MINISTRY OF HEALTH

NATIONAL HEALTH SURVEILLANCE AGENCY

BOARD

RESOLUTION OF THE COLLEGIATE BOARD OF DIRECTORS-RDC NO. 884, OF JUNE 26, 2024

RET., 07/02/2024 - Section 1

Amends the Resolution of the Collegiate Board of Directors RDC No. 591, of December 21, 2021 .

THE COLLEGIATE BOARD OF DIRECTORS OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, in the exercise of the powers conferred on it by article 15, items III and IV, of Law No. 9,782, of January 26, 1999 , and considering the provisions of article 187, item VI and §§ 1 and 3, of the Internal Regulations , approved by the Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021 , resolves to adopt the following Resolution of the Collegiate Board of Directors - RDC, as resolved at a meeting held on June 26, 2024, and I, Chief Executive Officer, determine its publication.

Art. 1 The Resolution of the Collegiate Board of Directors - RDC No. 591, of December 21, 2021 , published in the Federal Official Gazette No. 245, of December 29, 2024, Section 1, page 182, is now in force with the following amendments:

" Article 1 .....

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." (NR)

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" Article 6 .....

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." (NR)

" Article 7 .....

....

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;

....." (NR)

" Article 8 .....

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." (NR)

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" Article 15 . .....

I - 3.5 years for medical devices of risk class IV;

II - 4 years for risk class III medical devices;

III - 5 years for risk class II medical devices;

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

....."

Article 2 The Annexes to the Resolution of the Collegiate Board of Directors - RDC No. 591, of December 21, 2021 , Section 1, page 182, are now in force in the form of the annexes to this Resolution.

Article 3 Paragraph 1 of article 8 of the Resolution of the Collegiate Board of Directors - RDC No. 591, of December 21, 2021, is hereby revoked.

Art. 4 This Resolution enters into force on the date of its publication.

ANTONIO BARRA TORRES
Chief Executive Officer

ANNEX I

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

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. If applicable, critical warnings or contraindications (as indicated on the label), which include: a. Contains latex (s/n), b. Compatible with Magnetic Resonance Imaging (s/n), c. Other warnings or critical contraindications.

20. 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. 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.

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This text does not replace the Official Publication.