Ministry of Health - MS
National Health Surveillance Agency – ANVISA

COLLEGIATE BOARD OF DIRECTORS RESOLUTION - RDC No. 591, OF DECEMBER 21, 2021

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

The **Collegiate Board of Directors of the National Health Surveillance Agency**, in the exercise of the powers conferred upon it by Art. 15, III and IV, allied to Art. 7, III and IV, of Law No. 9.782, as of January 26, 1999, and Art. 53, VI, §§ 1 and 3 of the Bylaws approved by the Collegiate Board of Directors Resolution - RDC No. 255, as of December 10, 2021, hereby resolves to adopt the following Collegiate Board of Directors Resolution, as decided at a meeting held on December 21, 2021, and I, the Chief Executive Officer, Deputy, hereby determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Purpose

Art. 1 This Resolution provides for the identification of medical devices regulated by Anvisa, through the Unique Medical Devices Identification (UDI) system, which allows for the identification of devices in the Country.

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

Section II

Scope

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

Section III Definitions

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

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

II - Configuration: A manufacturer-specified combination of medical device items that work together as a device to achieve its intended use. The combination of items can be modified, adapted, or customized to meet 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; and,

b) ventilators, breathing circuits, vaporizers combined to perform an intended task in anesthesia.

III - Shipping container: Package in which the traceability is controlled by a specific process from the logistics systems. Example: maritime container used exclusively for logistics purposes;

IV - Notification or registration holder: legal entity, public or private, manufacturer or importer, responsible for the medical device in the national territory, which is the holder of the medical device marketing concession, 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 a medical device itself 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, as specified in the registration or notification of the product by Anvisa;

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

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

IX - Manufacturer: refers to the legal manufacturer, that is, any legal entity, public or private, responsible for the design, manufacture, packaging, and labelling of a medical device, with the intention of making it available for use under its name, being these operations 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), a technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object, for identification purposes;

XII - Unique Device Identification (UDI): Numeric or alphanumeric character string created through worldwide accepted device identification and coding standards. Allows the unambiguous identification of a specific device on the market. The UDI consists of UDI-DI and UDI-PI. The term “unique” does not imply the serialization of individual production units;

XIII - Unit of use identifier of the device, i.e., Unit of Use UDI-DI (UoU UDI-DI): Identifier assigned to an individual medical device when a UDI is not labelled at the level of the device unit of use Its purpose is to provide a DI to identify a device used on a patient when a DI is not present on the device tag. The unit of use identifier shall be assigned when the lowest packaging level contains a number of devices greater than one. Example of UoU UDI-DI application: Syringes packed with other syringes in multiple packaging;

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

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

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

XVII - Packaging levels: Multiple levels of device packaging containing a defined number of devices, such as a pack or a box. This does not include shipping containers;

XVIII - Unique medical device identification system (UDI system): System designed to provide a unique identification, globally harmonized, for the identification of medical devices during their distribution and use, which requires labels to carry a unique device identifier (to be converted using the 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, identification/linear barcode, matrix/two-dimensional (2D) barcode, RFID, etc;

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

XXI - Production Identifier (UDI-PI): Numeric or alphanumeric code that identifies the production unit of the device. 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), manufacture 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 regarding the UDI system by the manufacturers and notification or registration holders.

Art. 5 Manufacturers are required to comply with the determinations provided for in the caput of Art. 8 and Art. 9 of this Resolution, pursuant to the provisions of Annex II.

§ 1 The manufacturer's quality management system shall implement control mechanisms that ensure the correct assignment of the UDI to all devices manufactured by it or on its behalf, in compliance with the caput of Art. 8 of this Resolution.

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

Art. 6 It is incumbent upon the notification or registration holders to verify if the manufacturer has complied with the determinations provided for in Section I of Chapter III of this Resolution.

Sole paragraph. The notification or registration holder is also responsible for ensuring, with the manufacturer, the consistency and validity of the information submitted and transferred to the UDI database, in compliance with § 2 of Art. 8 of this Resolution.

CHAPTER III

UNIQUE MEDICAL DEVICES IDENTIFICATION

Section I

Unique Medical Devices 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, allowing access to the information provided for in Annex I;

II - a UDI-PI that identifies the unit of production of the device 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 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 of Directors Resolution - RDC No. 16, of March 28, 2013, or any standard that may replace it;

V - Storage of the UDI by health services and health professionals for a period equivalent to the term for keeping the patient's record, in compliance with the applicable legislation;

VI - Creation of an UDI database, pursuant to Section III of Chapter III of this Resolution.

