

OFFICIAL DIARY FROM THE UNITY

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Organ: Ministry from the Health/Agency National in Surveillance Health/Board Collegiate

RESOLUTION - DRC/ANVISA No. 886, IN 26 IN JUNE IN 2024

Change The Resolution from the Board Collegiate DRC no. 591, in 21 December 2021.

A BOARD OF DIRECTORS COLLEGIATE FROM THE AGENCY NATIONAL IN SURVEILLANCE SANITARY, at the use of

powers conferred on it by art.15, items III and IV, of Law No. 9,782, of January 26, 1999, and considering O willing at the art. 187, section SAW It is §§ 1st It is 3rd, of Regiment Internal, approved for the Resolution of the Collegiate Board - 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. 1st A Resolution from the Board Collegiate - DRC no. 591, in 21 in December in 2021, published in the Official Gazette of the Union nº 245, of December 29, 2024, Section 1, p. 182, becomes come into force with the following changes:

"Art. 1st

Single 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 - RDC nº 751, of September 15, 2022, and devices doctors for diagnosis in vitro regulated for the Resolution from the Board Collegiate - DRC No. 830, in 06 in December in 2023, or regulations later." (NR)

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"Art. 6th

Single paragraph. The holder of the notification or registration is also responsible for ensuring with the manufacturer the coherence and validity of the information presented and transferred to the database in data UDI, us terms of paragraph single of art. 8th of this Resolution." (NR)

"Art. 7th

.....

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 for keeping patient records, in accordance with applicable legislation;

..... " (NR)

"Article 8

Single 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)

.....

"Art. 15.

I - 3.5 years for you devices doctors in class in risk IV;

II - 4 years for you devices doctors in class in risk III;

III - 5 years for you devices doctors in class in risk II;

IV - 6 years for you devices doctors in class in risk I.

..... "(NR)

Art. 2nd You Attachments from the Resolution from the Board Collegiate - DRC no. 591, in 21 in December in 2021, Section 1, pg. 182, come into force in the form of the annexes to this Resolution.

Art. 3rd He is revoked O §1º of art. 8th from the Resolution from the Board Collegiate - DRC no. 591, in 21 December 2021.

Art. 4th It is Resolution goes into in force at date from the your Publication.

ANTONIO BAR TORRES

CEO

ATTACH
MENT I

ELEMENTS IN DATA ESSENTIALS A TO SUPPLY A BASIS IN DATA UDI TOGETHER WITH O
UDI-DI US TERMS THIS RESOLUTION

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

1. Quantity per packaging configuration ,
2. O UDI-DI of device It is your entity broadcaster, good as O UDI-DI It is your entity issuer for each packaging level as specified in Annex II,
3. How device production is controlled: serial number, batch number, and/or date of expiration date (or date of manufacture) or software version or SaMD release date (y/n),
4. If applicable, UoU UDI-DI (if no there is recommendation in UDI at the label of device to the level of its unit of use, a device unit of use identifier is assigned to associate the use of the device with a specific patient),
5. Manufacturer's name and address, as well as Customer Service information (as indicated on the label),
6. O code GMDN, acronym English in Global Medical Device nomenclature, of device doctor,
7. Name commercial (such as indicated for the manufacturer),
8. Model commercial of device,
9. Number in catalog (optional),
10. If applicable, clinically relevant dimensional characteristics (including volume, length, caliber, diameter),
11. Description additional of product (optional),
12. If applicable, conditions in storage and/or handling (such as indicated at the label),
13. Labeled as device of use single (y/n),
14. If applicable, number maximum in reuses,
15. Device labeled as at the state sterile (y/n),
16. Need in sterilization before from the use (y/n),
17. If applicable, method in sterilization,
18. URL for information supplementary, as to the instructions in use electronics (optional),
19. If applicable, warnings or contraindications reviews (such as indicated at the label), what include:
 - a. Contains latex (y/n),
 - b. Compatible with environment in Resonance Magnetic (y/n),
 - c. Others warnings or contraindications criticism.
20. Date in discontinuation of device (referring The devices what no they are most placed at the Marketplace).

