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COLLEGIATE BOARD RESOLUTION - RDC No. 591, OF DECEMBER 21, 2021
(Published in DOU No. 245 of December 29, 2021)

It provides for the identification of medical devices regularized in Anvisa, through the Unique Identification of Medical Devices (UDI) system.

The Collegiate Board of the National Health Surveillance Agency, in the use of the attribution conferred on it by article 15, III and IV, together with article 7, III, and IV, of Law No. 9,782, of January 26, 1999, and article 187, VI, §§ 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 Board of Executive Officers, as resolved at a meeting held on December 21, 2021, and I, the Chief Executive Officer, Substitute, determine its publication.

CHAPTER I
OF THE INITIAL PROVISIONS

Section I
Objective

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

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

Section II
Scope

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

Section III
Definitions

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

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

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

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

b) ventilators, respiratory circuits, vaporizers combined to perform an intended function in anesthesia.

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

IV - Holder of notification or registration: legal entity, public or private, manufacturer or importer, responsible for the medical device in national territory, which holds the concession of commercialization of medical device, issued by the sanitary authority;

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

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

VII - Base packing: lower level of packaging containing an UDI. The base package may contain multiple devices;

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

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

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

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

XII - Unique Device Identification (UDI): A sequence of numeric or alphanumeric characters created using globally accepted device identification and coding standards. It allows the unambiguous identification of a specific device on the market. The UDI consists of the UDI-DI and the UDI-PI. The term "single" does not imply the serialization of individual production units;

XIII - Unit of Use UDI-DI (UOU UDI-DI): An identifier assigned to the individual medical device where the UDI is not labeled at the utilization unit level. Its purpose is to provide a DI to identify a device used on a patient when a DI is not present on the device label. The Device Utilization Unit Identifier should be assigned when the lower-level package contains a number of devices greater than one. Example of application of UoU UDI-DI: syringes packed with other syringes in multipack;

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

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

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

XVII - Packaging levels: Multiple levels of device packaging that contain a set number of devices, such as a package or a box. This does not include shipping containers;

XVIII - Unique identification system for medical devices (UDI system): is a system designed to provide a unique, globally harmonised identification for the identification of medical devices during their distribution and use, which requires labels to carry a unique device identifier (to be converted using AIDC and, if applicable, HRI) based on standards, with the UDI-DI of this unique identifier also being linked to a public UDI Database;

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

XX - Device Identifier (UDI-DI): A unique numeric or alphanumeric code specific to a device model that is also used as an "access key" to 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), date of manufacture, and expiration date.

CHAPTER II
GENERAL REQUIREMENTS

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

Art.5 Manufacturers are obliged to comply with the determinations established in the caput of article 8 and in article 9 of this Resolution, in accordance with the provisions of Annex II.

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

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

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

Single 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 submitted and transferred to the UDI database, pursuant to § 2 of article 8 of this Resolution.

CHAPTER III
UNIQUE IDENTIFICATION OF MEDICAL DEVICES
Section I
Medical Device Unique Identification System

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

1.– a specific UDI-DI for each model of medical device of each manufacturer, allowing access to the information set out in Annex I;

2.– an UDI-PI identifying the unit of production of the device and, where applicable, the packaged devices as specified in Annex II;

3.– affixing the UDI to the label or to the device itself and to its upper packaging as specified in Annex II;

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

5.– Storage of the UDI by health services and health professionals for a period equivalent to the period of custody of patient records, according to applicable legislation;

6.– Creation of a UDI database, pursuant to Section III of Chapter III of this Resolution.

Art. 8 Before placing a device on the market, the manufacturer must assign to the device and, where applicable, to all higher levels of packaging, a UDI created in accordance with the

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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 holder of notification or registration is allowed to assign the UDI under the terms established in the caput, provided that authorized by the manufacturer

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

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

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

Single paragraph. For medical devices exempt from UDI-DI or UDI-PI, such as trays for orthopedic procedures whose content is configured for a specific request, it is not necessary to send the respective exempt information in the reports of adverse events, technical complaints and field actions, without prejudice to the notification requirements provided for in other regulations.