Art. 8 Before placing a device on the market, the manufacturer shall assign to the device and, where applicable, to all upper packaging levels, an UDI created in compliance with the rules of the issuing entity designated by Anvisa, pursuant to Section II of Chapter III of this Resolution.

§ 1 For imported medical devices that are not classified as medical devices in the country of the manufacturer, the notification or registration holder is entitled to assign the UDI pursuant to the caput, provided that it is authorized by the manufacturer

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

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

Art. 10. The UDI, including UDI-DI and UDI-PI, shall 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 orthopedic procedures whose content is configured for a specific order, 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 notification requirements set out in other regulations.

Section II

UDI Issuing Entities

Art. 11. Issuing entities shall operate an UDI allocation system pursuant to this Resolution, and which meets the following criteria.

I - The issuing entity is an organization incorporated under private law;

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

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

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

V - The issuing entity shall:

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

b) make available to Anvisa, whenever requested, information regarding its UDI allocation system; and,

c) continue to comply with the designation criteria and the terms on which the designation 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

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

Art. 13. Anvisa shall consider, in the design of its UDI database, the general principles provided for in Section IV of Annex II.

Art. 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 TRANSITIONAL PROVISIONS

Art. 15. After the effective date of this Resolution, the terms for assigning the UDI, pursuant to the caput of Art. 8, apply the UDI supports, as per § 2 of Art. 5 and Art. 9, transmit information to the UDI database, in compliance with the sole paragraph of Art. 8, as well as transmit the UDI in notifications of adverse events, technical complaints and field actions, as provided for by Art. 10, shall be of:

I - 2.5 years for risk class IV medical devices;

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. 9 is applicable two years after the end of the terms referred to in the caput for the respective class of medical devices.

§ 2 The inclusion of UDI support in traceability tags for the unique identification of stents for coronary arteries, drug-eluting stents for coronary arteries, and implants for hip and knee arthroplasty, is required as of the effective date of this Resolution.

§ 3 The terms provided for in the caput for transmitting information to the UDI database, referred to in the sole paragraph of Art. 8, shall start from the moment Anvisa publishes, in a normative instruction, that the Agency's UDI database is able to receive the UDI information from Annex I, as well as the conditions for submitting the data and the mechanisms made available to comply with Item 4.10 of Annex II.

§ 4 The terms provided for in the caput for transmitting the UDI in notifications of adverse events, technical complaints, and field actions, pursuant to Art. 10, shall start from the moment ANVISA publishes, in a normative instruction, that the Agency's electronic systems that receive those notifications are able to include the UDI information, as well as the conditions for submitting the data.

Art. 16. Compliance with the provisions of this Resolution is optional for the medical device manufactured prior to the deadline provided for in Art. 15.

Sole paragraph. In the cases of medical devices listed in § 2 of Art. 15 of this Resolution, the affixing of UDI support on traceability tags applies to devices manufactured after June 20, 2020.

Art. 17. Non-compliance with the provisions contained in this Normative Instruction constitutes a health infraction, pursuant to Law No. 6.437, of August 20, 1977, without prejudice to the applicable civil, administrative and criminal liabilities.

Sole 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 the legislation in force or inconsistency that justifies such health measure.

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

Art. 19. This Resolution shall enter into force on January 10, 2022.

MEIRUZE SOUSA FREITAS

Deputy Chief Executive Officer

~~**ANNEX I**~~

~~**ESSENTIAL DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE ALONG WITH THE UDI-DI IN COMPLIANCE WITH THIS RESOLUTION**~~

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

~~1- Amount 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 device production is controlled: serial number, batch number, and/or expiration date (or manufacture 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 its unit of use level, a device unit of use identifier is assigned to associate the device use with a given patient),~~

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

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

~~7- Trade name (as indicated by the manufacturer);~~

~~8- Business model of the device;~~

~~9- Catalog number (optional),~~

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

~~11- Complementary product description (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 condition (y/n),~~

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

~~17 - If applicable, sterilization method,~~

~~18- If applicable, information regarding the presence of carcinogenic, mutagenic, or toxic substances for reproduction and/or endocrine disruptors,~~