ANNEX II

SYSTEM UDI

Section I

1. Requirements general

1.1. A 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 their successors.

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

Section II

2. UDI

2.1 A UDI he must to be assigned to the own device or The your packaging. You levels superiors packaging must have their own UDI.

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

2.2. A UDI he must to contain two parts: O UDI-DI It is O UDI- PI.

2.3. O UDI-DI he must to be single in each one of the levels in packaging of device.

2.4. If a batch number, serial number, software version as a medical device or expiration date appear on the label, they must be part of the UDI-PI. If the label also indicates the date of manufacture, it is not necessary to include it in the UDI-PI. If the label only contains the date of manufacture, this 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 number of devices greater than one, then a UoU UDI-DI must be assigned, for connect O use of device The one patient. Per example, one UoU UDI-DI he must to be assigned to an individual electrode when the electrode is distributed in a pack of 10. In this case, the level The lowest UDI is attributed to the package with 10 units (base package).

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

2.7. You kits, including you kits IVD, must to have your own UDI.

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

2.9. He must to be required one new UDI-DI ever what there is one change what be likely to induce in error in identifying the device and/or causing ambiguity in its traceability. In particular, for any changing one of the following elements of the UDI database, a new UDI-DI is required:

- a. Name commercial (such as indicated for the manufacturer);
- b. Model commercial of device;
- c. Characteristics dimensional clinically relevant (including volume, length, gauge, diameter);
- d. Labeled as device of use single;
- e. Labeled as device sterile;
- f. Need in sterilization before of use;
- g. Amount in devices provided in packaging;

h. Warnings or contraindications reviews: per example, contains latex or DEHP.

2.10 To the companies It is services in health what perform O reprocessing in devices doctors from use single, according to regulation specific, It is without prejudice to the seals imposed for the Resolution - RE No. 2605 of 11/08/2006 or another that replaces it, must keep the record of the UDI from 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 refurbishment. The manufacturer or the company qualified and authorized by the original manufacturer that reconditions the product must create its own unique UDI that will replace the UDI assigned prior to reconditioning. The company that reconditions the product must keep a record of the UDI before and after reconditioning.

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

Section III

3. Support from the UDI

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

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

3.3. For Class I and Class II, single-use devices that are individually packaged and labeled, the UDI support does not need to appear on the packaging, but rather on a higher level of packaging, such as a box that contains multiple packaged devices individually. However, when using the device, when it is not possible to access the upper level of packaging of device, as at the context from the assistance doctor home, The UDI he must to be placed on the individual device packaging.

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

3.5. When AIDC supports other than the UDI support are part of the product labeling, the UDI support 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 that restrict the use of both AIDC and HRI on the label, only the AIDC format should be required to appear on the label. For devices that are intended to be used outside healthcare facilities, such as home healthcare devices, the HRI must still appear on the label, even if it means there will be no space for the AIDC.

3.8. O Format from the HRI he must follow to the rules from the entity broadcaster of code from the UDI.

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

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

b. O device no he can to be marked directly why no It is feasible of point in technological view

;

c. Determined for the manufacturer what O product no he can to be marked directly due The issues related to its size, design, materials, processing or device performance.

3.11. O support from the UDI he must to be readable during The use normal It is to the far away from the life useful device.

3.12. If O support from the UDI for readable easily It is, at the case from the AIDC, scannable, through device packaging, it is not necessary to place the UDI bracket in the packaging.

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

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

3.15. Barcode carriers displaying both UDI-DI and UDI-PI may display also data essential for O operation of device or others data.

Section IV

4. Principles general from the base in data UDI

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

4.2. No he can to be required The inclusion in information commercials confidential at base in data.

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

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

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

4.6. No if he must presume, for the fact in O UDI-DI appear from the base in data UDI, what O device is regularized with Anvisa.

4.7. A base in data he must to allow The binding in all you levels in packaging of the device.

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

4.9. You holders from the notification or of record must to update O record from the base in data UDI 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 must use internationally accepted standards for data transmission and updating.

4.11. The user interface of the UDI database must be available in the official language of Brazil. O use in fields in text free he must to be minimized The end in reduce to the overloads entailed for possible translations.

