National Agency of
Health Surveillance

MANUAL FOR REGULARIZATION OF MEDICAL EQUIPMENT AND SOFTWARE AS MEDICAL DEVICE AT ANVISA

Medical Equipment Technology Management - GQUIP

Brasilia/DF
2025

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Important notice:

This Manual has been updated with the changes provided for by ANVISA regulations described below:

BRAZIL. Anvisa. Resolution - RDC No. 751, of 15 September 2022. *Provides for the risk classification, notification and registration regimes, and labeling requirements and instructions for use of medical devices.*

BRAZIL. Anvisa. Resolution - RDC No. 657, of March 24 of 2022. *Provides for the regularization of software as a medical device (Software as a Medical Device - SaMD).*

BRAZIL. Anvisa. Resolution - RDC No. 848, of March 6 2024. *Provides for the essential safety and performance requirements applicable to medical devices and in vitro diagnostic (IVD) medical devices.*

BRAZIL. Anvisa. Normative Instruction - IN No. 74, of 16 September 2020. *Establishes the subjects for changes to information presented in the process of regularizing medical devices at ANVISA, under the terms of the Collegiate Board Resolution - RDC No. 340, of March 6, 2020.*

BRAZIL. Anvisa. Normative Instruction - IN No. 290, of 4 April 2024. *Establishes, under the terms of the Collegiate Board Resolution -RDC No. 741, of August 10, 2022, an optimized procedure for the purposes of analyzing and deciding on petitions for registration of medical devices, through the use of analyses carried out by an Equivalent Foreign Regulatory Authority (AREE).*

Summary

Summary

Introduction

Medical equipment under Health Surveillance include all equipment used in healthcare for the purpose of medical, dental, laboratory or physiotherapy, used directly or indirectly for diagnosis, therapy, rehabilitation or monitoring of human beings and also for beautification and aesthetic purposes.

Medical equipment falls into the device category medical, formerly called a health product (related), together with materials used in health (example: catheter and implants orthopedic, among others) and *in vitro* diagnostic products (reagents, catalysts, etc.), the latter not being covered in this Manual. Also excluded from this Manual are equipment responsible for analyzing the samples collected for for the purpose of clinical or laboratory analysis, together with the products of *in vitro* diagnostic use , and whose notification and registration management are the responsibility of the Diagnostic Product Management Vitro.

Medical equipment is mostly composed of active medical devices, implantable or non-implantable. In However, there may also be non-active medical equipment, such as for example, wheelchairs, stretchers, hospital beds, tables surgical and examination chairs, among others.

The same Management responsible for analyzing the equipment doctors, is also responsible for analyzing products called Software as a Medical Device – SaMD. These software programs meet the definition of a medical device.
medical, which may or may not be in vitro diagnostic (IVD), being intended for one or more medical indications, and which perform these purposes other than being part of medical device hardware (includes here also that software intended only to control the device manufacturer's doctor, even if installed on different hardware). Includes mobile applications and software for *in vitro purposes,* if their indications are included in the general definition of devices doctors.

This definition includes, among others, software licensed by subscription and centrally hosted (Software as a Service), which fall within the definition of medical devices.

As established in art. 12 of **Law No. 6,360, of 23 September 1976,** no product of interest to health, whether national or imported, may be industrialized, displayed for sale or delivered for consumption in the Brazilian market before being registered with the Ministry of Health. With the exception of those indicated in § 1 of Art. 25 of the aforementioned Law, that although exempt from registration, are subject to the regime of Health Surveillance. These are the notified products.

Failure to comply with the provisions set out in the legislation sanitary constitutes an infraction of Federal Health Legislation, with the offending company being subject, at the administrative level, to penalties provided for in **Law No. 6,437 of August 20, 1977,** without prejudice to the applicable civil or criminal sanctions. In the legal sphere, are responsible for the acts of infringement committed by the company its Legal and Technical Responsible, according to infractions and sanctions provided for in art. 273 of **Decree Law No. 2,848, of December 7, 1940** (Penal Code – Chapter III: Crimes against Public Health). **Law No. 9,782, of January 26, 1999,** according to its art. 8, assigned the National Health Surveillance Agency – ANVISA – the responsibility of regulate, control and monitor products and services involving risk to public health, which included, among other activities, the granting of product registration (item IX of art. 7 of Law No. 9.782/99).

Product registration and notifications at Anvisa are regulated by specific resolution. For equipment doctors, risk class I and II (notification), III and IV (registration), the Resolution intended for regularization is Resolution - **RDC No. 751, of 15 September 2022,** although complementary legislation will also be used in this process.

Registration or notification must be requested by means of submission to Anvisa of a petition requesting registration or notification, consisting of documents and information indicated in the Resolution - **RDC No. 751, of September 15, 2022,** and others relevant legislation, thus constituting a documentary process. The The forwarded process is analyzed by Anvisa's technical team, which will deliberate on the granting of the request, being able to request information and additional documents, when necessary. The granting of the registration or notification is made public by means of its publication approval in the Official Gazette of the Union – DOU (registration and notification).

The registration or notification of the product at Anvisa corresponds to a numerical sequence composed of 11 numbers, of which the seven first correspond to the Operating Authorization number of the Company – AFE, and the last four are sequential, following the ascending order of registrations and notifications granted for the same company. In this way, each registration or notification granted is represented by a unique automatically generated numeric sequence and electronically.

The correct interpretation of these resolutions that deal with the Registration or notification is essential for the smooth running of the process at Anvisa. Processes with deficient or incorrect information or incomplete have their analysis time increased due to the preparation of technical requirements by Anvisa, which aim to adaptation of the process to current health legislation.

Structure of the Equipment Registration or Notification Number or SaMD

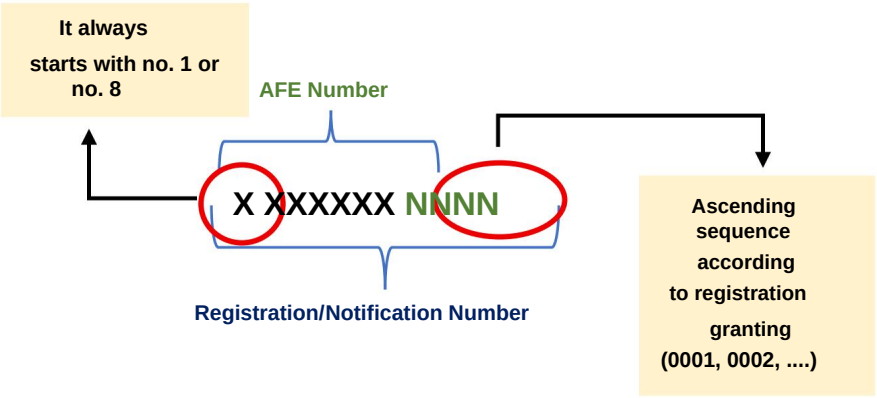


Figure 1 - Formation of the Anvisa Registration/Notification Number for Equipment Doctor or SaMD.

This Manual was prepared with the aim of assisting companies manufacturers or registration/notification holders of medical devices and SaMD, with regard to the interpretation of the provisions of Resolution - RDC No. 751/2022, RDC No. 657/2022, in addition to the legislation related, with the purpose of facilitating the preparation of processes for application for registration or notification of medical equipment and SaMD at Anvisa.

This Manual is structured as follows:

- **Chapter I** – General Information and Flowchart for requesting the Registration/Notification of Medical Equipment and SaMD at Anvisa;
- **Chapter II –** Notification of Medical Equipment and SaMD Classes I and II;
- **Chapter III** – Registration of Medical Equipment and SaMD Classes III and IV;
- **Chapter IV** – Change of Equipment Registration/Notification Doctors and SaMD;
- **Chapter V** – Revalidation of Registration of Medical Equipment and SaMD and other petitions.

ANVISA
Agência Nacional de Vigilância Sanitária

Chapter I

General Information and Flowchart for request of the Equipment Registration/Notification Doctor and SaMD at Anvisa

All procedures for regularizing the equipment doctor and SaMD are guided by the process filed with Anvisa. Understanding how the process is structured and referenced helps in monitoring of its progress within the Agency.

When initiating a process at Anvisa, the company does so through a petition of origin (registration petition – for risk classes III or IV - or notification - for risk classes I or II). When filed with Anvisa this petition receives a file number and gives rise to the process, here called “mother process”; from then on all subsequent petitions (amendment, revalidation, addition, cancellation, etc.), will be attached to their respective parent process.

The parent process is assigned a sequence ID numerical, composed of 11 (eleven) digits, followed by the year of beginning of the process and ending with the check digit; to the number complete is called “process number” (example of number for a process initiated in 2021: 25351.XXXXXX/2021-YY). To the parent process and each petition in the process is associated with a case number, composed of 7 (seven) digits, followed by the last two digits of the year of filing of the parent case or petition and finalized by check digit. The full number is called the “file number” (example of a file number for a petition filed in 2021: XXXXXXX/21-Y). In macro terms, the process is composed essentially by the petition that originated it **(primary petition – n that of process + file number)** and its subsequent petitions **(secondary petitions – n the office one).**

The information contained in the process, considered valid, always corresponds to the content of the last petition approved by Anvisa. Except when there are manifestations to the contrary.

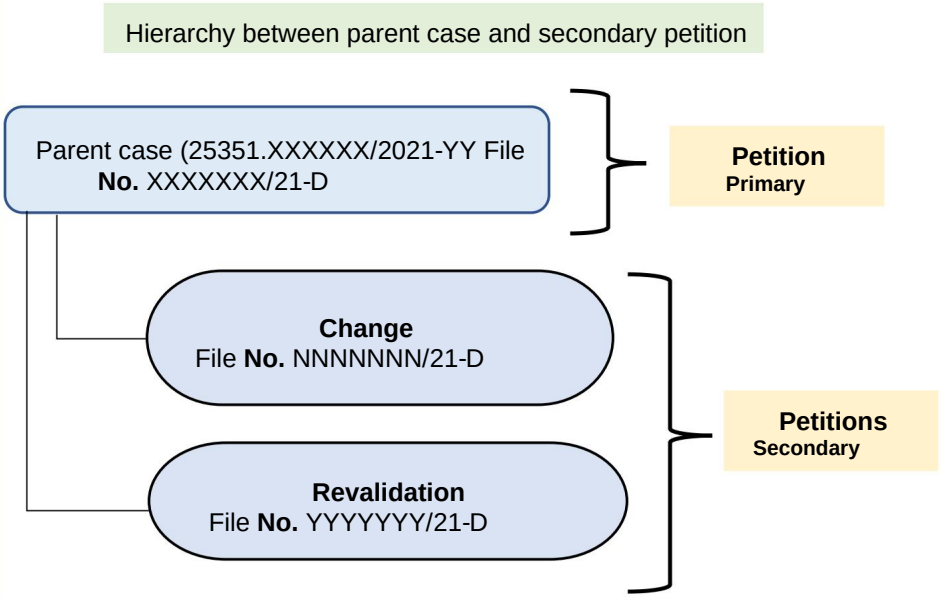


Figure 2 – Model of process initiated in 2021 and its petitions.

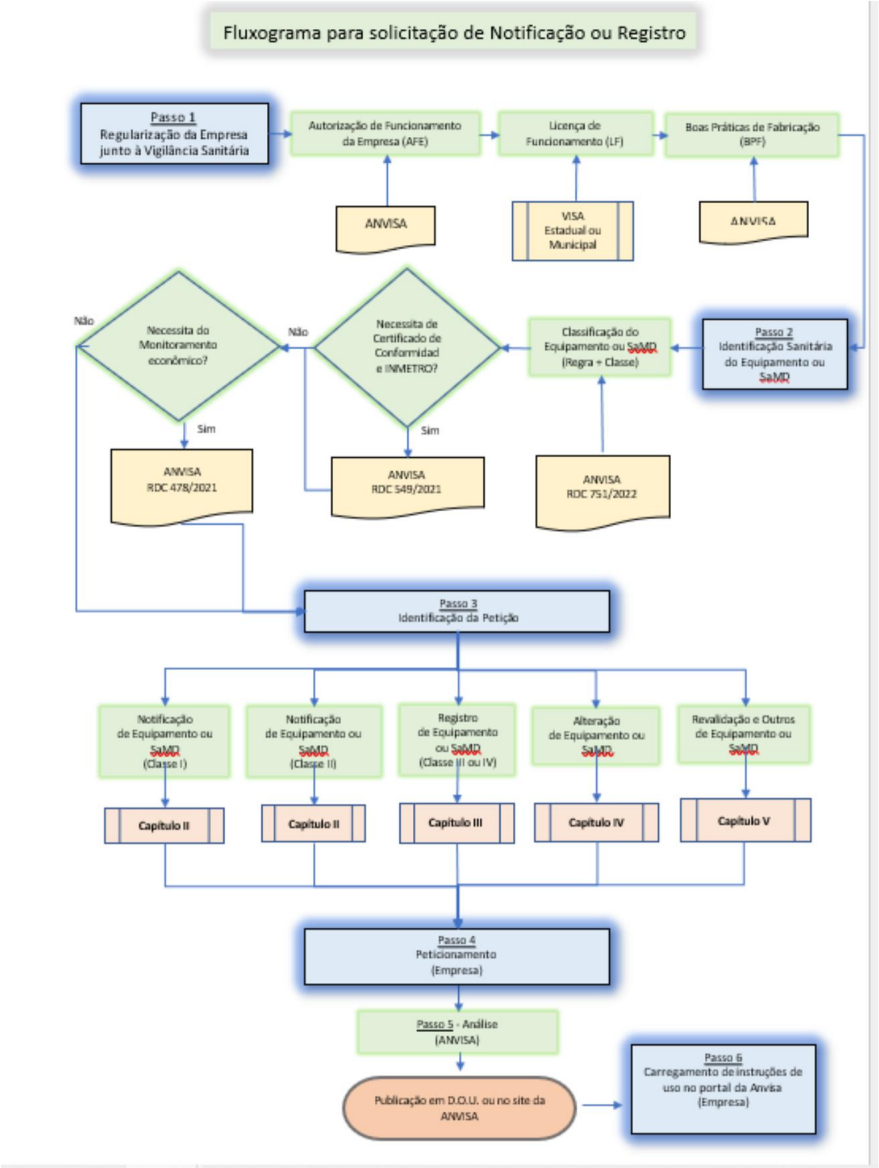


Figure 3 – Flowchart for requesting Notification or Registration.

Before requesting equipment registration or notification doctors or SaMD at Anvisa, the steps indicated in the flowchart presented must be strictly observed. The steps that precede the petition protocol need to be carefully evaluated, checking all documents and information that need to be obtained, which will make up the petition for the process. If Otherwise, during the analysis of the same by Anvisa, the process may enter into a technical requirement, which is a request for clarification on the documentation and information presented. In addition, it must be observed that the insufficiency of required technical documentation, when of the petition protocol, gives rise to its summary rejection, not subject to technical requirements, as per the sole paragraph of item II of § 2 of art. 2 of Anvisa Resolution - **RDC No. 204, of July 6, 2005,** and § 4 of art. 10 of Anvisa Resolution **– RDC No. 751, of September 15 2022.**

Below, you will find details of each step to be followed. A list of all referenced legislation is presented. in Appendix D of this Manual. You can also find all the legislation related to Medical Devices (Health Products) on the Anvisa portal, www.anvisa.gov.br ,in Legislation > Libraries Themes > Health Products.

Step 1

Company regularization with the Health Surveillance Agency: AFE, LF and BPF

The starting point for requesting registration or notification of medical equipment and SaMD at Anvisa is the regularization of the company with the Health Surveillance Agency, which includes obtaining the Company Operating Authorization (AFE) with Anvisa and Operating License (LF) from the Municipal Health Surveillance or the State, also known as Operating License (AF).

Without these authorizations, the protocol of the registration or notification petition it is not possible.

- **Company Operating Authorization – AFE**

The AFE is issued by Anvisa upon formal request from company, which must file an AFE request through a process based on the provisions of RESOLUTION - **RDC No. 16, of April 1, 2014.** Only companies legally constituted in the territory Brazilians can request such Authorization from Anvisa.

In this way, a foreign company that is interested in to market your products in the Brazilian market, you must have a commercial agreement with a company in Brazil. Not necessarily, this company must be a branch of the foreign company, being possible that the Brazilian company is just a **holder of the registration/notification,** which **will assume the technical and legal responsibility of the foreign company in Brazilian territory.**

It is worth noting that the AFE is granted per activity, per example: import, manufacturing, transportation, storage, distribution, etc.