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

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

~~a. Contains latex (y/n),~~

~~b. Compatible with MRI environment (y/n), Other critical~~

~~warnings or contraindications.~~

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

~~ANNEX II~~

~~Unique Medical Devices 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 labelling requirements provided for in RDC 185/2001, RDC 36/2015, and RDC 40/2015, subsequent regulations, or those that may replace them.~~

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

~~3-Only the manufacturer or the notification or registration holder upon authorization by the manufacturer and proof that the device is not a medical device in the country of the manufacturer can assign the UDI on the device or its packaging.~~

~~4-Only the codification standards provided by the issuing entities designated by ANVISA can be used, in compliance with Art. 11 of this Resolution.~~

~~Section II~~

~~2 - UDI~~

~~1- The UDI shall be assigned to the device itself or its packaging. Upper packaging levels shall have their own UDI. Shipping containers are exempt from this requirement. For example, the UDI is not required in a logistic unit; when a healthcare facility orders multiple devices using the UDI, or the model number of each device, and the manufacturer places those devices in a container for shipping or to protect the individually packaged devices, the container (logistics unit) is not subject to the UDI~~

~~requirements.~~

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

~~3-The UDI-DI shall be unique in 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 shall be part of the UDI-PI. If the label also indicates the manufacture date, it does not need to be included in the UDI-PI. If the label only contains the manufacture date, this shall be used as the UDI-PI.~~

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

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

~~7- The kits, including IVD kits, shall have their own UDI.~~

~~8- The manufacturer or the notification or registration holder, when applicable, shall assign the UDI to the device in compliance with the relevant coding standard.~~

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

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

~~b. Business model of the device;~~

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

~~d. Labeled as a single-use device; Labeled~~

~~as a sterile device;~~

~~f. Sterilization required before use;~~

~~g. Number of devices provided in a package;~~

~~h. Critical warnings or contraindications: e.g. contains latex or DEHP.~~

~~10. The reprocessed single-use product may not use the UDI assigned by the manufacturer to the original product. Companies and healthcare services that reprocess these devices with their own label shall create their own unique UDI that will replace the UDI provided by the manufacturer. These companies and healthcare services shall keep the UDI registration of the manufacturer of the original device.~~

~~11. Refurbished product may not use the same UDI assigned prior to refurbishing. The manufacturer or company qualified and authorized by the original manufacturer that refurbishes the product shall create its own unique UDI that will replace the assigned UDI prior to refurbishing. The company that refurbishes the product shall keep the UDI registration before and after refurbishing.~~

~~12. A labelling change to display or modify an UDI-DI shall not (by itself) impose the need for submitting a change in the product's health regularization, this being a non-reportable change.~~

~~Section III~~

~~3 - UDI Support~~

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

~~2- In case of important space constraints on the packaging of the unit of use, the UDI holder can be placed on the next upper packaging level.~~

~~3- For single-use Class I and Class II devices that are individually packaged and labeled, the UDI holder does not need to appear on the package, but it shall appear on a upper packaging level, such as a box containing multiple individually packaged devices. However, at the time of device use, when access to the upper packaging level of the device is not possible, such as in the context of home healthcare, the UDI shall be placed on the packaging of the individual device.~~

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

~~5- When AIDC holders, other than the UDI holder, form part of the product labelling, the UDI holder shall be easily identifiable.~~

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

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

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

~~9- If the manufacturer uses RFID technology, a linear or two-dimensional barcode shall also be included on the label, in compliance with the standard provided for by the issuing entities.~~

~~10- Reusable devices shall be supported by the UDI on the device itself. UDI support of reusable devices that require processing between uses in patients shall be permanent and legible after each processing performed so that the device is ready for the next use during its intended useful life. The requirement in this section does not apply to devices under the following circumstances:~~

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

~~b) The device cannot be directly marked because it is not technologically feasible;~~

~~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 shall be legible during normal use and for the intended useful life of the device.~~

~~12- If the UDI support is easily legible and, in the case of the AIDC, it can be scanned through the device packaging, it is not necessary to place the UDI support on the packaging.~~

~~13- In the case of single finished devices made up 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.~~

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

~~15- Barcode supports displaying both the UDI-DI and the UDI-PI may also display essential data for device operation or other data.~~

~~Section IV~~

~~4 - General principles of the UDI database~~

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

2- The inclusion of confidential business information in the database shall not be required.

