside of the package.

b. The UDI media shall be legible or, in the case of the AIDC, scannable, whether it is placed on the outside of the kit packaging or within a clear packaging.

5.4. IVD Kits.

5.4.1 The kit manufacturer shall be responsible for identifying the kit with a UDI that includes both the UDI-DI and the UDI-PI.

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 components that in itself qualify 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, the use of which is generally known to 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 holder.

d. Medical devices that do not require the application of a UDI holder at the relevant packaging level do not require the application of a UDI holder when packaged in conjunction with an IVD kit.

5.4.2. Placement of the UDI bracket in IVD kits:

a. As a rule, the UDI bracket in kits should be affixed to the outside of the package.

b. The UDI media shall be legible or, in the case of the AIDC, scannable, whether it is placed on the outside of the kit packaging or within a clear packaging.

5.5. Configurable devices:

5.5.1. The entire configurable device shall be assigned a UDI which shall be referred to as the "Configurable Device UDI".

5.5.2. The "Configurable Devices UDI-DI" shall 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.

5.5.3 Each configurable device shall be assigned its 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.

5.5.4. The configurable device UDI bracket shall be placed in the assembly that is least likely to be swapped over the lifetime of the system and shall be identified as the "configurable device UDI".

5.5.5 Each component that is classified as a device and that is available on the market on its own shall be assigned a separate UDI.

5.6. Software as a Medical Device (SaMD)

5.6.1. UDI allocation criteria a. The UDI shall be assigned at system level of the software as a medical device. This requirement applies only to software that is available on its own on the market and to software that is itself a device.

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

5.6.2. A new UDI-DI shall be required whenever there is a major modification of the software as a medical device. Major changes 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, the architecture, new user interfaces or new interoperability channels.

5.6.3. Minor software revisions require a new UDI-PI and not a new UDI-DI.

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

Minor software revisions should be identified using a manufacturer-specific identification method, such as version, revision number, serial number, and so on.

5.6.4. IDU placement criteria for software as a medical device

a. When software as a medical device is delivered on physical media, e.g. on a CD or DVD, each packaging level must contain the full AIDC and HRI representation of the UDI assigned to the software as a medical device. In the UDI applied to the physical media that contains 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 the recording batch of the physical media;

b. The UDI must be provided on a screen that is easily accessible to the user in an easy-to-read plain text format, as an "about" file or included on the home screen;

c. Software as a medical device that does not have a user interface, such as intermediate software for image conversion, must be able to transmit the UDI through the application programming interface (API);

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

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

f. The human-readable (human-readable) format of the UDI for the software as a medical device shall include the identifiers of the application of the issuing entity standard that was used to assist the user in identifying the UDI and determining the standard used to create it.

(*) Republished because it was incorrect in the original, published in the Federal Official Gazette No. 245, of December 29, 2021, Section 1, page 182.

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