Section II
UDI Issuing Entities

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

I - The issuing entity is an organisation having legal personality;

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

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

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

V - The issuing authority shall:

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

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

c) continue to meet the criteria for designation and the terms on which it was made.

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

Section III
UDI Database

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

Art. 13. Anvisa will consider in the design of its UDI database the general principles established 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 free of charge to the public.

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CHAPTER IV
FINAL AND TRANSITIONAL PROVISIONS

Art. 15. After the date of entry into force of this Resolution, the deadlines to assign the UDI, according to the caput of article 8, apply the supports of the UDI, according to § 2 of article 5 and article 9, transmit information to the UDI database, according to the sole paragraph of article 8, as well as transmit the UDI in the notifications of adverse events, Technical complaints and field actions, according to art. 10, will be:

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 IDU support in traceability labels for the unique identification of stents for coronary arteries, drug-eluting stents for coronary arteries and implants for hip and knee arthroplasty is mandatory as of the entry into force of this Resolution.

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

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

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

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

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

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

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

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

MEIRUZE SOUSA FREITAS
Substitute Chief Executive Officer

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ANNEX I (*)
KEY DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH UDI-DI PURSUANT TO 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 level of packaging as specified in Annex II,
3. How device production is controlled: serial number, batch number, and/or expiration date (or date of manufacture) or software version or SaMD release date (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 unit identifier of use of the device is assigned to associate the use of the device with a particular patient),
5. Name and address of the manufacturer, as well as the information of the Customer Service (as indicated on the label), Name and address of the manufacturer, as well as the information of the Customer Service (as indicated on the label),
6. The GMDN code, which stands for Global Medical Device Nomenclature, of the medical device,
7. Trade name (as indicated by the manufacturer),
8. Commercial model of the device,
9. Catalogue number (optional),
10. Where applicable, clinically relevant dimensional characteristics (including volume, length, caliber, diameter),
11. Additional description of the product (optional),
12. Where applicable, storage and/or handling conditions (as indicated on the label),
13. Labelled as a single-use device (y/n),
14. If applicable, maximum number of reuses,
15. Device labelled as sterile (y/n),
16. Need for sterilisation before use (y/n),
17. If applicable, sterilization method,
18. Where applicable, information relating to the presence of substances that are carcinogenic, mutagenic or toxic to reproduction and/or endocrine disruptors,
19. URL for supplementary information, such as electronic instructions for use (optional),
20. Where applicable, critical warnings or contraindications (as indicated on the label), which include:
    a. Contains latex (y/n),
    b. Compatible with Magnetic Resonance (y/n) environment,
    c. Other critical warnings or contraindications.
21. Device discontinuation date (for 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 labelling requirements set out in RDC 185/2001, RDC 36/2015 and RDC 40/2015, subsequent regulations or those that succeed them.

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1.2. The manufacturer must assign and maintain unique UDI for its devices. For imported medical devices, the holder of the notification or registration is allowed 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 country of the manufacturer.

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

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

Section II

2. UDI

2.1 The UDI shall be assigned to the device itself or to its packaging. Higher levels of packaging should have their own IDU.

Transport containers are exempt from this requirement. For example, the UDI is not required in a logistics unit; where a healthcare service orders multiple devices using the UDI or model number of each device and the manufacturer places those devices in a container for transport or to protect the individually packaged devices, the container (logistics 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, software version such as 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 does not need to be included in the UDI-PI. If only the date of manufacture is on the label, it shall be used as UDI-PI.

2.5. When the UDI is not assigned to the unit level of use of a device and the lower-level packaging 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 distributed in a package of 10 units. In this case, the lowest level of UDI is assigned to the package with 10 units (base pack).