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 contained in the UDI database, and this responsibility may be delegated to the manufacturer by the holder.

4- Appropriate methods/procedures shall be used to validate the data provided.

5- The notification or registration holder shall periodically verify that all data important to the medical devices that were 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, given the fact that the UDI-DI is in the UDI database, that the device is regularized with ANVISA.

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

8- Data regarding a new UDI-DI shall be available when the device is placed on the market.

9- The notification or registration holders shall update the UDI database record within 30 days after a change is made 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 shall use internationally accepted standards for data transmission and updating.

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

12- Data regarding discontinued devices shall be kept in the UDI database.

Section V

5 - Rules applicable to specific types of devices 1-

Implantable devices

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

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

serial number for active implantable devices;

~~b. The serial number or batch number in the case of other implantable devices.~~

~~3- The UDI of the implantable device shall be identifiable prior to implantation.~~

~~2- Reusable devices that require processing between uses~~

~~1- The UDI of such devices shall be placed on the device and be legible after each processing.~~

~~2- The UDI-PI shall have at least the following characteristics: the batch or the serial number.~~

~~3- Kits (non-IVD).~~

~~1- The kit manufacturer shall be responsible for identifying the kit with an UDI that includes both the UDI-DI and the UDI-PI; for imported kits, the notification or registration holder may assign the UDI, provided it is authorized by the manufacturer and 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 a specific order do not require the application of UDI-DI or UDI-PI.~~

~~2- The contents of the kit device shall have the UDI support in the respective packaging or on the device itself.~~

~~Exceptions:~~

~~a) Individual single-use disposable devices, whose use is generally known to the people for which 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, do not require their own UDI support; 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 removed from the kit.~~

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

~~3- Placing the UDI support on kits:~~

~~a) As a general rule, the UDI support on kits shall be affixed on the outside of the packaging.~~

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

~~4- IVD Kits.~~

~~1- The kit manufacturer shall be responsible for identifying the kit with an UDI that includes both the UDI-DI and the UDI-PI; for imported IVD kits, the notification or registration holder may assign the UDI under this item, provided it is authorized by the manufacturer and 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 required for use and identification by automated systems. This does not constitute an UDI.~~

~~c) Single-use medical devices packaged together with an IVD kit, the use of which is generally known to the intended users, 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 an UDI support at the relevant packaging level do not require the application of an UDI support when packaged together with an IVD kit.~~

~~2- Placing the UDI support on IVD kits:~~

~~a) As a general rule, the UDI support on kits shall be affixed on the outside of the packaging.~~

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

~~5- Configurable devices:~~

~~1- An UDI must be assigned to a configurable device in its entirety, which shall be called the "UDI of the configurable device".~~

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

~~3- The respective UDI-PI shall be assigned to each configurable device. A later change to a component, part, or accessory of a configurable device does not require changing the UDI-DI of the configurable device.~~

~~4- The configurable device UDI support shall be placed in the set that is least likely to be changed during the useful life of the system, and it shall be identified as the "configurable device UDI".~~

~~5- Each component that is framed as a device and that is available on the market by itself shall be assigned a separate UDI.~~

~~6- Software as a Medical Device (SaMD) 1-~~

~~UDI assignment criteria~~

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

~~b) The version of the software as a medical device shall be considered as the manufacturing control mechanism and shall be included in the UDI-PI.~~

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

~~a) The original performance and efficacy;~~

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

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

~~3- Minor software revisions require a new UDI-PI, and not a new UDI-DI.~~
~~DI~~

~~Minor software revisions are often associated with bug fixes, non-security usability improvements, security patches, or operational efficiency.~~

~~Minor software revisions shall be identified using a manufacturer specific identification method, such as version, revision number, serial number, among others.~~

~~4- UDI placement criteria for software as a medical device~~

~~a) When the software as a medical device is delivered on a physical media, for example on CD or DVD, each packaging level shall support the AIDC and HRI representation of the complete the UDI assigned to the software as a medical device. In the UDI applied to 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, such as an "about" file or included in the home screen;~~

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

~~d) Only the legible (human legible) 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 AIDC on electronic displays, such as the "about" menu, the startup screen, etc.;~~

~~e) Software as a medical device that are not distributed on physical media (CD, DVD or similar) do not require the affixing of an AIDC.~~