• **Operating License - LF**

The LF is issued by the Health Surveillance agency, municipal or state, also known as local VISA, in which the company Brazilian (national manufacturer or holder of registration/notification) is headquartered. Issuing the license at the municipal or state level will depend on the level of decentralization of health surveillance actions of each Brazilian state and municipality. For more information about the To obtain the LF, the local VISA must be consulted. On the Anvisa Portal The addresses and telephone numbers of these VISAs can be obtained.

State and municipal VISAs are linked entities directly to the Health Departments of their respective states and municipalities, **there being no** hierarchical situation **between the Anvisa and these VISAs.** These are independent of each other, working jointly as members of the National Surveillance System Sanitary – SNVS – in order to promote and guarantee the safety of health of the Brazilian population.

In some situations, LF and AFE requests may occur concurrently, since one of the documents that The AFE request petition includes the inspection report of establishment, carried out by the local VISA, which also serves for the obtaining the Operating License.

• **Good Manufacturing Practices - GMP**

Meet Good Manufacturing Practice requirements, established in Resolutions **–RDC No. 665, of March 30, 2022** and **RDC No. 687, of May 13, 2022,** is the obligation of every company that intends to manufacture or import medical devices to be offered to the Brazilian market, as established by **Law No. 6,360 of 23 September 1976.**

Proof of compliance with GMP is verified through *on-site* health inspection and is a requirement for obtaining the Certificate Good Manufacturing Practices - CBPF issued by Anvisa. In national territory, the inspection is carried out by the local VISA and can count with the participation of technical experts from Anvisa. In companies located outside Brazil, the inspection is carried out directly by Anvisa or by recognized auditing bodies (RDC No. 497, of May 20 2021). The request for said certification must be filed with the ANVISA, through the respective subject code and will be analyzed by ANVISA Management responsible for Inspection and Certification of companies.

Compliance with the legal provisions of Resolution - RDC No. 665, of March 30, 2022 **is MANDATORY for ALL companies of the medical devices sector,** as established by Decree No. 8,077, of August 14, 2013. If proven, through a health inspection, failure to comply with these provisions, company will be subject to applicable administrative sanctions, without prejudice of legal actions and criminal sanctions, depending on the severity of the case.

For the presentation of the CBPF when requesting the registration of the equipment or SaMD with Anvisa, RDC No. 665, of March 30, 2022 and RDC No. 687, of May 13, 2022 must be observed, which establish the mandatory certification of companies manufacturers (national or foreign) of products of risk classes III and IV. Companies manufacturing products that are classified exclusively in risk classes I and II, that is, they do not manufacture products classified in risk classes III and IV, although manufacturers of medical devices exempt from presentation of the CBPF in notification process, are **not** exempt from complying with the requirements established in RDC No. 665, of March 30, 2022.

Step 2

Sanitary Equipment Identification or SaMD

Health identification of medical equipment or SaMD corresponds to its identification and classification, according to criteria adopted by Anvisa. At this point, it should also be verified whether the equipment or SaMD requires certifications and reports complementary to obtain registration or notification.

- **Equipment Classification (Class + Rule)**

This is the step that will lead to the assembly of the process. correctly, since the required documentation and information vary according to the type and classification of the equipment.

Medical equipment is classified into four classes of risk, according to the risk associated with their use:

- o Class I – low risk;
- o Class II – medium risk;
- o Class III – high risk; and
- o Class IV – maximum risk.

In addition to the risk classification, there is the framework by rules, which total twenty-two. The framework of the rule follows the indication and purpose of use of the equipment. In short, the classification by rule follows the following criteria:

- ÿ Non-invasive devices: Rules 1, 2, 3 and 4;
- ÿ Invasive devices: Rules 5, 6, 7 and 8;
- ÿ Active devices: Rules 9, 10, 11, 12, 13; and
- ÿ Special Rules: Rules 14, 15, 16, 17, 18, 19, 20, 21 and 22.

The item “Device Risk Classification Rules Doctors” of Annex I of the Technical Regulation approved by Resolution Anvisa Resolution - RDC No. 751/22, contains the description of all classification rules.

For better understanding, a classification guide of medical equipment is available in Annex C of this Manual.

- **INMETRO Certificate of Conformity**

Some medical equipment needs to present the Inmetro Certificate of Conformity, when requesting the regularization with Anvisa. These devices meet the criteria indicated in **Normative Instruction No. 283 of 07 March 2024,** or any other that may replace it. The legislation The specific resolution that deals with Certification is **Resolution - RDC No. 549, of 30 August 2021.**

To certify the conformity of this equipment, they must Product Certification Bodies – OCP should be contacted, accredited by Inmetro. For more information, visit: www.inmetro.gov.br.

- **Economic Monitoring**

Some medical equipment is subject to presentation of technical attribute information for each medical device model subject to economic monitoring, through a specific petition to the economic regulation area of Anvisa.

The need to present this information is described in **RDC No. 478, of March 12, 2021.**

Normative Instruction No. 84 is currently in force. March 12, 2021, which provides for the list of medical devices selected for economic monitoring by Anvisa.

Step 3

Petition Identification

When identifying the type of petition, some points must be taken into account: evaluated, taking as a basis the sanitary identification of equipment carried out previously. With this information in hand, the following must be verified:

a) whether the product in question is subject to registration or notification at Anvisa;

b) if, if there is more than one model, there is a possibility of registration by equipment family, in accordance with the **Resolution - RDC No. 542, of August 30, 2021;**

c) which accessories can be included in the registration or equipment notification; and

d) if the product is already registered or notified, what other petition is desired (change, cancellation, revalidation, transfer of ownership, amendment or rectification of publication).

- **Registration or notification?**

There are four types of medical equipment and SaMD regularization with Anvisa: risk class IV registration, risk class III, risk class II notification and class notification of risk I. Notification is a simplified regularization procedure, applicable only to products belonging to Risk Classes I and II. The procedures for notifying equipment doctors and SaMD are defined in Resolution RDC No. 751/2022. The medical equipment and SaMD subject to registration are those classified in risk classes III and IV, by Resolution RDC No. 751/2022.

• **Single Equipment or Family of Equipment?**

The process may refer to equipment or SaMD unique (only one model in the process) or to a family of equipment or SaMD (several models in the same process). To be considered a family or group of equipment or SaMD, as specifies **Resolution - RDC No. 542, of August 30, 2021,** all the models in the family must be manufactured by the same manufacturer and have the following similar characteristics:

ÿ Technology, including the fundamentals of its operation and its action, its content or composition and its performance, as well as the accessories that make it up;

ÿ Indication, purpose or use for which the products are intended, according to indicated by the manufacturer; and

ÿ Precautions, restrictions, warnings, special care and instructions on storage and transportation of products.

There is no limit to the inclusion of models in the family of equipment or SaMD, as long as they all meet the requirements indicated above. The fee for registering a family of equipment or SaMD is higher than that for registering a single equipment or SaMD. The fee for equipment family notification or SaMD is the same for equipment notification or single SaMD.

It is possible for the company to start a family registration process with a single product, in cases where there is interest in, at throughout the validity of the registration, if it includes other models in the family in question. In this case, a family tax must be filed and collected. equipment or SaMD at the time of requesting said registration, or that is, from the beginning.

However, a process for which a petition has been filed and collected single product registration fee may not, subsequently, its publication, be changed to family registration, even if the company is willing to supplement the fee later. In this In this case, the company must file a new application for family registration. equipment or SaMD, where registration documentation must be included of all models, including the previously registered model.

Remembering that, there is still the issue regarding the registration of Equipment System, where it should be used in cases that deal with of a set of equipment designed to be used in a associated, where the lack of at least one member of the system makes the whole system down.

- **Items that may be included in the Registration/Notification of equipment or SaMD**

Some medical products may be included in the registry or notification of the medical equipment or SaMD for which it is intended. The conditions for inclusion are described below, according to their nature and situation:

a) Piece of medical equipment:

The parts of a medical device include the elements that physically make up the device. They are characterized technically by its functional individuality.

In general, the parts are considered raw materials of the production process of medical equipment, examples of parts are: mains connection cable, power supplies, control board video, electronic components, cabinets, screws, wires, among others.

In isolation, the parts are not considered devices. doctors, not being subject to registration or notification in the Anvisa.

b) Medical equipment accessory:

According to RDC nº 751/2022, accessory is defined as: product intended by its manufacturer to be used in conjunction with one or several specific medical devices, to enable or assist in a specific and direct that the medical device(s) be used in a according to the intended purpose.

Medical equipment accessories consist of a or more pieces or parts, and are manufactured exclusively to make part of medical equipment. They are essential parts for this perform their intended function. They can be produced by the same equipment manufacturer or purchased ready-made from companies outsourced.

When regularizing or making changes involving accessories, it is important to send tests that prove the compatibility of the accessories with the minimum equipment or characteristics that must have the equipment you want to connect. Example: cable ECG, temperature sensor.

In isolation, they are considered finished medical devices, although they are characterized by having medical functionality only through the connection to the medical equipment for which it is intended. For example, an ultrasound transducer for therapy is considered an accessory of the equipment, being only functional when connected to the equipment ultrasound for which it was designed.

In specific cases, accessories must be regularized separately with Anvisa. For example: sensors for oximetry pulse sold directly to the health service, except when treat the original equipment sensor provided by the manufacturer of the oximetry monitor.

The medical equipment accessory is contained in the equipment registration or notification when it is an active medical product, intended to connect to another active medical product (e.g. transducer ultrasound, electrosurgical unit electrode, pulse oximetry sensor wrist, multiparameter monitor modules). If this accessory is compatible with multiple devices from the same manufacturer must be

indicated in each registration process, or notification of compatible equipment. **However, for the accessory to be included in the registration or equipment notification cannot have a risk classification superior to that of the equipment for which it is intended and must be, must be supplied to the end user by the manufacturer of this equipment,** with exclusive use clearly identified on the label on the primary packaging of the accessory. **If the accessory, although active, does not fit into these situations, it should have separate registration.**

The medical equipment accessory must be registered or own notification to ANVISA when:

ÿ It is marketed by third parties other than the manufacturer of the medical equipment for which it is intended;

ÿ It is not an active medical product, although intended for connection or use with an active medical product, and in addition, is subject to registration/notification in another area of Anvisa (medical materials, products for *in-vitro* diagnostic use , sanitizing products, cosmetics, medicines, etc.); or

ÿ Has a higher risk rating than medical equipment for which it is intended.

c) Generic medical equipment accessory:

The generic medical equipment accessory or SaMD is the product that provides a complementary feature to the equipment or SaMD, not being essential for it to perform its function intended (e.g., material support tray, rod for supporting materials) serum, carts for packaging and transporting equipment, mechanisms for fixing to ambulances, etc.).

These can be included in the equipment registration or SaMD as long as they are produced exclusively to integrate the medical equipment or SaMD, subject of the registration application or notification.

ALERT:

Excludes **“conferring a complementary characteristic”**

- **Amendment, Revalidation, Addition, Cancellation, Transfer of Ownership or Rectification of Publication – When to apply?**

Change - whenever there is any modification of information presented to Anvisa in the notification process or registration of the medical device and its respective secondary petitions. It can be petitioned at any time during the period of validity of the registration or notification.

Revalidation - whenever the company is interested in revalidating the registration of the product for another 10 years, must request such revalidation within a period of one year to six months before the expiration of the registration. **No modifications to the process or product are accepted within a revalidation petition.** Any desired change must be petitioned separately. Class I and II risk products, subject to notification regime, are valid for an indefinite period and do not require revalidation according to Resolution RDC No. 751/2022. It is
It is important to maintain the certificate of conformity issued by Inmetro valid, thus complying with Resolution - RDC No. 549/2021, regardless the product's risk class.

Addendum - for sending any document or communication that the company wishes to attach to the parent case (petition primary) or secondary petitions. This petition being analyzed in together with the document to which it refers. It has only one character informative or complementary.

Cancellation - in the event that you wish to cancel the registration or notification, and the reason for cancellation must be informed.

Transfer of ownership - only in cases where resulting from corporate operations or commercial transactions, provided that the original technical requirements of the already registered equipment remain unchanged. The terms and conditions necessary for the transfer of ownership due to the change in ownership of the company are:
if in Resolution - RDC No. 903, of September 6, 2024.

Correction of publication - whenever the company observes discrepancies between the information presented in the documentation request for registration or notification and those published in DOU (e.g.: commercial name of the equipment, company name of the manufacturer, models, product origin, etc.). Exception is made with regard to health framework (rule and class) and the technical name of the equipment or SaMD, because in cases where the company informs these data erroneously, Anvisa corrects them without it being necessary issue technical requirements to the company.

Detailed information on the content of the documents and information required for each of the petitions must be checked in the specific chapters of this Manual:

- Chapter II – Notification of Medical Equipment and SaMD Classes I and II;
- Chapter III – Registration of Medical Equipment and SaMD Classes III and IV;
- Chapter IV – Change of Registration or notification of Medical Equipment and SaMD;
- Chapter V – Revalidation of Registration and other petitions.

Step 4

Electronic Petitioning (Request)

Electronic petitioning is the action that effectively initiates the request for registration or notification of a product with Anvisa. Always that you wish to include a supplementary petition (amendment, cancellation, revalidation, transfer of ownership, amendment or publication rectification) to an existing process, electronic petitioning must also be carried out, always informing the number of the parent process.

To make an electronic petition, you must access the ANVISA's website and fill in the requested information. However, the company must first register with Anvisa's electronic system.

To fill in the information requested in the petition electronically, it is necessary for the company to have previously classified its product and identified the type of petition that want to carry out (registration, notification, change, revalidation, cancellation or addition; and if it corresponds to the product family, system or single product).

- Electronic access page for petitioning and registering companies at:

https://www.gov.br/anvisa/pt-br/sistemas

- "Step-by-step" information guides for each of these procedures are available on the indicated website.

- To identify the Generating Factor of the petition, check the indicated list on the website:

https://www.gov.br/anvisa/pt-br/sistemas/assuntos-de-peticao

- Choose "Health Products (related)"

Step 5

Petition Protocol

The delivery of documentation must be carried out in accordance with the current procedure, which is established by the Management of ANVISA documentation. From the effective date of **RDC No. 947 of 12 December 2024,** the protocol of documents at Anvisa must occur exclusively electronically, through the systems electronic petitioning made available for protocol documents, except in cases specified in the standard. Larger information on petitioning procedures is available on Anvisa's website.

It is essential that the petition documentation, when filed, is duly signed by its applicants, who must be the Legal Representative and the Technical Manager of the company, as determined by art. 6 of Law No. 9,784, of January 29, 1999. According to Resolution RDC No. 751/2022, both the petition form Registration or Notification, such as the Declaration of Change of Registration or

notification, such signatures must be included.

The applicant must submit signed documents digitally by legal and technical managers, as required in applicable regulations or when indicated in the list of procedural instruction documents. In digitized documents, the qualified electronic signature, which uses a digital certificate issued by ICP-Brasil, must be used. In native-digital documents, it must qualified electronic signature may be used, which employs a digital certificate issued by ICP-Brasil, or an advanced electronic signature, example from gov.br https://www.gov.br/governodigital/pt-br/assinatura-eletronica . It is recommended that the applicant confirm the validation of the signatures of the Legal and Technical Representatives through the link https://validar.iti.gov.br/ .

The filed petition receives its own number, composed of 11 (eleven) numbers, accompanied by the year of protocol of the petition and ending with the check digit; the complete number is called the **protocol number** (example of protocol number for a petition filed in 2021: 25352.XXXXXX/2021-YY), which will be converted into

- the process number + file number (mother process or primary petition) or the
- file number (secondary petition). The company will monitor the case using the protocol number, the process number or the
- the office hours, on the website: https://consultas.anvisa.gov.br/#/

You must be careful, as **the protocol number does not match to the process number or file number,** as the latter two are generated only after the inclusion of the petition in the computerized system of Anvisa.

It is suggested that the consultation be made the day after the protocol. **When the company wishes to obtain any information about the process or a specific petition, it must always reference the process number or file number.**

- Resolution - RDC No. 857 of May 6, 2024 and its amendments later define the tax values.