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

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 could mislead the identification of the device and/or give rise 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. Commercial model of the device;

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

d. Labeled as a single-use device;

e. Labeled as sterile device;

f. Need for sterilization before use;

g. Number of devices supplied 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. Healthcare companies and utilities that reprocess these devices with their own label must create their own unique UDI that will replace the UDI provided

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by the manufacturer. These companies and healthcare services must keep the UDI record of the manufacturer of the originating device.

2.11. The refurbished product will not be able to use the same UDI assigned before the refurbishment. The manufacturer or 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 the refurbishment. The company that refurbishes the product must keep the UDI record before and after the reconditioning.

2.12. A labeling change to display or modify an 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 The UDI holder (AIDC and HRI representation of UDI) must be placed on the label or on the device itself and on all upper levels of packaging. The upper levels of packaging do not include shipping containers.

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

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 packaging, but rather on a higher level of packaging, such as a box containing several individually packaged devices. However, at the time of use of the device, when access to the upper level of device packaging is not possible, such as in the context of home medical care, the UDI should be placed on the packaging of the individual device.

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

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

3.6. If linear barcodes are used, UDI-DI and 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 restricting 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 for use outside healthcare facilities, such as devices for home health care, HRI should still appear on the label, even if it means that there will be no room for the 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 shall 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 processing between uses in patients must be permanent and legible after each processing performed for the device to be ready for next use during its intended lifespan. The requirement in this section does not apply to devices in the following circumstances:

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

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

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

3.11. The UDI holder shall be legible during normal use and throughout the intended lifetime 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 package.

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3.13. In the case of single finished devices consisting of multiple parts which have to be assembled before their first use, it is sufficient to affix the UDI holder to only one part of the device.

3.14. The UDI holder shall be placed in such a way 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 to 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 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 holder of the notification or registration shall be responsible for the initial submission and updating of the 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 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 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, due to the fact that the UDI-DI is included in the UDI database, that the device is regularized at Anvisa.

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

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

4.9. Notification or registration holders must update the UDI database record 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 should be minimized in order to reduce the overloads caused by any 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 marked 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 batch number in the case of other implantable devices.

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

5.2. Reusable devices that require cross-use processing

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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 (not IVD).

5.3.1. The kit manufacturer should be responsible for identifying the kit with a UDI that includes both UDI-DI and UDI-PI; for imported kits, the holder of the notification or registration is allowed to assign the UDI, provided that it is authorized by the manufacturer and proven that the kit is not classified as a medical device in the country of the manufacturer.

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 holder in its packaging or on the device itself.

Exceptions:

a. Individual single-use disposable devices the use of which 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 do not require their own UDI support; For example, an individually packaged unpackaged sterile syringe supplied in one 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 the UDI holder at the relevant packaging level do not require such support when included in a kit.

5.3.3. Placement of the UDI bracket in kits:

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

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

5.4. Kits IVD.

5.4.1 The kit manufacturer should be responsible for identifying the kit with a UDI that includes both UDI-DI and UDI-PI; for imported IVD kits, the holder of the notification or registration may assign the UDI pursuant to this item, provided that it is authorized by the manufacturer and proven that the device is not classified as a medical device in the country of the manufacturer.

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 by itself is framed 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 an IDU.

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 support.

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

5.4.2. Placement of UDI support in IVD kits:

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

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

5.5. Configurable devices:

5.5.1. The entire configurable device shall be assigned a UDI which shall be designated as the "configurable device UDI".

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

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5.5.3 Each configurable device shall be assigned its UDI-PI. 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 UDI bracket of the configurable device should be placed in the assembly with the lowest probability of being swapped out over the lifetime of the system and should 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 on its own shall be assigned a separate UDI.

5.6. Software as a Medical Device (SaMD)

5.6.1. Criteria for awarding the UDI

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

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

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

a. The original performance and effectiveness;

b. The security 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. Small software revisions require a new UDI-PI and not a new UDI-DI.

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

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

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

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

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

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

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

(*) Republished for having left with inaccuracy in the original, published in the Official Gazette No. 245, of December 29, 2021, Section 1, p.182.

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