~~f) The legible format (human legible) of the UDI for software as a medical device shall 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.~~

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

ANNEX I (*)

ESSENTIAL DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE ALONG WITH THE UDI-DI IN COMPLIANCE WITH THIS RESOLUTION

(Re-published in the Official Federal Gazette No. 5, of January 7, 2022)

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

1. Amount 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 device production is controlled: serial number, batch number, and/or expiration date (or manufacture 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 its unit of use level, a device unit of use identifier is assigned to associate the device use with a given patient),

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

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

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

8. Business model of the device,

9. Catalog number (optional),

10. If applicable, clinically relevant dimensional characteristics (including volume, length, gauge, diameter),

11. Complementary product description (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 condition (y/n),

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

17. If applicable, sterilization method,

18. If applicable, information regarding the presence of carcinogenic, mutagenic, or toxic substances for reproduction and/or endocrine disruptors,

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

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

a. Contains latex (y/n),

b. Compatible with MRI environment (y/n),

c. Other critical warnings or contraindications.

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

ANNEX II

UDI SYSTEM

Section I

1. General requirements

1.1 The UDI marking is a supplementary requirement - it does not replace any of the other marking or labelling requirements provided for in RDC 185/2001, RDC 36/2015, and RDC 40/2015, subsequent regulations, or those that may replace them.

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

1.3. Only the manufacturer or the notification or registration holder upon authorization by the manufacturer and proof that the device is not a medical device in the country of the manufacturer can assign the UDI on the device or its packaging.

1.4. Only the codification standards provided by the issuing entities designated by ANVISA can be used, in compliance with Art. 11 of this Resolution.

Section II

2. UDI

2.1 The UDI shall be assigned to the device itself or its packaging. Upper packaging levels shall have their own UDI.

Shipping containers are exempt from this requirement. For example, the UDI is not required in a logistic unit; when a healthcare facility orders multiple devices using the UDI, or the model number of each device, and the manufacturer places those devices in a container for shipping or to protect the individually packaged devices, the

container (logistics unit) is not subject to the UDI requirements.

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

2.3. The UDI-DI shall be unique in each level of the device packaging.

2.4. If a batch number, serial number, software version such as a medical device, or expiration date appear on the label, they shall be part of the UDI-PI. If the label also indicates the manufacture date, it does not need to be included in the UDI-PI. If the label only contains the manufacture date, this shall be used as the UDI-PI.

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

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

2.7. The kits, including IVD kits, shall have their own UDI.

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

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

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

b. Business model of the device;

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

d. Labeled as a single-use device;

e. Labeled as a sterile device;

f. Sterilization required before use;

g. Number of devices provided in a package;

h. Critical warnings or contraindications: e.g. contains latex or DEHP.

2.10. The reprocessed single-use product may not use the UDI assigned by the manufacturer to the original product. Companies and healthcare services that reprocess these devices with their own label shall create their own unique UDI that will replace the UDI provided by the manufacturer. These companies and healthcare services shall keep the UDI registration of the manufacturer of the original device.

2.11. Refurbished product may not use the same UDI assigned prior to refurbishing. The manufacturer or company qualified and authorized by the original manufacturer that refurbishes the product shall create its own unique UDI that will replace the assigned UDI prior to refurbishing. The company that refurbishes the product shall keep the UDI registration before and after refurbishing.

2.12. A labelling change to display or modify an UDI-DI shall not (by itself) impose the need for submitting a change in the product's health regularization, this being a non-reportable change.

Section III

3. UDI Support

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

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

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

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

3.5. When AIDC holders, other than the UDI holder, form part of the product labelling, the UDI holder shall be easily identifiable.

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

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

3.8. The format of the HRI shall 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 shall also be included on the label, in compliance with the standard provided for by the issuing entities.

3.10. Reusable devices shall be supported by the UDI on the device itself. UDI support of reusable devices that require processing between uses in patients shall be permanent and legible after each processing performed so that the device is ready for the next use during its intended useful life. The requirement in this section does not apply to devices under the following circumstances:

a. Any type of direct marking that interferes with the security or performance of the device;

b. The device cannot be directly marked because it is not technologically feasible;

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 support shall be legible during normal use and for the intended useful life of the device.

3.12. If the UDI support is easily legible and, in the case of the AIDC, it can be scanned through the device packaging, it is not necessary to place the UDI support on the packaging.