- Calculation basis for the fee:
ÿ Nature of the petition (registration, notification, revalidation or amendment);
ÿ Petition for product family or single product;
ÿ Product size (small, medium or large); and
ÿ Company size (micro, small, medium or large).

- Regarding the guidelines on the collection of the fee, it must be consulted the ANVISA website

- It is possible to monitor the process or petition through the ANVISA website.

- The protocol (Issuance and Monitoring) can be obtained on the page ANVISA electronics:

https://consultas.anvisa.gov.br/#/documentos/administrativo/

Analysis of the process by Anvisa

The analysis of the process will be carried out by the Management of Medical Equipment Technology – GQUIP. The analysis verifies if the documents submitted in the application for registration or notification comply with current health legislation. The result of this analysis is published in the DOU, in its Section 1 through Resolution-RE, with the favorable or unfavorable opinion on the granting of registration or equipment notification or SaMD, depending on the quality of the documents presented and compliance with any request for further clarification.

If non-compliance with current legislation is found, there is two actions to be taken:

a) **REJECTION -** due to lack of one or more mandatory technical documents1 , as per the sole paragraph of item II of § 2 of art. 2 of the Anvisa Resolution - **RDC No. 204, of July 6, 2005,** and § 4 of art. 10 of Anvisa Resolution **– RDC No. 751, of September 15, 2022;** or

b) **TECHNICAL REQUIREMENT –** for presenting incomplete or erroneous information. In this case, a TECHNICAL REQUIREMENT is issued for the company, in which clarifications, corrections are requested, verification or supplementation of information or documents complementary. The deadline for compliance with the requirement will be 120 (one hundred and twenty) days, non-extendable, counted from the date of the confirmation of receipt of the requirement, according to **RDC No. 23, of 5 June 2015.**

The Technical Requirement generated has an electronic format and is available for company consultation on the Anvisa website at: https://www.gov.br/anvisa/pt-br/sistemas

Companies are responsible for verifying with to Anvisa's electronic address, in the Company's mailbox, regarding the existence of requirements relating to their petitions under analysis. After accessing the process requirement on the website of Anvisa, the company has a period of 120 days (consecutive) to present **full compliance** with the technical requirements generated, and may also during this period, challenge, with a well-founded technical basis, the requirement generated.

One option is to send the inquiry regarding the requirement via Contact Us indicating the process number and office hours, the query will be forwarded to the responsible technician.

Compliance with Requirement must be filed, in digital form, according to a specific procedure, on the website of ANVISA, including the respective documentation and information requested in the electronic request. Once filed, this compliance will be forwarded electronically to GQUIP.

1 Mandatory technical document corresponds to all documents required when filing the petition with Anvisa as stipulated in current health legislation

Compliance with Requirement must be accompanied by company statement, signed by the technical and legal managers, stating exactly what information was inserted or changed in the documents to meet the requirements set out, as well as the indication of the location of this information.

If the information presented in this Compliance are unsatisfactory, the petition will be rejected, and no new ones will be accepted. demands to reiterate what has already been requested and not met. Only in situations where new clarifications and information are necessary, another Technical Requirement may be drawn up.

If compliance with the requirement presented is satisfactory, the granting of the petition, granting the registration of the equipment or SaMD, is forwarded for publication in the Official Gazette.

There will be no issuance of technical requirements for petitions notification, change of notification, and change of registration (immediate implementation), without prejudice to the implementation, at any time, of documentary or fiscal assessments on notification processes and registration and its changes, and, if necessary, the request for additional information or clarification.

The flowchart below illustrates the petition trajectory from its filing to publication in the Official Gazette.

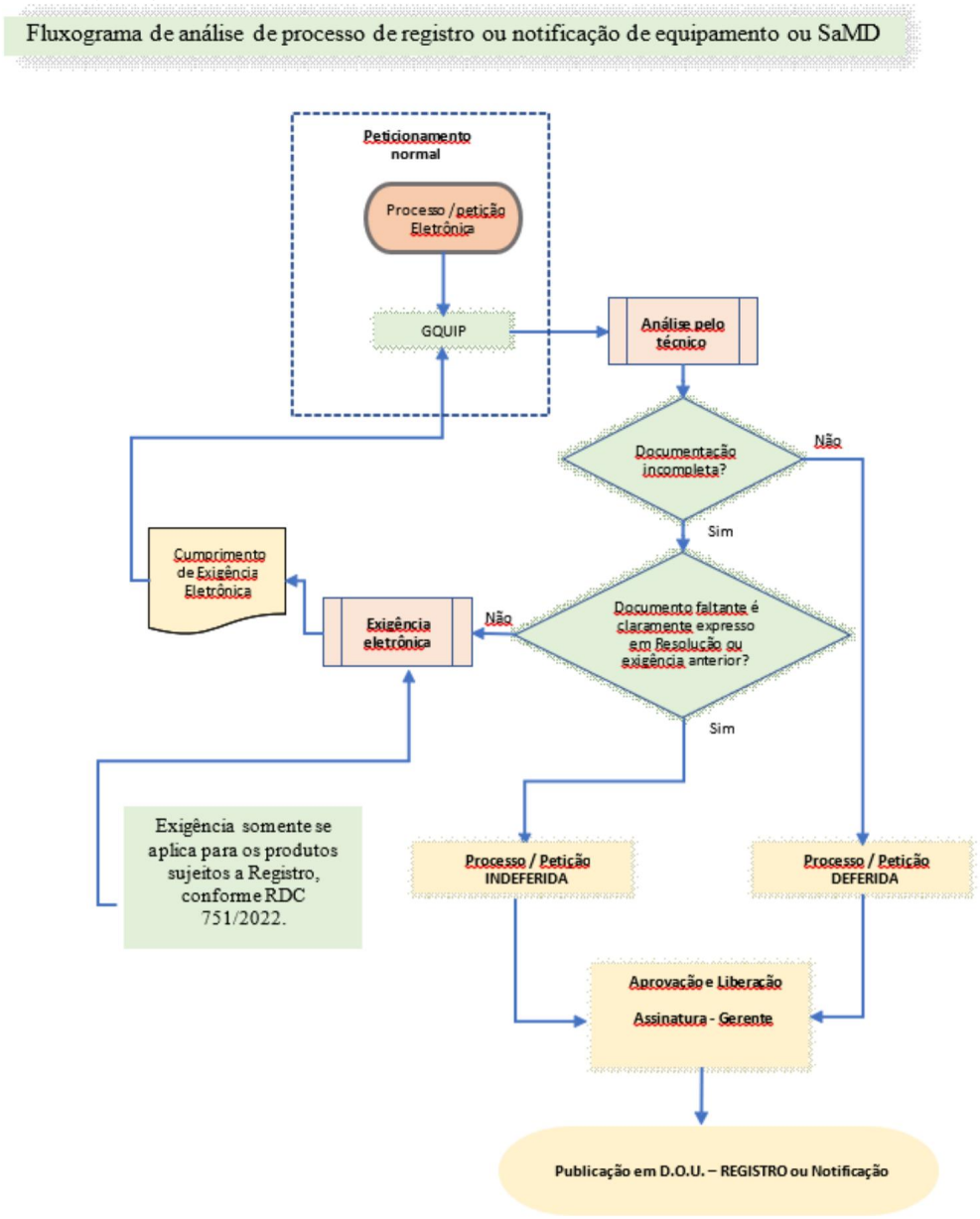


Figure 4 - Petition analysis flow.

Observations:

1) The Response to the Requirement may be: full compliance with the requirement and/or contestation of the requirement formulated;

2) The mandatory technical documents correspond to those indicated in this Manual (instructions for use, technical dossier, forms, labeling models, certificates, declarations, etc.)

After publication in the Official Gazette of the granting of the petition, the equipment will be authorized to be sold throughout the territory national. To prove registration with Anvisa, the company may use the copy of the DOU with the approval or, according to the **Resolution - RDC No. 545, of August 30, 2021,** issue electronically submit the Registration/Notification Certificate for your product to Anvisa. To obtain this certificate, the company must follow the guidelines of Art. 7, access, on the ANVISA website, the electronic petitioning and select the petition modality electronically, there is no need to send the documentation in paper. However, **the application for the Certificate of Registration/Notification is completely voluntary,** and the company can prove the registration of its product only with publication in DOU, both having the same value legal.

- If the petition is rejected, the company still has the “Administrative Appeal” petition available, which must be filed within a maximum period of 30 calendar days, counting from the date of publication of the rejection in **the Official Gazette (DOU), according to Collegiate Board Resolution No. 266, of February 8, 2019.**

- The request for an Administrative Appeal must include a justification, prepared by the company, defending the granting of the petition and an Administrative Appeal Cover Sheet, the template for which is available at:

https://consultas.anvisa.gov.br/#/

ANVISA
Agência Nacional de Vigilância Sanitária

Chapter II

Medical Equipment Notification and SaMD Risk Classes I and II

Medical Equipment Notification
RESOLUTION - RDC No. 751, of SEPTEMBER 15, 2022

The notification of medical equipment is governed by the **Resolution - RDC No. 751, of September 15, 2022,** which establishes the scope and form of application of the notification regime for the sanitary control of medical devices. This Resolution applies to the products indicated in § 1 of Art. 25 of Law No. 6360/76, which although exempt from registration, they are subject to the Surveillance regime Sanitary, and classified in risk classes I and II.

This Resolution establishes that to request notification The documentation described in Art. 13 must be sent to Anvisa of Resolution – RDC No. 751/2022. They are:

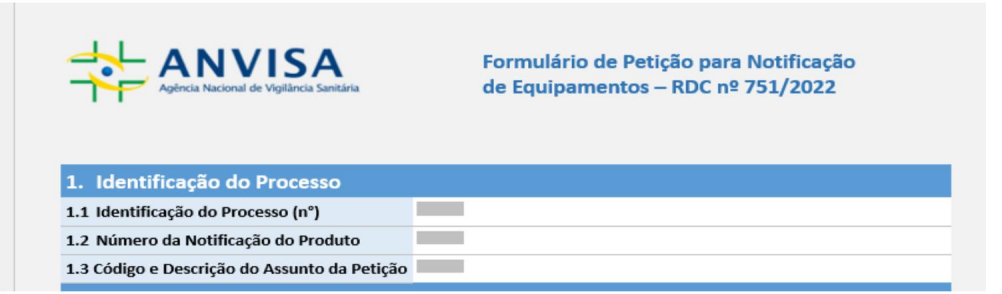
1) Form for notification of medical device, duly completed, available on the ANVISA electronic portal;
2) For imported medical devices: declaration issued by the legal manufacturer, consularized or apostilled, written in Portuguese, English or Spanish or accompanied by translation sworn, for a maximum of two years when there is no express validity indicated in the document, authorizing the company requesting to represent and market its(their) product(s) in Brazil;
3) Copy of the Certificate of Conformity issued under the Brazilian Conformity Assessment System (SBAC), applicable only to certified medical devices compulsory, related by Anvisa in regulations specific; and
4) Proof of compliance with legal provisions determined in technical regulations, in accordance with legislation which regulates specific medical devices.

The statement referred to in item 2 must contain the company name and full address of the legal manufacturer and the requesting company, express authorization for the requesting company to represent and market their products in Brazil, and the statement about the knowledge and compliance with Good Practice requirements Manufacture of Health Products established in the **Resolution of Collegiate Board - RDC No. 665, of March 30, 2022,** or regulation that replaces it.

The notification of a product has indefinite validity, that is, does not need to be renewed, however some conditions must be met complied with so that the notification remains in force. The maintenance of the notification is linked to compliance with the requirements of Good Manufacturing Practices, applicable technical standards and specific regulations, where applicable. Products subject to certification of compliance within the scope of the SBAC may only be imported and sold with a valid Certificate of Conformity, respecting the product's manufacturing date.

Equipment that has had its classification changed from notification from risk class II to notification from risk class I or vice-versa versa, they will maintain their initial risk class I notification numbers or previously published risk class II notification.

1. Process Identification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Formulário de Petição para Notificação de Equipamentos – RDC nº 751/2022

1. Identificação do Processo	
1.1 Identificação do Processo (n°)	
1.2 Número da Notificação do Produto	
1.3 Código e Descrição do Assunto da Petição	

In this initial field, the information of the process, if the company does not yet have this information If this is a primary petition, you must leave these fields blank.

The Petition Subject Code and Petition Description fields Petition Subject must be completed for all petitions, whether primary or secondary. The subject code and its description must be obtained from the Subject List, available on the Anvisa website.

https://consultas.anvisa.gov.br/#/consultadeassuntos/

2. Data of the Notification Holder (National Manufacturer) or Importer)

2. Dados do Detentor da Notificação (Fabricante Nacional ou Importador)	
2.1 Razão Social	
2.2 Nome Fantasia	
2.3 CNPJ	
2.4 Endereço	
2.5 Cidade/UF	
2.6 CEP	
2.7 Telefone (com código de área)	
2.8 E-mail	
2.9 Sítio Eletrônico (URL)	
2.10 Autorização de Funcionamento na Anvisa (nº)	

The information presented in this item must always correspond to the registration information **of the company requesting the notification,** which are constant in the publication of your AFE – Company Operating Authorization - issued by Anvisa.

In the event that any change to the AFE (address, technical manager, legal representative, etc.) has been requested, but has not yet been assessed by Anvisa, a document proving this must be presented. the change **APPROVED by the Local Health Surveillance** (e.g. publication of the State/Municipal Official Gazette or copy of the new license issued).

Also, a copy of the protocol for the change of
AFE requested from Anvisa. The change protocol will not be accepted.
of the operating license with the Health Surveillance – VISA – local.

> NOTE: Local VISA corresponds to the health surveillance of municipalities and states. The operating license may be issued by municipal or state VISA, depending on the state/municipality where the company is located, and also the level of decentralization of the health surveillance activities of this State (see Chapter I).

The telephone and email fields MUST **ALWAYS** match the
of the company requesting registration and **NEVER** of the company providing
consultancy or technical advice in the area of device regulation
doctors. **The requirements and contacts, when made by Anvisa, will be always with the company holding the notification, responsible for the product, and not with third parties.**

3. Origin of the Medical Device

3. Origem do Dispositivo Médico	
☐ Brasil	
☐ Externa	
ATENÇÃO: se houver mais de um fabricante legal, estes devem ser do mesmo grupo fabril e a empresa deverá apresentar documento comprobatório.	
3.1 Identificação do Fabricante Legal (pessoa jurídica, pública ou privada, com responsabilidade pelo projeto, manufatura, embalagem e rotulagem de um produto, com a intenção de disponibilizá-lo para uso sob seu nome, sendo estas operações realizadas pela própria empresa ou por terceiros em seu nome):	
1. Nome:	
Endereço – Cidade e País:	
Número da AFE (somente para fabricante nacional)	
2. Nome:	
Endereço – Cidade e País:	
Número da AFE (somente para fabricante nacional)	

This item provides information about the origin of the equipment and your place of manufacture. Correct information of this data is extremely important importance, especially for imported products, as they are given essential to facilitate customs clearance of the equipment. **It is not allowed entry into the country of products whose origin is countries, manufacturers other than those declared in this field of the form.**

It is possible for equipment to be manufactured by companies different, as long as they belong to the same business group. To In this case, a document must be presented proving that such companies are members of the same business group.

This item must be informed:

- **Origin of the product: internal (Brazil) or external?**

  This field refers to the product's manufacturing location: Brazil - national product; External - imported product.

- **3.1 Legal Manufacturer Identification**

  In this field you must enter the name of the manufacturer of the product, in Brazil (national product) or abroad (imported product).

  The manufacturer declared in this field must correspond to the manufacturer informed in ALL other process documents (label, indelible label, instructions for use, technical dossier, etc.).

  For **imported medical equipment,** in cases of outsourcing, partial or total, of production, in the field of manufacturer must only the name of the sole company responsible for the product must be included abroad (legal manufacturer), formally recognized by the authority health of their country of origin. Outsourced companies must not be indicated in this field.

  For **domestically manufactured medical equipment,** the same procedure applies.

  The country of manufacture of the product must be the country where its legal manufacturer is based, regardless of some steps productive activities to be carried out in other countries.