4.12. Data relating to discontinued devices must be kept in the UDI database.

Section V

5. Rules applicable The types specific in devices

5.1. Devices implantable

5.1.1. You devices implantable must, to the level in packaging base to be identified, or marked using AIDC, with a UDI (UDI-DI + UDI-PI).

5.1.2. O UDI-PI he must to present for the any less to the following characteristics:

- a. O number in series at the case of the devices implantable active;
- b. O number in series or O number in batch at the case of the others devices implantable.

5.1.3. A UDI of device implantable he must to be identifiable before from the implantation.

5.2. Devices reusable what need in processing in between uses

5.2.1. A UDI in such devices he must to be placed at the device It is to be readable after each processing.

5.2.2. O UDI-PI he must to present for the any less to the following characteristics: O batch or O number in

serie
s.

5.3. Kits (no IVD).

5.3.1. O manufacturer of kit, he must to be responsible per identify O kit with one UDI what include so much
o UDI-DI as O UDI- PI.

Exception:

a. Trays for procedures orthopedic whose content It is configured for one Specific request does not require the application of UDI-DI or UDI-PI.

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

Exceptions:

a. You devices disposable in use single individual whose use it is in one mode known general of people per who if intended The to be used, what do part in one kit It is what no are intended The one use individual outside of context of kit no require O your own support from the IDU; for example, a non-individually packaged sterile syringe provided in a kit cannot be used in another procedure due to the lack of a sterile barrier once it is removed from the kit.

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

5.3.3. Placing of support from the UDI in kits:

- a. Via in rule, O support from the UDI in kits he must to be posted at the outdoor from the packaging.
- b. UDI support must be readable or, in the case of AIDC, scannable, whether placed on the outside of the kit packaging or inside a transparent packaging.

5.4. Kits IVD.

5.4.1 The kit manufacturer must be responsible per identify the kit with a UDI that includes both the UDI-DI and the UDI-PI.

a. O kit IVD It is one device doctor It is all you aspects of this regulation The he if apply. If one kit IVD no includes none component what per yes only it is framed as one device doctor, the only UDI required It is The UDI of kit IVD properly said.

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

c. Single-use medical devices packaged together with an IVD kit, whose use is generally known to the 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 carrier.

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 together with an IVD kit.

5.4.2. Placing of support from the UDI in kits IVD:

a. Via in rule, O support from the UDI in kits he must to be posted at the outdoor from the packaging.

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

5.5. Devices configurable:

5.5.1. The configurable device in its entirety must be assigned a UDI which must be designated as "configurable device UDI".

5.5.2. The "UDI-DI of configurable devices" must be assigned to configuration groups 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 must be assigned its respective UDI-PI. A subsequent change to a component, part, or accessory of a configurable device does not require a change to the UDI-DI of the configurable device.

5.5.4. Configurable device UDI support it must be placed in the set with the lowest probability of being changed during the lifespan of the system and should be identified as the "Configurable Device UDI".

5.5.5 A each component that is framed as a device and that is available alone on the market should be assigned a separate UDI.

5.6. Software as Device Doctor (SaMD)

5.6.1. Criteria in assignment from UDI

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

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

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

a. O performance It is efficiency originals;

b. A security or O use intended of software as device doctor.

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

5.6.3. To the small reviews in software require one new UDI-PI It is no one new UDI- DI.

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

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

5.6.4. Criteria in placing from the UDI for software as device doctor

a. When software as a medical device is delivered on physical media, for example on CD or DVD, each packaging level must contain the AIDC and HRI representation of the full assigned UDI to the software as device doctor. At UDI applied The media physical what contains O software

as a medical device and its packaging, it is optional to include additional production identifiers that allow greater traceability, such as the date of recording or the recording batch of the physical media;

b. A UDI he must to be provided in screen easily accessible to the user on one Format in plain text in reading easy, as one file "about" or included at screen initial;

c. O software as device doctor what no it has in one interface in user, as the software intermediary for conversion in images, he must to be able in to transmit The UDI through from the interface schedule in application (API);

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

e. You software as devices doctors what no be distributed in media physical (CD, DVD or similar) do not require the affixing of a AIDC.

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

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