3.13. In the case of single finished devices made up 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 support shall be placed so that the AIDC can be accessed during normal use or storage of the device.

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

Section IV

4. General principles of the UDI database

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

4.2. The inclusion of confidential business information in the database shall not 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 contained in the UDI database, and this responsibility may be delegated to the manufacturer by the holder.

4.4. Appropriate methods/procedures shall be used to validate the data provided.

4.5. The notification or registration holder shall periodically verify that all data important to the medical devices that were 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, given the fact that the UDI-DI is in the UDI database, that the device is regularized with ANVISA.

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

4.8. Data regarding a new UDI-DI shall be available when the device is placed on the market.

4.9. The notification or registration holders shall update the UDI database record within 30 days after a change is made 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 data transmission and updating.

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

4.12. Data regarding discontinued devices shall be kept 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 marked using the AIDC, with an UDI (UDI-DI + UDI-PI).

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

a. The serial number for active implantable devices;

b. The serial number or batch number in the case of other implantable devices.

5.1.3. The UDI of the implantable device shall be identifiable prior to implanting.

5.2. Reusable devices that require processing between uses

5.2.1. The UDI of such devices shall be placed on the device and be legible 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 an UDI that includes both the UDI-DI and the UDI-PI; for imported kits, the notification or registration holder may assign the UDI, provided it is authorized by the manufacturer and 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 a specific order do not require the application of UDI-DI or UDI-PI.

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

Exceptions:

a. Individual single-use disposable devices, whose use is generally known to the people for which 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, do not require their own UDI support; 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 removed from the kit.

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. Placing the UDI support on kits:

a. As a general rule, the UDI support on kits shall be affixed on the outside of the packaging.

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

5.4. IVD Kits.

5.4.1. The kit manufacturer shall be responsible for identifying the kit with an UDI that includes both the UDI-DI and the UDI-PI; for imported IVD kits, the notification or registration holder may assign the UDI under this item, provided it is authorized by the manufacturer and 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 required for use and identification by automated systems. This does not constitute an UDI.

c. Single-use medical devices packaged together with an IVD kit, the use of which is generally known to the intended users, 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 an UDI support at the relevant packaging level do not require the application of an UDI support when packaged together with an IVD kit.

5.4.2. Placing the UDI support on IVD kits:

a. As a general rule, the UDI support on kits shall be affixed on the outside of the packaging.

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

5.5. Configurable devices:

5.5.1. An UDI shall be assigned to a configurable device in its entirety, which shall be called the "UDI of the configurable device".

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

5.5.3 The respective UDI-PI shall be assigned to each configurable device. A later change to a component, part, or accessory of a configurable device does not require changing the UDI-DI of the configurable device.

5.5.4. The configurable device UDI support shall be placed in the set that is least likely to be changed during the useful life of the system, and it shall be identified as the "configurable device UDI".

5.5.5 Each component that is framed as a device and that is available on the market by itself shall be assigned a separate UDI.

5.6. Software as a Medical Device (SaMD)

5.6.1. UDI assignment criteria

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

b. The version of the software as a medical device shall be considered as the manufacturing control mechanism and shall be included in the UDI-PI.

5.6.2. A new UDI-DI shall be required whenever there is a major change of the software as a medical device. Major changes are complex or significant changes that affect:

a. The original performance and efficacy;

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

These changes may include new or modified algorithms, database structures, operating platform, 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 often associated with bug fixes, non-security usability improvements, security patches, or operational efficiency.

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

5.6.4. UDI placement criteria for software as a medical device

a. When the software as a medical device is delivered on a physical media, for example on CD or DVD, each packaging level shall support the AIDC and HRI representation of the complete the UDI assigned to the software as a medical device. In the UDI applied to 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 shall be provided on a screen that is easily accessible to the user in an easy-to-read plain text format, such as an "about" file or included in the home screen;

c. The software as a medical device that does not have a user interface, such as

intermediate software for image conversion, shall be capable of transmitting the UDI through the application programming interface (API);

d. Only the legible (human legible) 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 AIDC on electronic displays, such as the "about" menu, the startup screen, etc.;

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

f. The legible format (human legible) of the UDI for software as a medical device shall 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.

(*) Re-published due to incorrect information in the original publication, published in the Official Federal Gazette No. 245, of December 29, 2021, Section 1, page 182.