3.2 Identificação da(s) Unidade(s) Fabril(is) (local onde ocorre uma ou mais etapas de fabricação, podendo ser o próprio fabricante legal, fabricante contratado ou fabricante original de produto):
Obs: unidade fabril baseado pela RDC nº 687/2022

1. Nome:	
Endereço – Cidade e País:	
Número da AFE (somente para fabricante nacional)	
2. Nome:	
Endereço – Cidade e País:	
Número da AFE (somente para fabricante nacional)	
3. Nome:	
Endereço – Cidade e País:	
Número da AFE (somente para fabricante nacional)	

- **3.2 Identification of Manufacturing Unit(s)**

List the manufacturing unit or units that perform the steps production of the equipment, their addresses and countries of location.

Only manufacturing units based on the RDC No. 687/2022.

4. Medical Device Data

4.1 Medical Device Identification

4. Dados do Dispositivo Médico	
4.1 Identificação do Dispositivo Médico	
4.1.1 Nome Técnico	
4.1.2 Código do Nome Técnico	
Consulta de nomes técnicos disponível em: https://consultas.anvisa.gov.br/#/nomes-tecnicos/	
4.1.3 Regra de Classificação	
4.1.4 Classe de Risco do Dispositivo Médico	☐ Classe I ☐ Classe II
4.1.5 Nome Comercial	
4.1.6 Modelo(s) Comercial (is) da Família / Componentes do Sistema	
4.1.6.1 Para Família: Informar os códigos referentes aos modelos comerciais, quando aplicável. 4.1.6.2 Para Sistema: Informar códigos referentes ao sistema bem como de seus componentes, quando aplicável.	
4.1.7 Acessórios (produto destinado pelo seu fabricante a ser utilizado em conjunto com um ou vários dispositivos médicos específicos, para permitir ou ajudar de forma específica e direta que o(s) dispositivo(s) médico(s) sejam usados de acordo com a finalidade pretendida).	
4.1.8 Formas de apresentação comercial do produto (descrever quantitativamente os itens que acompanham o equipamento).	

• 4.1.1 – Technical Name

The technical name is the name commonly used in the “medical field” to identify the equipment. Do not confuse the technical name with the name product's commercial name. The list of technical names, called the “table of coding of medical products”, is available for consultation, on the Anvisa website at: https://consultas.anvisa.gov.br/#/nomes-tecnicos/

It may happen that the technical name of the equipment, which the company you wish to register or notify, does not exist on the aforementioned list. In this case, the company must use the technical name that most closely resembles its equipment. When the process reaches the technical area at Anvisa, it will be Verify that there is no corresponding technical name. If not, the technical department will create one. It is Anvisa's prerogative to create and define the technical name that will be applied to the product.

For secondary petitions, the name must always be observed. technician informed in the primary petition.

• **4.1.2 - Technical Name Identification Code**

The identification code is the code corresponding to the name technician indicated in the "medical product coding table" list, already mentioned.

• **4.1.3 - Classification Rule and 4.1.4 - Risk Class**

Equipment must be classified according to its rule and class, as per the provisions of Annex I of Resolution - RDC No. 751/2022. Annex C of this Manual contains a guide to classification of medical equipment.

It is Anvisa's prerogative to determine whether the class and rule granted by the company to its product, are correct.

In the case of notification of medical equipment, the class of risk will always be Class I or II.

• **4.1.5 – Commercial Name**

This is the name by which the company requesting the notification wishes its equipment to be known and sold in the Brazilian market. It does not necessarily need to have the technical name.

incorporated into this identification, although the company, in many cases, choose to incorporate it to make it easier to identify your equipment by users.

• **4.1.6 - Business Model(s)/System Components**

The commercial model corresponds to the versions or variations of the equipment that you wish to notify. Applicable in cases of equipment family notification, where for the **SAME NAME COMMERCIAL there is more than one MODEL (variation of the same equipment),** with its own identification that differentiates it from the others family models (e.g. A, B, AB, FULL, etc.). The indication of equipment family classification must comply with the requirements established in Resolution - RDC No. 542, of August 30, 2021.

Single product notifications must also indicate the product model. For example:

ÿ Commercial name of the Product: **YYYYYYYYY Equipment**

ÿ Product Commercial Model: **X1**

The choice of name and commercial model of equipment is free to the company requesting the notification. However, Anvisa may interfere in the choice of the name and/or commercial model of the product, in cases where they may lead to misinterpretation on the part of users, according to art. 5 of Law nº 6.360/1976.

System components are the individual parts that makes up the system, generally identified by names or codes that identify each part (e.g., Straight Tip, Curved Tip, Connection Cable, Handle, Double External Connector, Single External Connector).

- **4.1.7 Accessories that accompany/are part of the equipment**

If the equipment has accompanying accessories, these must be listed in item 4.1.7 of the notification form. To see which accessories may be an integral part of the medical equipment should be checked in Chapter I of this manual. The inclusion of accessories in disagreement with ANVISA regulations constitutes a health infraction, unauthorized marketing. It may be detected in notification audit, and causing, at any time, documentary or fiscal assessments of the notification processes and their changes, and, if necessary, the request for information or additional clarifications. Examples: non-exclusive use accessories, that should have their own registration; accessories that are classified in a higher risk class than the product, etc.

- **4.1.8 Forms of commercial presentation of the product**

Mention the forms of commercial presentation of the product, for each model presented.

4.2 Medical Device Specifications

4.2 Especificações do Dispositivo Médico

4.2.1 Indicação de Uso/Finalidade (Descrever as indicações de uso do equipamento, seus componentes e acessórios)

4.2.2 Princípio de Funcionamento/ Mecanismo de Ação

4.2.3 Compatibilidade com outros dispositivos médicos (estes produtos não integram a notificação do equipamento, possuindo registro/notificação próprio na Anvisa)

4.2.4 Público destinado a operar o equipamento

☐ Leigo ☐ Leigo com prescrição de profissional de saúde
☐ Profissional de saúde ☐ Profissional de saúde com treinamento do fabricante/fornecedor
☐ Outros, especificar:

4.2.5 Tipo de ambiente destinado ao equipamento

☐ Doméstico ☐ Hospital/Clínica
☐ Laboratório Clínico ☐ Serviço de Hemoterapia
☐ Consultório/Ambulatório ☐ Ambulância
☐ Outros, especificar:

4.2.6 Tipo de usuário (paciente)

☐ Adulto ☐ Pediátrico ☐ Neonatal ☐ Outros, especificar:

4.2.7 Especificações técnicas (descrever os requisitos técnicos do equipamento, seus componentes e acessórios)

- **4.2.1 – Indication/Purpose of Use**

Clearly specify the intended use of the equipment.
Indicate, when applicable, the clinical indication for the device, the pathology or disorder to be treated.

- **4.2.2 - Operating Principle/Mechanism of Action**

Describe the operating principle of the equipment, highlighting the technology involved in this process. This item should contain information clear techniques and, where applicable, an explanation of how the interaction with the patient.

- **4.2.3 - Compatibility with other medical devices**

If medical equipment is to be installed or connected to other products to function as intended,
Sufficiently detailed information must be provided about its minimum operating characteristics, which make it possible to identify the

products that can be used with this equipment, so that a safe combination is obtained. In these cases, these other medical devices are not included in the equipment notification, having its own registration/notification with Anvisa.

- For products with their own registration/notification at ANVISA (e.g., consumables, surgical instruments, diagnostic kits, calibrators and *in vitro use controls, etc.),* the registration/notification numbers for these products must be provided.
If these numbers are not available, inform that the products in question have their own registration/notification number at ANVISA.

• 4.2.4 - Audience intended to operate the equipment

Select the category that best describes the user audience. what the equipment is intended for, as declared by the manufacturer

• 4.2.5 - Type of environment intended for the equipment

Select the category that best describes the location to which the equipment is intended to be used as stated by the manufacturer.

• 4.2.6 - User type (patient)

Indicate the patient category for which the equipment is intended intended to treat, as stated by the manufacturer.

• 4.2.7 - Technical Specifications

Indicate the technical specifications relevant to the equipment, e.g.: supply voltage, consumption power, measured parameters, alarms, battery characteristics, type of energy delivered, load maximum supported, etc. The International System of Units – SI in relevant references.

- When the product has a battery, include: battery type, voltage, useful life, autonomy and minimum time for full recharge.

4.2.8 Informações sobre medicamentos incorporados/associados/administrados

☐ Não se aplica, não há medicamentos incorporados, associados ou administrados pelo equipamento.

4.2.9 Informações sobre alarmes

☐ Não se aplica, o equipamento não possui alarmes.

4.2.10 Prazo de validade do produto

4.2.11 Produto Estéril

☐ Sim
Método de Esterilização:

☐ Não
☐ Necessária a esterilização antes do uso
Método de Esterilização:

4.2.12 Caso aplicável, informar lista de código, método de esterilização e prazo de validade de todos os acessórios que são fornecidos estéreis:

- **4.2.8 - Information on medicines incorporated/associated/managed**

Inform if the equipment contains products with principles assets or no (dyes, excipients) incorporated/associated/administered, their concentration and the participation of the drug in the product's indications. The principle asset must be regularized with ANVISA or be in the process of regularization, the regularization number or the process of regularization must be informed on the form.

- **4.2.9 - Alarm information**

Report the alarms that the product has, trigger mode (sound, visual, combination of forms), its purpose, conditions of actuation, adjustments, muting and measurement method used to drive.

- **4.2.10 - Product Expiration Date**

Inform the sterilization expiration date, if applicable, and the

product validity. Validity is understood as the time in which a product can be used safely, maintaining its material and operational characteristics. The concept of validity is applicable to products that have parts that cannot be exchanged or maintained and that deteriorate over time or cycles of use.

- **4.2.11 – Sterile Product**

Answer the questions about sterilization by marking the answer and inform the validated sterilization method for the product, if applicable. More than one sterilization method may be specified, if the product has more than one validated sterilization method.

- **4.2.12 – If applicable, provide code list, method sterilization and expiration date of all accessories that are supplied sterile.**

4.2.13 Reprocessamento

☐ Produto com reprocessamento proibido.
☐ Produto passível de reprocessamento

Obs: Serão considerados dispositivos médicos com reprocessamento proibido os que constam no Anexo da Resolução RE nº 2605/2006, ou legislação e regulamentos que vierem a substituí-la, e aqueles que apresentam evidência técnica documentada da impossibilidade do reprocessamento devido ao comprometimento na limpeza, desinfecção ou esterilização, bem como a perda de desempenho e/ou da sua funcionalidade e integridade.

4.2.14 Requisitos de manutenção (informar a periodicidade da manutenção e o responsável pela execução)

4.2.15 Condições para Armazenamento

4.2.16 Condições para Transporte

4.2.17 Condições para Operação

4.2.18 Requisitos de infra-estrutura (caso o equipamento necessite de condições especiais de infra-estrutura física e ambiental para sua operação correta e segura)

4.2.19 Advertências/Precauções

4.2.20 Contraindicações

☐ Não se aplica
Em caso contraindicações existentes, descrever:

- **4.2.13 - Reprocessing**

Indicate whether or not the equipment can be reprocessed.

Medical devices with prohibited reprocessing will be considered those listed in the Annex to Resolution RE No. 2605/2006, or legislation and regulations that replace it, and those that present documented technical evidence of the impossibility of reprocessing due to compromised cleaning, disinfection or sterilization,

as well as the loss of performance and/or functionality and integrity.

• 4.2.14 - Maintenance requirements

Specify the equipment maintenance requirements (corrective and preventive), indicating the frequency and the person responsible for execution. If any maintenance activity can be performed by the operator of the equipment, this activity must be specified and the steps of development must be clearly described in the manual user. NOTE: There is no need to describe the steps step by step in this form.

• 4.2.15 - Storage conditions

Information on storage conditions (e.g.: maximum stacking of boxes, protect from rain, fragile, this side upwards, maximum and minimum storage temperature, etc.) must be included on the medical equipment label, where applicable, following the standard defined in the Collegiate Board Resolution – RDC No. 751, of 2022.

- If it is necessary to observe specific environmental conditions (temperature, pressure and humidity) for the storage, conservation or handling of the product, these conditions must be clearly indicated on the label.

- Where appropriate, information may be presented in the form of symbols or colors, which must comply with current regulations or technical standards. Examples: symbols indicated in the ABNT NBR ISO 15223 technical standard for storage, distribution, transportation, handling, and other conditions , including the meaning of these symbols.

• 4.2.16 - Conditions for transportation

Specify the transport conditions appropriate to the equipment so as not to compromise its integrity, safety, quality and effectiveness, where applicable.

• 4.2.17 - Conditions for Operation

Specify the handling conditions appropriate to the equipment so as not to compromise its integrity, safety, quality and efficiency. Informs in this field whether the equipment can be operated by laypeople or only by a qualified professional.

• 4.2.18 - Infrastructure requirements

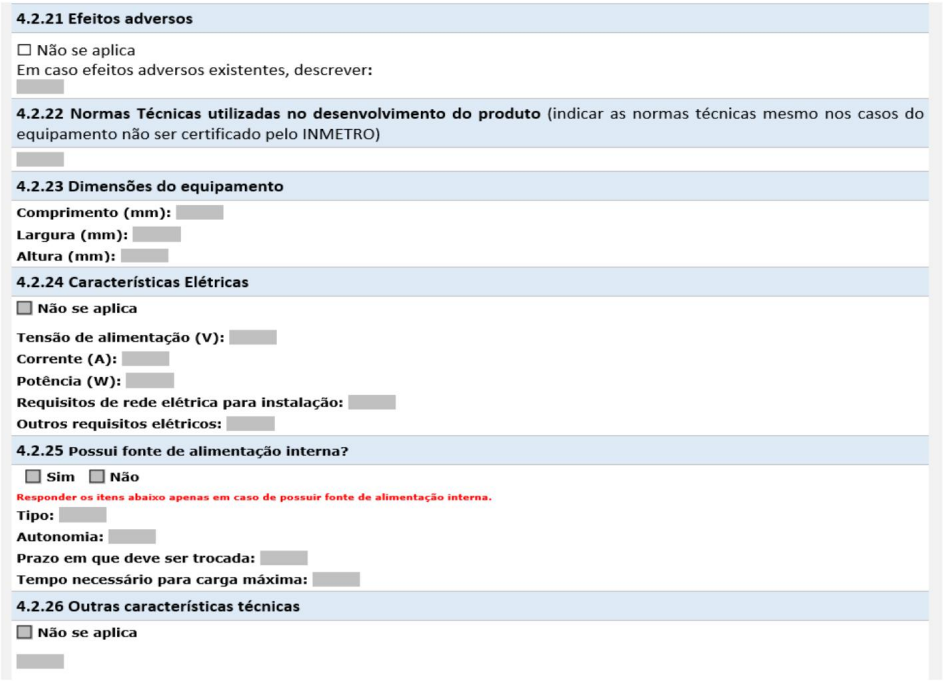
If the equipment requires specific operating conditions, physical or environmental infrastructure for its safe operation, these conditions must be described.

• 4.2.19 – Warnings / Precautions

Indicate the warnings and precautions that must be observed for the correct and safe use of the equipment, as per determined by the manufacturer.

• 4.2.20 – Contraindications

Specify in this field any contraindications for using the equipment. Mark the item as “not applicable” if the equipment does not present contraindications. NOTE: if this field is selected, if the company being questioned must be able to prove what was reported through studies, tests and evaluations.



4.2.21 Efeitos adversos

☐ Não se aplica
Em caso efeitos adversos existentes, descrever:

4.2.22 Normas Técnicas utilizadas no desenvolvimento do produto (indicar as normas técnicas mesmo nos casos do equipamento não ser certificado pelo INMETRO)

4.2.23 Dimensões do equipamento

Comprimento (mm):
Largura (mm):
Altura (mm):

4.2.24 Características Elétricas

☐ **Não se aplica**

Tensão de alimentação (V):
Corrente (A):
Potência (W):
Requisitos de rede elétrica para instalação:
Outros requisitos elétricos:

4.2.25 Possui fonte de alimentação interna?

☐ **Sim** ☐ **Não**

Responder os itens abaixo apenas em caso de possuir fonte de alimentação interna.

Tipo:
Autonomia:
Prazo em que deve ser trocada:
Tempo necessário para carga máxima:

4.2.26 Outras características técnicas

☐ **Não se aplica**

- **4.2.21 - Adverse effects**

Specify in this field any adverse effects observed in the use of the equipment. Mark the item as “not applicable” if the equipment does not present adverse effects. NOTE: if selected this field, if the company is questioned it must be able to verify the information through studies, tests and evaluations.

- **4.2.22 - Technical Standards used in development of the product**

List the technical standards used for development and met by the product.

- **4.2.23 - Equipment dimensions**

Provide the external dimensions of the equipment.

- **4.2.24 - Electrical characteristics**

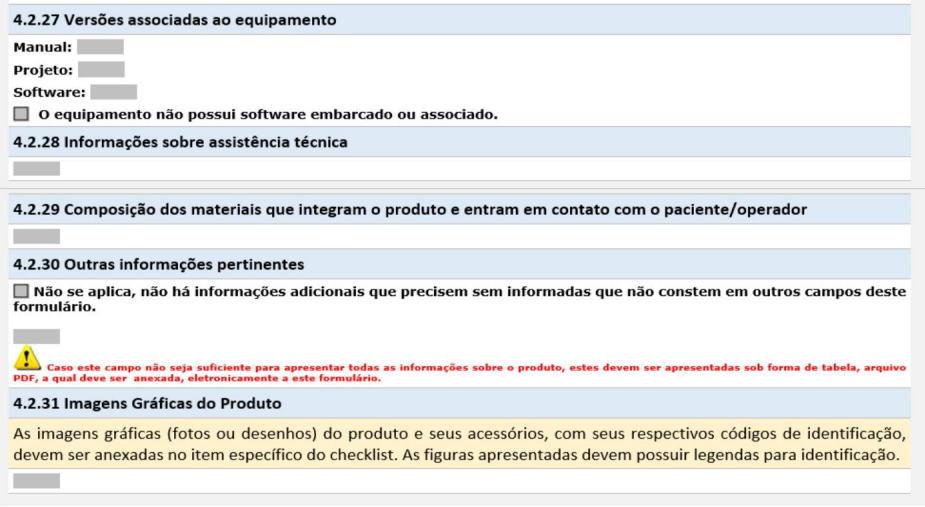
Provide answers about electrical characteristics

- **4.2.25 - Does it have an internal power supply?**

Inform about internal power sources such as batteries, capacitors or other sources.

• **4.2.26 - Other technical characteristics**

Provide other information that the company deems relevant, but did not fit into other fields of this form.



• **4.2.27 - Versions associated with the equipment**

Enter the current version number of the user manual, design of the equipment and the software embedded in the equipment. If do not have software, tick the corresponding box.

• **4.2.28 - Technical assistance information**

Provide addresses, contacts and telephone numbers for assistance services techniques, call center telephone numbers, customer service and other forms of assistance technical or consumer.

• **4.2.29 - Composition of the materials that make up the product and come into contact with the patient/operator**

List the parties that come into contact with the patient or the operator and the material from which they are made.

• **4.2.30 - Other relevant information**

Provide other information that the company deems relevant, but that does not fit into other fields on this form.

- **4.2.31 – Graphic images of the product**

Graphic images (photos or drawings) of the equipment, its accessories and parts, with their respective identification codes, must be sent as an attachment. The electronic format must be .docx or .pdf. The figures presented must have captions for identification.

5. INMETRO Certificate

5. Certificado INMETRO
Observar as legislações específicas para dispositivos médicos com certificação compulsória (RDC nº 549/2021 e Instrução Normativa nº 116/2021, ou aquelas que vierem a substituir)
5.1 Possui certificação INMETRO?
☐ Sim ☐ Não
5.2 Número do Certificado
5.3 Identificação do Organismo de Certificação do Produto (OCP)
5.4 Normas Técnicas utilizadas na certificação
5.5 Versão do Manual do Usuário Avaliado na certificação
5.6 Versão do projeto do equipamento avaliado na certificação
5.7 Acessórios e Partes ensaiados em conjunto com o equipamento
5.8 Possui Relatório Consolidado? (art. 6º da RDC nº 549/2021)
☐ **Sim** ☐ **Não**
5.9 Número do(s) Relatório(s)
5.10 Identificação do Organismo de Certificação do Produto (OCP) que emitiu o(s) Relatório(s)

- **5.1 - Do you have INMETRO Certification?**

Inform whether the product has an Inmetro certificate of conformity.

- **5.2 - Certificate number**

Enter the certificate number and date of issue.

- **5.3 - Identification of the Certification Body Product (OCP)**

Provide the name of the body that carried out the certification.

• 5.4 - Technical Standards used in certification

List the technical standards to which the product was subjected during certification.

• 5.5 - User Manual Version Reviewed at certification

Inform the version of the manual evaluated during certification

• 5.6 - Version of the equipment project evaluated in the certification

Inform the valid project version used at the time of certification.

• 5.7 - Accessories tested in conjunction with the equipment

List the accessories that were tested with the equipment to obtain the INMETRO certificate of conformity.

• 5.8 - Do you have a Consolidated Report?

If it has been impossible to issue the certificate for a product compulsory certification, a consolidated report may be presented, in accordance with paragraph 4 of art. 4 of **Resolution - RDC No. 549, of 30 August 2021.**

• 5.9 - Report(s) No.

In this case, you must indicate and inform the report number, as well as as the date of issue.

• 5.10 – Identification of the Product's Certified Body (OCP) that issued the Report

Provide the name of the organization that issued the Report Consolidated.

6. Legal and Technical Responsibility

6. Responsabilidade Legal e Técnica	
Nome do Responsável Legal:	
Cargo:	
Nome do Responsável Técnico:	
Conselho de Classe Profissional:	
Número do Conselho/UF:	

The penultimate item identifies those legally and technically responsible for the equipment in Brazil. The names given in these items must correspond to the professionals indicated in the approved AFE. The position indicated for each person in charge, must correspond to the position he or she holds occupies within the hierarchical-organizational structure of the company. It must the professional council to which the technical manager belongs must be informed part, as well as its board number.

7. Declaration of the Legal Guardian and Responsible Person Technical

7. Declaração do Responsável Legal e Responsável Técnico

Declaro que as informações prestadas neste formulário são verdadeiras, podendo ser comprovadas por documentos disponíveis na Empresa. Declaro ainda que:

a. O produto será comercializado com todas as informações previstas na legislação sanitária vigente;

b. As instruções de uso e rótulo do produto atendem aos requisitos estabelecidos no Capítulo VI da Resolução Anvisa RDC nº 751/2022; e

c. Embora sob regime de notificação, o produto foi projetado e fabricado atendendo as disposições da Resolução Anvisa RDC nº 546/2021 (Requisitos Essenciais de Segurança e Eficácia) e Resolução Anvisa RDC nº 665/2022 (Requisitos de Boas Práticas de Fabricação e Controle).

A empresa está ciente que o não atendimento às determinações previstas na legislação sanitária caracteriza infração à legislação sanitária federal, estando a empresa infratora sujeita, no âmbito administrativo, às penalidades previstas na Lei nº 6.437, de 20 de agosto de 1977, sem prejuízo das sanções de natureza civil ou penal cabíveis. Na esfera jurídica, respondem pelos atos de infração praticados pela empresa os seus Responsáveis Legal e Técnico, conforme infrações e sanções previstas no art. 273 do Decreto Lei n.º 2.848, de 07 de dezembro de 1940 (Código Penal – Cap. III: Dos Crimes contra a Saúde Pública).

<ASSINATURA ELETRÔNICA>
Nome do Responsável Legal, cargo e assinatura.

<ASSINATURA ELETRÔNICA>
Nome do Responsável Técnico, cargo e assinatura.

This last field must be signed by the Technical Manager

and by the company's Legal Representative, making them aware of what

is being declared.

- The applicant must submit documents digitally signed by the legal and technical representatives, as required by applicable regulations or when indicated in the list of procedural supporting documents. For digitized documents, a qualified electronic signature, which uses a digital certificate issued by ICP-Brasil, must be used. For native-digital documents, a qualified electronic signature, which uses a digital certificate issued by ICP-Brasil, or an advanced electronic signature, such as gov.br , must be used . It is recommended that the applicant confirm the validation of the signatures of the Legal and Technical Representatives through the link https:// validar.iti.gov.br/.

Software as a Medical Device Notification

Resolution - RDC No. 751, of September 15, 2022

Resolution – RDC No. 657, of March 24, 2022

Notification of software as a medical device is also governed by **Resolution - RDC No. 751, of September 15, 2022,** in conjunction with **Resolution - RDC No. 657, of March 24, 2022.**

In the same way as for equipment, when requesting the SaMD notifications must be forwarded to Anvisa with the documentation described in Art. 13 of Resolution – RDC No. 751/2022. They are:

1) Form for notification of Software as a medical device, duly completed, available on the ANVISA electronic portal;
2) For imported medical devices: declaration issued by the legal manufacturer, consularized or apostilled, written in Portuguese, English or Spanish or accompanied by a sworn translation, there is maximum two years when there is no express validity indicated in the document, authorizing the requesting company to represent and market your product(s) in Brazil;
3) Copy of the Certificate of Conformity issued within the scope of the System Brazilian Conformity Assessment System (SBAC), applicable only for medical devices with compulsory certification, related by Anvisa in specific regulations (required if any accessory used by the software falls within the scope of the standards cited in the Certification Normative Instruction); and
4) Proof of compliance with the legal provisions determined in technical regulations, in accordance with the legislation that regulates specific medical devices.

The statement referred to in item 2 must contain the company name and full address of the legal manufacturer and the requesting company, express authorization for the requesting company to represent and market their products in Brazil, and the statement about the knowledge and compliance with Good Practice requirements Manufacture of Health Products established in the **Resolution of Collegiate Board - RDC No. 665, of March 30, 2022,** or regulation that replaces it.

The notification of a SaMD has indefinite validity, that is, does not need to be renewed, however some conditions must be met complied with so that the notification remains in force. The maintenance of the notification is linked to compliance with the requirements of Good Manufacturing Practices, applicable technical standards and specific regulations, where they exist.

Software that has had its framework changed from notification from risk class II to risk class I notification or vice versa, will maintain their initial risk class I notification numbers or previously published risk class II notification.

- All information contained in the equipment notification form also applies to Software as Medical Devices, with the exception of item 4 - Software Data as Medical Device, which we will detail below.

4. Software Data as a Medical Device

4.1 Identification of Software as a Medical Device

4. Dados do Software como Dispositivo Médico	
4.1 Identificação do Software como Dispositivo Médico	
4.1.1 Nome Técnico	
4.1.2 Código do Nome Técnico	
Consulta de nomes técnicos disponível em: https://consultas.anvisa.gov.br/#/nomes-tecnicos/	
4.1.3 Regra de Classificação	
4.1.4 Classe de Risco do Dispositivo Médico	☐ Classe I ☐ Classe II
Classe de risco III ou IV devem usar o formulário de registro, o mesmo destinado a equipamentos.	
4.1.5 Nome Comercial	
4.1.6 Modelo(s) Comercial (is) da Família / Componentes do Sistema	
4.1.6.1 Para Família: Informar os códigos referentes aos modelos comerciais, quando aplicável. 4.1.6.2 Para Sistema (software composto de diversos módulos/partes): Informar códigos referentes ao sistema ou módulos bem como de seus componentes, quando aplicável.	
4.1.7 Acessórios (produto, software ou hardware, destinado pelo seu fabricante a ser utilizado em conjunto com um ou vários softwares como dispositivos médicos específicos, para permitir ou ajudar de forma específica e direta que o(s) software(es) como dispositivo(s) médico(s) sejam usados de acordo com a finalidade pretendida)	
4.1.8 Formas de apresentação comercial do produto (descrever a forma de distribuição do produto e/ou quantitativamente os itens que acompanham o software como dispositivo médico)	
4.1.9 Endereço na internet para Download do Manual do Usuário (se existir manual disponível em internet)	

- **4.1.1 - Technical Name**

The technical name is the name commonly used in the “medical field” to identify the software. Do not confuse the technical name with the name product's commercial name. The list of technical names, called a “table of coding of medical products”, is available for consultation, on the Anvisa website at: https://consultas.anvisa.gov.br/#/nomes-technicians/

It may happen that the technical name of the software, which the company you wish to register or notify, does not exist on the aforementioned list. In this case, the company must use the technical name that most closely resembles its software. When the process reaches the technical area at Anvisa, it will be verified whether there really is no corresponding technical name; if not, it will be created by the technical area. It is the prerogative of Anvisa creates and defines the technical name that will be applied to the product.

For secondary petitions, the following must always be observed: technical name provided in the primary petition.

• 4.1.2 - Technical Name Identification Code

The identification code is the code corresponding to the name technician indicated in the "medical product coding table" list, already mentioned.

• 4.1.3 - Classification Rule and 4.1.4 - Risk Class

Software should be classified according to its rule and class, as per the provisions of Annex I of Resolution - RDC No. 751/2022. Annex C of this Manual contains a guide to classification of medical equipment.

It is Anvisa's prerogative to determine whether the class and rule granted by the company to its product, are correct.

In the case of software, the rule will always be rule 11.

In the case of SaMD notification, the risk class will always be Class I or II.

• 4.1.5 – Commercial Name

It is the name by which the company requesting the notification wishes to that your software is known and sold in the Brazilian market.
It does not necessarily need to have the technical name incorporated into this identification, although the company, in many cases, chooses to incorporate it to make it easier for users to identify your software.

• 4.1.6 - Business Model(s)/System Components

The commercial model corresponds to the versions or variations of the software to be notified. Applicable to cases of notification of a family of software, where the **SAME TRADE NAME**
there is more than one MODEL (variation of the same software), with own identification that differentiates it from the other models in the family (e.g.: A, B, AB, FULL, etc.). The indication of SaMD family classification must comply with the requirements established in Resolution - RDC No. 542, August 30, 2021.

Single product notifications must also indicate the product model. For example:

ÿ Commercial name of the Product: **Software YYYYYYYY**

ÿ Product Commercial Model: **X1**

The choice of name and commercial model of equipment is free for the company requesting the notification. However, Anvisa may interfere in the choice of the name and/or commercial model of the product, in cases where they lead to misinterpretation due to part of the users, according to art. 5 of Law nº 6.360/1976.

System components are the individual parts that makes up the system, generally identified by names or codes that identify each part (e.g., modules/parts/components).

• 4.1.7 Accessories that accompany/are integrated with the software

If the SaMD has accompanying accessories, these must be listed in item 4.1.7 of the notification form. To see which accessories may be an integral part of the SaMD, the Chapter I of this manual. The inclusion of accessories that do not comply with ANVISA regulations constitute a health violation, not authorized thus, its commercialization. It may be detected in a notification audit, resulting in the cancellation of the notification. Examples:

accessories for non-exclusive use, which should have their own registration;

accessories that are classified in a higher risk class than the product, etc.

• 4.1.8 Forms of commercial presentation of the product

Mention the forms of commercial presentation of the product, for each model presented.

• 4.1.9 Internet address for downloading the User Manual User

Enter the internet address to download the software user manual, if the manual is available on the Internet.

4.2 Medical Device Software Specifications

4.2 Especificações do Software como Dispositivo Médico

Alerta I: No preenchimento dos itens 4.2.5, 4.2.6, 4.2.15, e 4.2.16, a empresa pode optar por empregar a expressão "**Ver o anexo do formulário de notificação**", e apresentar as informações solicitadas em anexo, no presente formulário. Essa possibilidade se justifica, pois os relatórios solicitados podem ser considerados sigilosos pela empresa, e tendo em vista a possível publicação da versão em formato eletrônico deste formulário de notificação na base de dados da ANVISA.

4.2.1 Indicação de Uso/Finalidade (Descrever as indicações de uso do software como dispositivo médico, seus componentes e acessórios)

4.2.2 Descrição do Software: (Um resumo geral das características e do ambiente de operação do software. Exemplos de especificações técnicas: limites; tipo de terapia e/ou exames e/ou funcionalidades; tipos de controles; etc. ATENÇÃO: Caso alguma característica ou especificação do software seja omitida, a ANVISA considera que a mesma não está contemplada no Registro ou Notificação do Produto)

4.2.3 Princípio de Funcionamento/ Mecanismo de Ação (algoritmos/heurísticas utilizados)

4.2.4 Compatibilidade, Interoperabilidade e Comunicação com outros dispositivos médicos, incluindo outros softwares ou dispositivos para diagnóstico de uso in vitro (estes produtos não integram a notificação do software como dispositivo médico, possuindo registro/notificação próprio na Anvisa)

4.2.5 Arquitetura de Software (Vide Alerta I): (Exemplo: **Diagrama de Componentes** - Na UML, do inglês Unified Modeling Language, diagramas de componentes mostram a estrutura do sistema de software, que descreve os componentes do software, suas interfaces e suas dependências. Utilizam-se diagramas de componentes para modelar sistemas de software em um alto nível ou para mostrar componentes em um nível de pacote mais baixo. ATENÇÃO: diagramas alternativos, porém de mesmo conteúdo, poderão ser empregados para ilustrar as relações entre os módulos do software)

- **4.2.1 – Indication/Purpose of Use**

Clearly specify the intended use of the software. Indicate, when applicable, the clinical indication for the device, the pathology or disorder to be treated.

- **4.2.2 – Software Description**

Describe a general summary of the characteristics and environment of software operation. Examples of technical specifications: limits; types therapy and/or exams and/or functionalities; types of controls. ATTENTION: If any feature or specification of the software is omitted, Anvisa considers that it is not covered by the product registration or notification.

- **4.2.3 - Operating Principle/Mechanism of Action**

Describe the software's operating principle, scoring the technology involved in this process.

This item must contain information on the algorithms/heuristics used in software development.

- **4.2.4 – Compatibility, interoperability and communication with other medical devices, including other software or devices for diagnostics of *in* use *vitro.***

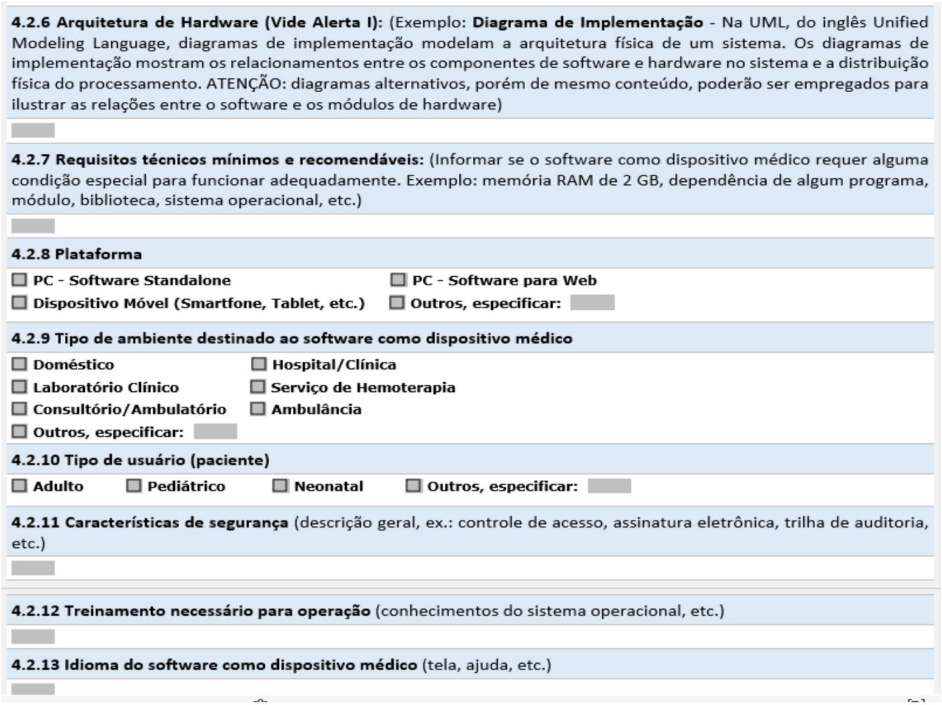
For software that has an interface (whether it is operation, control, or etc.) of generic operation with others medical devices, even other software, it is necessary that this information must be made explicit so that it is possible to carry out a more comprehensive health risk analysis of the system. In these cases, these other medical devices are not included in the notification of the software, having its own registration/notification with Anvisa.

Compatibility must be described and proven with tests also for commercial products that are not devices doctors, but which are used by software, for example, smartwatch, virtual reality glasses, cameras, monitors, smartphones, etc., any product that needs to have a configuration or characteristics specific techniques and functions to be used properly with the SaMD.

- **4.2.5 - Software Architecture:**

In this section, the company is expected to provide diagrams that illustrate the architecture of the software being developed. As defined in software engineering standards, there are several tools capable of providing such understanding, like the UML, there are class diagrams, component diagrams, among others; however, There are also other tools capable of illustrating the relationships between the system modules at the software level. Due to the lack of regulations with provisions to the contrary, the company may present diagrams that were used throughout the development of the project, but that do not employ any formal standard, as if observed in agile development methodologies. Thus, the point most relevant aspect of the topic is to illustrate, in some way and through

schematic, all the relationships between the system modules.



4.2.6 Arquitetura de Hardware (Vide Alerta I): (Exemplo: **Diagrama de Implementação** - Na UML, do inglês Unified Modeling Language, diagramas de implementação modelam a arquitetura física de um sistema. Os diagramas de implementação mostram os relacionamentos entre os componentes de software e hardware no sistema e a distribuição física do processamento. ATENÇÃO: diagramas alternativos, porém de mesmo conteúdo, poderão ser empregados para ilustrar as relações entre o software e os módulos de hardware)

4.2.7 Requisitos técnicos mínimos e recomendáveis: (Informar se o software como dispositivo médico requer alguma condição especial para funcionar adequadamente. Exemplo: memória RAM de 2 GB, dependência de algum programa, módulo, biblioteca, sistema operacional, etc.)

4.2.8 Plataforma

- ☐ PC - Software Standalone
- ☐ PC - Software para Web
- ☐ Dispositivo Móvel (Smartfone, Tablet, etc.)
- ☐ Outros, especificar:

4.2.9 Tipo de ambiente destinado ao software como dispositivo médico

- ☐ Doméstico
- ☐ Hospital/Clínica
- ☐ Laboratório Clínico
- ☐ Serviço de Hemoterapia
- ☐ Consultório/Ambulatório
- ☐ Ambulância
- ☐ Outros, especificar:

4.2.10 Tipo de usuário (paciente)

- ☐ Adulto
- ☐ Pediátrico
- ☐ Neonatal
- ☐ Outros, especificar:

4.2.11 Características de segurança (descrição geral, ex.: controle de acesso, assinatura eletrônica, trilha de auditoria, etc.)

4.2.12 Treinamento necessário para operação (conhecimentos do sistema operacional, etc.)

4.2.13 Idioma do software como dispositivo médico (tela, ajuda, etc.)

- **4.2.6 - Hardware Architecture**

The company is expected to provide diagrams capable of illustrate the architecture of the hardware employed in the use of the software in question, throughout its entire life cycle. As defined in software engineering standards, there are several tools capable of to provide such understanding, like UML, there are diagrams of implementation, among others. Although the form is not essential, the important thing here is to be able to illustrate, through diagrams, all the hardware components employed in the operation of the software and the interdependencies between them, such as the computer itself, tablets, smartphones, printers, firmware writers, graphics cards serial communication, cellular modules, hardware devices owners, and etc.

- **4.2.7 - Minimum and recommended technical requirements**

The company must present the minimum hardware requirements necessary for the system to operate as intended. established in its development, approval and production. The information in this topic must be consistent with the reports of validation present in the consolidated technical report, in the sense that, for example, it is not applicable, in the absence of technical justification appropriate, the system approval was carried out in an environment with settings higher than those recommended in this topic.

The minimum technical requirements of commercial products that are not medical devices, but are used by the software to achieve their clinical function must be presented in this item, for example, smartwatch, virtual reality glasses, cameras, monitors, smartphone etc.

- **4.2.8 - Platform**

The company must inform on which platforms its system operates. It is worth noting that, in the case of the system employ multiple devices/platforms, all must be informed, in order to validate the information presented in the software and hardware diagrams.

- **4.2.9 - Type of environment intended for software such as medical device**

Select the category that best describes the location to which the software is intended to be used as stated by the manufacturer.

- **4.2.10 - User type (patient)**

Indicate the category of patient for which the software is intended treat as stated by the manufacturer.

- **4.2.11 - Security Features (general description, e.g.: access control, electronic signature, trail of audit, etc.).**

Given the sensitive nature of the information that routinely traffic in medical software, it is expected that these

have information security mechanisms, such as: authentication in systems using username and password, authentication through tokens, external authentication through the help of OTPs, system registration and operations log, ensuring integrity and authenticity of information with the help of electronic signatures, guarantee of confidentiality with the help of cryptographic techniques, among others. Obviously, it is up to the company to define the appropriate level of security that your system needs, after joint evaluation of the report of elaborate risk management; in any case, it is highly desirable that this information is present in the current form so that reinforce the safety measures employed in the product under analysis. It is also important to inform how the product meets the requirements of Law No. 13,709, of August 14, 2018 (LGPD) and which mechanisms employs to ensure the security of protected data.

- **4.2.12 – Training required for operation**

The company must inform what type of training is necessary to operate the software, knowledge of the operating system, etc.

- **4.2.13 – Software language as a medical device**

The company must inform what types of languages are available available for the software.

4.2.14 Requisitos de infraestrutura: (caso o software necessite de condições especiais de infraestrutura física e ambiental para sua operação correta e segura, sala, iluminação especial, roupa etc.)

4.2.15 Verificação (Vide Alerta I): (Sumário dos testes que foram realizados no software, incluídos os critérios de sucesso/falha, e discriminadas as taxas de sucesso obtidas. A título de exemplo, poder-se-ia empregar o sumário dos testes: unitários; de integração; de sistema e etc.)

4.2.16 Anomalias/Bugs não resolvidos (Vide Alerta I): (Indicar a existência de problemas sabidamente existentes na versão atual do software e que não foram corrigidos. Complementarmente, indicar as implicações destas possíveis falhas no gerenciamento de riscos do produto)

4.2.17 Informações sobre medicamentos associados/administrados (cálculo de dose etc)

☐ **Não se aplica, não há medicamentos associados ou administrados pelo software como dispositivo médico.**

4.2.18 Informações sobre alarmes

☐ **Não se aplica, o software como dispositivo médico não possui alarmes.**

4.2.19 Advertências/Precauções

4.2.20 Contraindicações (caso o software não possa ser usado em uma certa faixa de idade ou enfermidade etc.)

☐ Não se aplica
Em caso contraindicações existentes, descrever:

4.2.21 Efeitos adversos

☐ Não se aplica
Em caso efeitos adversos existentes, descrever:

- **4.2.14 - Infrastructure requirements**

This item should not be confused with topic 4.2.6 Hardware Architecture, nor with item 4.2.7 Technical Requirements. minimum and recommended, insofar as they define the software operating characteristics/requirements in isolation, when step in which this item alludes to the requirements in a more comprehensive, and may even include building elements, such as, for example, example, the need for a safe room, servers redundancy, or even physical control of access to environments operation of the software, or characteristics of the usage environment, such as brightness, ventilation, noise, etc.

• 4.2.15 - Verification

Throughout the development/life cycle of a software, several tests must be performed. From the perspective of software engineering, and focusing on systems developed in the context of object orientation (although it is a perfectly applicable item in the development of structured systems), tests must be developed capable of validating all the individual modules of the system, subsequently, their individual integration and, finally, the operation of the software and its modules in a systemic way, as occurs in tests of approval of a system. Thus, it is expected that the company present a list with the names of the tests performed (summary of tests), their failure/success criteria and the passing percentage obtained in these.

• 4.2.16 - Unresolved Anomalies/Bugs

For software, and in opposition to what can happen with other medical devices, the reality is that there are always anomalies or bugs that were not properly addressed before the expiration date. product launch, despite these being previously known. Eventually, such behavior will be observed when analyzing joint risk management report that can point out the apparent insignificance of the failure. The problem worsens when observed that, despite the correct use of techniques and methodologies of software engineering, the complexity of computer systems grows exponentially while coding does so in a linear. Thus, it is feasible that due to the large number of problems found in a software, in a first version, the team focus on critical issues that, when resolved, would be sufficient to ensure the patient's well-being. Finally, even if the practice is recurrent, all known problems, but not treaties should be presented in this topic for further analysis complete information on the health risk that the product poses.

• 4.2.17 - Information on medicines associates/administrators

Inform if the software has medications associated/administered. The active ingredient must be regularized with ANVISA or be in the process of regularization, the number regularization or the regularization process must be informed in the form.

• 4.2.18 - Alarm information

Report the alarms that the product has, trigger mode (sound, visual, combination of forms), its purpose, conditions of actuation, adjustments, muting and measurement method used to drive.

Also inform which measures are adopted to mitigate the risk of the alarm being turned off or disabled by the operating system or hardware, example: warning in the instructions for use, warning on the usage screen, impossibility of disabling by the system, system of alternative alert etc.

• 4.2.19 – Warnings / Precautions

Indicate the warnings and precautions that must be observed for the correct and safe use of the software, as determined by the manufacturer.

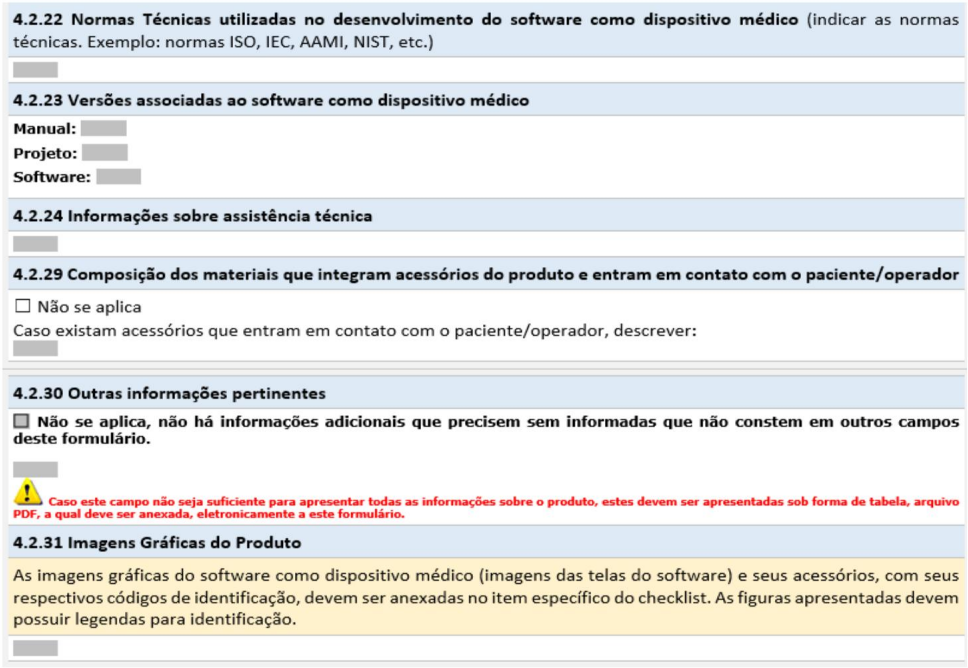
4.2.20 – Contraindications

Specify in this field the contraindications for using the software. Mark the item as “not applicable” if the software has no contraindications. NOTE: If this field is selected, if the company is questioned must be able to prove what was reported by through studies, tests and evaluations.

• 4.2.21 - Adverse effects

Specify in this field any adverse effects observed in the use of the software. Mark the item as “not applicable” if the software does not present any adverse effects. NOTE: If this is selected field, if the company is questioned it must be able to prove the informed through studies, tests and evaluations.

- When completing items 4.2.5, 4.2.6, 4.2.15, and 4.2.16, the company may choose to use the expression "See the notification form attachment" and submit the requested information as an attachment to this form. This option is justified because the requested reports may be considered confidential by the company.



4.2.22 Normas Técnicas utilizadas no desenvolvimento do software como dispositivo médico (indicar as normas técnicas. Exemplo: normas ISO, IEC, AAMI, NIST, etc.)

4.2.23 Versões associadas ao software como dispositivo médico

Manual:
Projeto:
Software:

4.2.24 Informações sobre assistência técnica

4.2.29 Composição dos materiais que integram acessórios do produto e entram em contato com o paciente/operador

☐ Não se aplica

Caso existam acessórios que entram em contato com o paciente/operador, descrever:

4.2.30 Outras informações pertinentes

☐ **Não se aplica, não há informações adicionais que precisem sem informadas que não constem em outros campos deste formulário.**

Caso este campo não seja suficiente para apresentar todas as informações sobre o produto, estes devem ser apresentadas sob forma de tabela, arquivo PDF, a qual deve ser anexada, eletronicamente a este formulário.

4.2.31 Imagens Gráficas do Produto

As imagens gráficas do software como dispositivo médico (imagens das telas do software) e seus acessórios, com seus respectivos códigos de identificação, devem ser anexadas no item específico do checklist. As figuras apresentadas devem possuir legendas para identificação.

- **4.2.22 - Technical Standards used in development of software as a medical device**

List the technical standards used for development and met by the product. Examples: ISO, IEC, AAMI, NIST standards, etc.

- **4.2.23 - Versions associated with software as a device doctor**

Enter the current version number of the user manual, software design and software as a medical device.

- **4.2.24 - Technical assistance information**

Provide addresses, contacts and telephone numbers for technical assistance, call center telephone numbers, customer service and other forms of assistance technical or consumer.

- **4.2.25 - Composition of the materials that make up the product accessories and come into contact with the patient/operator**

List the parties that come into contact with the patient or the operator and the material from which they are made.

- **4.2.26 - Other relevant information**

Provide other information that the company deems relevant, but did not fit into other fields of this form.

- **4.2.27 – Graphic images of the product**

Graphic images of software as a medical device (images of the software screens) and their accessories, with their respective identification codes, must be sent as an attachment. The figures presented must have captions for identification.

ANVISA
Agência Nacional de Vigilância Sanitária

Chapter III

Registration of Medical Equipment and SaMD

Risk class III and IV

For the registration of Medical Equipment or SaMD **manufactured in the Brazil or imported goods** classified in classes III and IV must be presented to Anvisa, the following documents:

a) Form for registration of medical device, duly completed, available on Anvisa's electronic portal.

b) Technical Dossier, as provided for in Chapter VII of Resolution RDC No. 751/2022;

c) For imported medical devices: declaration issued by the legal manufacturer, consularized or apostilled, written in Portuguese, English or Spanish or accompanied by translation sworn, for a maximum of two years when there is no express validity indicated in the document, authorizing the company requesting to represent and market its(their) product(s) in Brazil;

d) For imported medical devices: proof of registration or free trade certificate or equivalent document, granted by the competent authority of the country where the device medical is manufactured and marketed or just marketed, issued no more than two years ago when there is no validity expressly indicated in the document, and must be consularized or apostilled, and accompanied by a sworn translation when is not written in Portuguese, English or Spanish;

e) Certificate of Good Manufacturing Practices issued by Anvisa or proof of protocol request for Certificate of Good Manufacturing Practices;

f) Copy of the Certificate of Conformity issued under the Brazilian Conformity Assessment System (SBAC), applicable only to certified medical devices compulsory, related by Anvisa in regulations specific; and

g) Proof of compliance with legal provisions determined in technical regulations applied to devices specific doctors.

NOTE: In addition to these documents, the following must be observed: constant in the electronic petition *checklist* .

Document Details

Further explanations are provided below for the following documents:

- Label;
- Indelible Label;
- Instructions for Use;
- Technical Dossier;
- Proof of compliance with legal provisions determined in the technical regulations;
- Letter of authorization for representation in Brazil;
- Free Trade Certificate (CLC);
- Certificate of Good Manufacturing and Control Practices (CBPFC).

LABELS

The label is a printed identification applied directly onto the packaging of the medical product, which must be appropriate to the size of the packaging, whether primary or secondary.

The label must be able to clearly identify the contents of the package, as well as its origin. Your importance consists in indicating information that allows the traceability and origin of medical equipment, among others that guarantee its use, handling and storage in a manner appropriate and safe. For this reason, labels must have a strict control over its preparation, alteration, storage and distribution, in the equipment production process.

The information contained on the product labeling must contain, at least:

1. Name of the Registration Holder and Legal Manufacturer of the Device.

a) For national equipment or SaMD: company name and address of the registration holder and legal manufacturer of the equipment or SaMD in Brazil, which must correspond to those indicated in the Medical Device Registration form;

b) For imported equipment: company name and address of the registration holder and legal manufacturer abroad, who must correspond, respectively, to the Registration form Medical Device.

- The corporate name and address of the national legal manufacturer or holder of the registry must correspond exactly to those indicated in the AFE granted by Anvisa.

- For imported medical equipment, if outsourcing exists total or partial of the production process and that these are indicated in some way in the international labeling of the product, the indication on the national label must only include the name of the sole company responsible for the product abroad (legal manufacturer), formally recognized by health authority of your country of origin. Outsourced companies should not be indicated in this field. The indication that production steps are outsourced should only appear in Chapter 6 of the Technical Dossier, under the manufacturing process (Flowchart). The same applies to national medical equipment that has partial or complete production steps outsourced. Note: Outsourcing steps should only be indicated for manufacturers considered manufacturing units, where applicable.

Resolution **RDC No. 687, of May 13, 2022.**

2. Information that allows the user to identify the medical device and the contents of its packaging.

The label must contain a description of the contents of the package, explaining all information that can identify the equipment:

a) The name and commercial model of the product, identical to that stated in the Medical Device Registration form;

b) The accessories that accompany the product, including the options and consumables with their respective codes, or other number that references them;

- In the packaging of equipment containing medical devices that have their own registration with Anvisa (e.g. conductive gel, heat-sensitive paper, surgical instruments, diagnostic kit, calibrator and controller for in - use *vitro,* etc.), their respective registration numbers must be informed.

NOTE: The original packaging and labels of the products with their own registration at Anvisa and which are included in the equipment packaging, cannot undergo modifications in relation to what is stated in the process registration of these products. If these numbers are not available, inform that the products in question have their own registration number at Anvisa and are not an integral part of the equipment registration.

c) Support materials accompanying the product, such as manuals, products for assembly and protection, among others;

d) Specifications and technical characteristics of the equipment, such as such as: integral parts, dimensions, weight, volume, tension and network frequency for electrical supply, power of electrical consumption, operating temperature limits, radiation, number of units or other information product characteristics. The System must be used International System of Units – SI, in the relevant references.

- When the product has a battery, include: battery type, voltage, useful life, autonomy, minimum time for full recharge.

3. For sterile products, the word “Sterile” must appear prominently on the labeling.

The label must contain, where applicable, information regarding the sterility of the product, clearly informing whether it is supplied sterile or not. The sterilization method used in the process must also be informed.

Standardized symbol for such indication, such as the one indicated in the technical standard ABNT NBR ISO 15223, it can be used, as long as, the meaning of this information is included in the product's instructions for use. symbol.

- For products supplied sterile, warning not to use the product in case of violation or deterioration of the packaging, must be clearly and prominently indicated.

4. The label must indicate the serial/batch number of the product. that is inside the packaging.

The equipment serial number is an essential health requirement and necessary for its traceability.

- The serial/batch numbers of the accessories must be indicated that accompany the equipment (e.g., ultrasound transducer, oximetry sensors, etc.).
- The equipment serial number must be on its body and on its packaging (see Indelible Label item).

5. The label must contain information about the expiration date. manufacture of the device and deadline for use or date of validity for devices with perishable characteristics (e.g. sterility).

Equipment and accessories that have an expiration date determined must have this information indicated in their respective labels.

For non-perishable devices, the date must at least be included. of its manufacture, considering at least month and year.

Devices that are supplied sterile must have labels that indicate the date of sterilization or manufacturing and the date of sterilization validity, deadline for use of the device.

6. Indication of single-use product.

Devices that, due to design characteristics, must be discarded after first use must have this information indicated on their labels, clearly and prominently.

- The indication “reprocessing prohibited” should only be included on the label when the provisions of RESOLUTION - RDC No. 156, OF AUGUST 11, 2006.
- For products classified as subject to reprocessing, according to RDC Anvisa nº 156/06, at the discretion of the manufacturer or importer, the label may contain the following indication **“The manufacturer recommends single use”.**

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7. Special storage and conservation conditions and/or handling of the medical device must be described on the label.

Information on storage conditions (e.g.: maximum stacking of boxes, protect from rain, fragile, this side upwards, maximum and minimum storage temperature, etc.) must be included in the labeling of medical equipment, where applicable.

- Standardized symbols (e.g. symbols indicated in the ABNT technical standard) NBR ISO 15223) for storage, distribution, handling and other conditions may be used, provided that the meanings of these symbols are included in the product's instructions for use.

8. Instructions for correct and safe use of the device

~~doctor must be described on the label.~~

If possible, include the product's instructions for use in your packaging. If this is not possible, indicate that it must the accompanying document (instructions for use) should be consulted. Ex.: “Read User Manual before using the equipment”.

9. All warnings and/or precautions to be taken for the safe use of the device must be described in the label.

Without fail, the precautions and warnings regarding the storage, distribution and sterility of the product must be included in the packaging.

Other warnings and precautions associated with the product must be included in the accompanying documents (instructions for use) and may also appear on the packaging, where possible.

10. In cases of products supplied sterile, the method of sterilization (ETO, wet steam, gamma rays, etc.) used by the manufacturer must be informed on the label.

If the product is not supplied sterile, but requires prior sterilization before use must be informed on its label that method should be used.

11. The label must contain the name of the technical manager of the company requesting registration, legally qualified for the function, as well as its registration number and acronym of your respective professional advice, all in perfect correspondence to what is stated in the company's AFE.

12. The label must contain a field for entering the serial number. registration of the medical product, preceded by the identification acronym of the Anvisa (e.g.: Anvisa Registration No.: .....).

- For packages containing more than one medical device, with different registration numbers, all registration numbers must appear on the general packaging, outer packaging.

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General Considerations for Medical Equipment Labeling:

- The labeling model information is described in the article 46 and 47 of Resolution - RDC No. 751/2022.
- The information printed on the product label must be **legible** and written in Portuguese.
- In the case of family registration of medical equipment, they must label models for all products will be presented family members, and these labels can be presented individually (one label for each product in the family) or collective (one label for the whole family).

For collective labels, it must be possible for the user identify exactly, among the list of models indicated, which is inside the packaging.

- Accessories that are included in the equipment registration must have a label for their marketing packaging, clearly indicating the exclusive use of the equipment in question and the registration number of this equipment.
- Due to limited physical space on the label, they may be contained only in the User Manual:
  - ÿ Instructions for use;
  - ÿ Specifications and technical characteristics of the product, except those related to electrical power supply; and
  - ÿ Warnings and precautions regarding the use of the equipment.

However, the label must indicate, for example: “Read Owner’s Manual User before using the Equipment” or corresponding symbol.

- According to the Consumer Protection Code, Law No. 8,078, of September 11, 1990, article 31, the presentation of products must ensure correct and clear, precise, ostensive and in Portuguese about data such as the origin of the product. Therefore, the labeling must state the origin of the product's manufacture. equipment, indicating at least the country of origin of the unit factory.

Indelible Label

The indelible label2 must be of such size and proportion that can be affixed (indelibly) to the equipment. It must contain the following information:

a) identification of the legal manufacturer (company name or brand), as indicated on the Device Registration form Doctor;

b) product identification (name and commercial model) as per indicated on the Medical Device Registration form;

c) serial number or other identifier that allows the equipment traceability;

d) product registration number at Anvisa.

The difference between the indelible label and the label, in addition to the minimum amount of information, is that the label is affixed to the product packaging and the indelible label must be affixed directly to the body of the equipment.

[2] Indelible label information may be available on more than one label, as long as they are all indelible and affixed in a visible location.

- This label allows the user to identify the product with the minimum necessary information. Just like the label of the packaging, this is also essential to ensure the traceability and origin of the product.
- On equipment, the indelible label usually also contains, other information, mainly about the electrical supply: voltage, frequency, power, current, danger of electric shock, etc. And also, the information required by ABNT technical standards applicable to this equipment.
- In the case of medical equipment, the indelible label must be attached in a visible place on the outside of it. It is commonly affixed to its back.
- Accessories included in medical equipment records must also contain indelible labels, respecting the limiting factors for attaching them.

Limiting factors for attaching the indelible label

a) Physical characteristics of the product – some products have characteristics that make it impossible to attach the indelible label, either because it is implantable, due to its reduced size, composition of the material or others, intrinsic to the product (example: device in-ear hearing aid, etc.). In this case, identification of the manufacturer or brand and information elements will be required. traceability.

b) Products supplied sterile – products that are supplied sterile, ready for use (e.g., implantable cardiac pacemaker, implantable infusion pump, etc.), are exempt from having indelible labels affixed to their bodies, however, it must be affixed to its primary packaging.

In both cases, these products must, at a minimum, have engraved or affixed to its body, the serial/batch number and identification of its manufacturer (brand, logo or name) for purposes to guarantee its traceability.

NOTE: Equipment for use is excluded from these requirements. single non-implantable..

Instructions for Use

The instructions for use of the medical device correspond to the User Manual, brochures or other documents, which present information necessary for correct use and equipment safety. These documents must be, must be written in Portuguese and easy to understand. understanding, with language appropriate to the target audience. Verify that not all items indicated in the Resolution apply necessarily to all equipment, so the company must carry out a critical analysis, considering your product's Risk Management, to assess which items are applicable or not. It is The purpose of this Manual is to reduce the number of requirements in the processes of registration, however if the company fails to address any item of the Resolution that Anvisa deems necessary, requirement requesting clarifications will be issued.

Resolution RDC No. 751/2022 establishes rules for provision of instructions for use in non-printed format medical device, establishing requirements for it and the content of these instructions. This Resolution allows the provision of instructions for use in physical media or made available on the Internet or other format that meets all the requirements of this Resolution. It also prohibits the exclusive provision of instructions for use in a non-fiction format printed for the following products:

I. equipment for use in healthcare that is indicated for:

a) general domestic use, including use in service home care - SAD; and

b) operation by laypersons, regardless of the place of operation use;

II. health materials used by lay people;

In the case of SaMD, if the software distribution is virtual, the company is exempt from physical presentation, labeling and instructions for use.

The instructions for use presented to Anvisa, in the process equipment registration, must faithfully correspond to those that will be delivered to the user of the product, at least as far as concerns its content. Only the presentation of the document in its layout and final printing.

The instructions for use model must provide information to respect to the version and year of the document, following the criteria of "document control" procedure of the Goods System Company Manufacturing Practices. If the equipment is capable of certification within the scope of SBAC (INMETRO), the version of the manual presented must correspond to that contained in the Certificate of Compliance presented.

When information about maintenance activities or installation of the equipment, **which can or should be performed by the user himself,** are only available in the User Manual Services, prospectuses or other documents, these must also be be presented to Anvisa.

The instructions for use model must contain, at a minimum, the following: following information:

1. Information on the label.

Label information must be included in the instructions for use. use of the product, including those that, for some reason, could not be

presented on labels and packaging.

Information about serial/batch number, expiration date and expiration date manufacturing, and name of the technical manager are exempt from appear in the product's instructions for use.

The importance of the following information is highlighted:

ÿ **The information necessary for the user to be able to identify the product:**

a) Graphic information, such as intelligible figures or photos, which allow viewing of the equipment and its accessories;

b) Brief description of the fundamentals of the equipment technology;

c) List of accessories that come with the equipment or that are recommended for use with it, as well as its codes or control numbers that represent them, as well as all optional extras and consumables used by him;

d) Code or control number that references the equipment.

e) List of supporting materials that accompany the product, such as manuals, warranty terms, products for assembly and protection, among others.

f) Specifications and technical characteristics of the product, such as composition, dimensions, weight, volume, voltage and power electrical, temperature, pressure or flow limits, radiation, quantity of units or other information and characteristics of the product, using the International System of Units.

ÿ **Ways to use the product:**

a) The identification and function of each control, command and alarm of the equipment,

b) The technical procedures necessary for the user or operator connect, handle and use the accessories with the equipment, including graphical information such as figures or intelligible photos, for better understanding of the description of the procedures;

c) A description of the procedures for use and complete operation of the equipment;

d) If necessary, an indication that the equipment may only be be used or operated by a professional with defined qualifications or who has specific training provided by the company.

- For equipment that has logical supports *(software)* in foreign language, the instructions for use must provide information detailed information about each command screen and control bar, written in Portuguese, so that the user can correct and safe use of the equipment. The same applies to functions of the controls, commands and operating indicators used in the equipment.
- Equipment that requires visual or audible alarms, due to characteristics of its technology or purpose, must present, in their instructions for use, information about these alarms, clearly described, including detailed information on how carry out periodic verification tests.

Anvisa Resolution RDC No. 848/2024 should be consulted for compliance with this requirement, with regard to the identification of these equipment.

ÿ **Warnings and precautions to be taken for use of the equipment, its transportation, handling and storage,** including warning for equipment that can only be used under medical prescription or under your supervision.

2. Indication, purpose of use, side effects and contraindications of medical equipment.

The instructions for use must contain information about the equipment performance assigned by the manufacturer, which includes:

a) the indication, purpose or use for which the equipment is intended, including the target audience and the environment of use;

b) secondary or side effects; c) contraindications.

3. Joint operation with other medical devices (compatibility with other products).

If medical equipment is to be installed or connected to other products to function as intended, Sufficiently detailed information must be provided about their characteristics that make it possible to identify the products that can be used with this equipment, in order to obtain a safe combination;

The User Manual must provide all necessary information on products compatible with medical equipment, including technical specifications of these products and, if necessary, indication of brands and suppliers thereof.

4. Installation, maintenance and calibration of the medical device.

The instructions for use must contain all the information that make it possible to verify whether a medical device is in good working order installed and can function correctly and safely. They must be information on installation, corrective maintenance, preventive maintenance and calibration of the product, detailed in the form described below:

ÿ **Installation**

When the equipment can be installed by the user himself, the information must contain:

a) Description of the technical procedures necessary to carry out the installation of the equipment, including graphical information, such as as intelligible figures or photos, for better understanding of the description;

b) Sufficient and adequate guidance that enables the user check that the equipment is correctly installed and can function correctly and safely. Including alleged defects, their causes and corrective actions to be taken in each case;

c) Minimum specifications for physical, electrical, and infrastructure hydraulics and gases, when necessary for operation correct and safe use of the equipment.

d) Minimum specifications for environmental conditions (temperature, pressure, humidity, static control, interference control) electromagnetic, etc.) necessary for correct operation and equipment insurance. If constant monitoring of these conditions is necessary, information about this should be provided. appear in the instructions for use;

e) Reference the technical standards for physical, electrical, and hydraulic and gas conditions that must be observed for correct product installation.

In the case of installation carried out by technical assistance authorized, the information must contain:

a) Indication that the installation will be carried out exclusively by authorized technical assistance and the data to access this assistance;

b) The specifications of physical, electrical, hydraulic and infrastructure gases, among other conditions, that the user must provide for product installation;

c) Reference the technical standards for physical, electrical, and hydraulic and gas conditions that must be observed for correct product installation;

d) Minimum specifications of environmental conditions (temperature, pressure, humidity, static control, interference control electromagnetic, etc.) necessary for correct operation and equipment insurance. If constant monitoring is required of these conditions, information in this regard must be included in the instructions for use.

ÿ **Corrective Maintenance**

The instructions for use must contain the necessary data to access technical assistance authorized to carry out maintenance corrective medical equipment.

The conditions and terms of the Term must also be described. Guarantee of technical assistance of the product and, when applicable, of the accessories, in compliance with the provisions of the Consumer Protection Code - CDC (Law No. 8,078, of September 11, 1990).

In the case of corrective maintenance that may be carried out by the user himself, inform in detail, in the User Manual or in another document (e.g., Service Manual), the procedures for this activity, including intelligible figures or photos and where to purchase them parts and spare parts.

- The User Manual must alert the user that the use of service providers or replacement of parts not indicated by the equipment manufacturer is your sole responsibility.

ÿ **Preventive Maintenance and Calibration3 .**

The instructions for use must contain a description of all the preventive maintenance and calibration actions to be performed by the user to ensure the correct and safe operation of the product:

a) The nature and frequency of preventive maintenance and calibration; and

b) The technical procedures necessary to carry out the preventive maintenance and calibration, including information graphics, such as figures or photos, for better understanding description of procedures.

- When there is a need to use technical assistance authorized to carry out preventive maintenance procedures, corrective maintenance and calibration, in addition to the actions performed by user, the instructions for use must explain this need and inform the nature and frequency of these procedures, in addition to providing the contact details of the technical assistance indicated for each activity.

- The instructions for use must emphasize the importance of ensuring the traceability of the calibration performed, whether it is performed by the person user, authorized technical assistance or third parties. To parameters that have traceable standards within the Brazilian Calibration Network – RBC, their calibration must be traced within this scope.

[3] Although calibration can be included within the definition of Preventive Maintenance, this activity is highlighted in this item to draw attention to its importance.

5. Implantable medical equipment.

In the case of implantable medical equipment, the operating instructions use must contain information about the situations and conditions in which this can be implemented, as well as the care to be taken observed by users of these products in order to avoid risks when it is subjected to certain situations or conditions.

6. Interference with other medical devices in specific investigations or treatments.

If the medical equipment cannot be used simultaneously with another product in the same patient, due to features of its design or particularities of its technology, this information must be clear and highlighted in your instructions for use.

7. Damage to the packaging of supplied medical devices sterile and suitable methods for resterilization.

In the case of a medical product delivered for consumption in the condition sterile, the instructions for use must inform, in case of damage to the sterility protective packaging:

a) The risks involved in using the sterile product whose protective packaging has been tampered with or damaged. In addition to recommend its immediate disposal, if it is not possible to resterilization;

b) Appropriate resterilization methods, when the product can be reused or resterilized, due to damage packaging or other factors that have compromised the its sterility;

c) Recommendations for disposal, when the product is in use single.

8. Cleaning, disinfection, packaging and storage methods resterilization.

If the medical equipment manufacturer determines that the equipment, its parts and accessories, can be reused,

information on appropriate procedures for reuse,
including cleaning, disinfection, packaging and, as appropriate,
the sterilization method, must be included in the instructions for use of the
equipment.

Recommended sanitizers must also be provided.
for these activities that do not compromise the integrity of the
equipment and its accessories.

For non-sterile products that need to be
sterilized before use, or products that can be re-sterilized,
the instructions for use must contain:

a) Cleaning and disinfection procedures, in addition to the form
adequate packaging before, during and after its
sterilization;

b) The sterilization methods that can be used;

c) Restrictions on the number of re-sterilizations that can be performed
be carried out without compromising the safety of the equipment.

These instructions must be detailed enough to
ensure that, when correctly executed, the product maintains the
performance and safety as established by the manufacturer.

- The indication 'reprocessing prohibited' should only be included in instructions for use when the provisions of the Resolution are met - RDC No. 156, of August 11, 2006, or any other that may come to be replace it.

- For products classified as subject to reprocessing, according to Resolution - RDC No. 156, of August 11, 2006,
At the discretion of the manufacturer or importer, the instructions for use may contain the following indication: “The manufacturer recommends single use”.

9. Procedures required before using the equipment doctor.

All procedures to be adopted before using the medical equipment must be described in their instructions for use, which includes clinical patient preparation procedures and technical and operational procedures to prepare the equipment for use (e.g., sterilization, alarm testing, calibration, assembly, parameter configuration, etc.).

If the equipment requires use by a qualified professional, the obligation and the method of use must be explicitly mentioned. required qualification (doctor, nurse, dentist, physiotherapist, participant in a course offered by the company, etc.).

10. Medical equipment emitting radiation for medical purposes doctors.

The instructions for use of equipment that emits radiation to medical purposes must contain detailed information on:

a) Nature;

b) Type;

c) Intensity; and

d) Radiation distribution.

The instructions for use must also include information on contraindications and precautions, means of patient protection and of the operator, ways to avoid erroneous manipulations and eliminate risks arising from the equipment.

11. Precautions to be taken in case of changes in the functioning of medical equipment.

When a change in operation implies a risk to health and can be identified by the patient, operator or third parties, clear information on how to proceed must be indicated in the instructions for use (e.g. *troubleshooting* table – Problem Resolution problems).

Special attention must be paid to equipment intended for use by laypeople or unqualified professionals (e.g.: home glucometers). The instructions for use of these devices must provide the necessary information on how to proceed in the event of change in operation, in the clearest and most direct way possible.

12. Precautions to be taken regarding equipment exposure doctor to special conditions.

If a product is sensitive to reasonably foreseeable environmental conditions under normal use situations (temperature, pressure, humidity, etc.), electromagnetic influences, discharges electrostatics, acceleration, vibration, ignition sources, among others, precautions to be taken regarding the exposure of the product to these situations must be indicated in the instructions for use.

13. Information about the medicine(s) and medicinal gases that the medical equipment is intended to administer.

Medical equipment intended for the administration of medications (e.g., Infusion Pumps) must have indications on their instructions for use the types of medicines that can be administered by the equipment in question.

If there are any restrictions regarding the choice of a medication, due to the physical-chemical characteristics of substances that integrates it, this information must be clearly stated in the instructions of equipment use.

It must be clear in the instructions for use that these medicines are not included in the medical equipment register and must have own registration with Anvisa.

14. Precautions for disposal and disposal of the medical product and its parts.

Medical equipment, parts or waste thereof that present a risk associated with their elimination, they must contain in their instructions for use precautions to be taken in case of disposal and disposal of these products. Resolution - RDC No. 222, of March 28, 2018

must be considered, as well as other health or environmental issues that address this issue.

15. Medicines incorporated into the medical product as part member of this.

Instructions for use of medical products containing drugs as an integral part of the product, must contain information regarding to the drug, provided for in the legislation governing these substances, including the drug's registration number with Anvisa.

16. The level of precision attributed to medical equipment measurement.

Medical equipment that performs parameter measurements physiological or other parameters of interest to health (e.g., biochemical analyzers, physiological monitors, gas analyzers, etc.) must indicate in your instructions for use the limits of precision and accuracy associated with the measures taken.

General Considerations of the Equipment's Instructions for Use Doctor

- Information regarding instructions for use is described in article 48 of **Resolution - RDC No. 751, of September 15, 2022.**

- Resolution **- RDC No. 848, of March 6, 2024,** which deals with of the essential safety and performance requirements applicable to medical devices, also presents requirements that must be included in the instructions for use and labeling.

- The information contained in the instructions for use must be written in Portuguese and be intelligible to the level of knowledge of users for whom the medical equipment is intended.

- When the registration request corresponds to a family of medical devices, the company must submit the information described above for all models in the family, in the form of a manual individual or collective. In the case of a collective manual, it must contain the information corresponding to all models, highlighting their particularities (similarities and differences). A comparative table between the models must be presented in the collective manual.

- Instructions for use of self-test equipment or self-administration must take special care, especially with regard to concerns: the description of the correct and safe way of use; specific indication of the purpose of use; the intelligibility of the information; the clear indication of care, warnings and precautions, either in the User Manual or by labels affixed to the equipment; other information that directly or indirectly indirectly, on equipment safety.

- The equipment and its accessories must be indicated on the instructions for use or in the User Manual their respective codes or other control numbers that reference them.

Technical Dossier

The Technical Dossier are documents that describe the elements that make up the product, indicating the characteristics, purpose, how to use, the content, the special precautions, the potential risks, the production process and additional information. These documents must present information about the equipment design, emphasizing information such as: composition and quality of materials, accessories that comprise it, technical description of the operating principle, bibliographic reviews and studies related to the technology used, form of equipment presentation, technical warnings, steps of production processes critical to equipment safety, test reports and validations carried out for project approval, among others.

The Technical Dossier must be filed with Anvisa as part of the request for registration of equipment and SaMD (Class of Products) risk III and IV). For medical devices subject to notification (Products risk class I and II), this Technical Dossier must be in the possession of of the company holding the notification.

According to article 57 of RDC nº 751/2022, the technical dossier must be structured into Chapters, as described in Annex II of this Resolution, which must consist of the following information:

1. Detailed description of the medical device, including:

a) Name and commercial model of the medical equipment, as per declared in the Medical Device Registration Form;

b) Graphic information, such as figures or photos, that enable view the equipment and its accessories;

c) Detailed description of the materials that come into contact with the human body and that make up medical equipment, presenting results of physical, chemical and biological tests (biocompatibility, sterility, pyrogenicity, irritability, toxicity) and mutagenicity;

d) **Detailed** description of the physical, chemical and biological, equipment technology.

- For equipment that manages or exchanges some type of energy with the human body, the desirable and undesirable physiological effects triggered must be described in detail resulting from the interaction with this energy.
- For equipment intended for diagnosis, the following must be described: form and the physical principle by which the equipment performs the diagnosis specified.
- For equipment associated with new technologies or that incorporate technological innovations, the following must be indicated and commented on bibliographical references and studies associated with product technology in question.
- The detailed description of the medical device must be compatible with those presented on the label and in the instructions for use.

e) List of accessories intended to integrate the product, as well as as well as all the optional extras and consumables for it used. The equipment, and its listed accessories, must have their respective codes or other numbers are indicated control;

- Equipment packaging containing medical devices that have their own registration with Anvisa (e.g. conductive gel, instruments surgical, diagnostic kit, calibrator and *in vitro use controller,* etc.), their respective registration numbers must be provided.

It is important to note: the original packaging and labels of the products with own registration with Anvisa, which are included in the equipment packaging, cannot undergo modifications in relation to what included in the registration process for these products. If these numbers are not available, inform that the products in question have own registration with Anvisa.

f) List of supporting materials accompanying the equipment, such as accompanying documents (manuals, handouts, etc.), products for their assembly and protection, among others.

g) Specifications and technical characteristics of the product, such as composition, dimensions, weight, volume, voltage and power electrical, temperature, pressure or flow limits, radiation, quantity of units or other information about the product's characteristics, using the International System of Units.

- Equipment that emits some type of radiation, for medical purposes, must have described: type, nature, intensity and distribution of this radiation.

2. Indication, purpose or use for which the device is intended doctor, as indicated by the manufacturer.

The Technical Dossier must describe the indication, purpose or use for which the medical equipment or SaMD is intended, compatible with the performance information presented in the instructions for use, with the physical principle and the foundation of technology indicated in the previous item

NOTE: when describing the indication for use, the target audience, the usage environment and operator type must be specified.

3. Precautions, restrictions, warnings, special care and clarifications on the use of the medical device, as well as such as its storage and transportation.

The Technical Dossier must describe the precautions, restrictions, warnings, special care and clarifications on use, storage and transportation of medical equipment, compatible with the information presented on the label and in the instructions for use.

This information should be based on risk management of the equipment, especially with regard to its residual risk.

4. Forms of presentation of the medical device.

The quantity of each item must be described and informed. (equipment, integral part, manual, accessory, etc.) which will be included in the equipment packaging, according to the information presented on the label and instructions for use.

For systems composed of several pieces of equipment or several modules of the same equipment, which can be grouped together different modes, all options must be presented composition in which the system will be offered.

For medical equipment with embedded *software* , you must the equipment software version must be informed.

5. Label templates and instructions for use

The Technical Dossier must contain the label models and instructions for use of the equipment or SaMD, in accordance with articles 46 to 49 of RDC No. 751/2022.

6. Flow diagram of production steps

The Technical Dossier must contain a summary flow diagram of the production stages of the medical equipment (all critical stages of the manufacturing process must be highlighted), accompanied by a brief summary of each stage presented and the list of the main Quality System documents associated with each stage. This diagram must begin with the acquisition of raw materials and end with obtaining the finished product, including all approval stages of the company's quality control.

- If quality control approval involves carrying out conformity verification tests, these must be briefly described.
- Production stages that are outsourced by the company must be clearly identified and equally described.
- Finished product approval tests must be indicated in the which concerns: Basic safety (e.g. electrical, mechanical, etc.); and Essential performance.

7. Description of device safety and performance doctor

Description of the safety and performance of the medical device must be based on **Resolution - RDC No. 848, of March 6, 2024,** which provides for the Essential Safety Requirements and Performance applicable to Medical Devices, and others relevant technical regulations.

To highlight the safety and performance of the equipment doctor, the company must take into account all the Management Equipment Risk Management, in order to identify, evaluate and control (when necessary) its risks (see Annex B).

All identified risks to the equipment, the risk acceptability criteria defined by company and the solutions adopted to achieve a global residual risk acceptable. General justifications in which the company just indicate the associated risks and declare to meet the requirements of current regulations. For each risk whose control is necessary, a specific, well-founded and duly justified solution must be presented validated. Whenever necessary, results of tests carried out (certificates, reports, test reports and others) tests) that prove the efficiency of the measure adopted.

- For all equipment and SaMD subject to registration, a compilation of the scientific bibliography of indexed publications related to clinical research or other studies carried out, associated with the technology used by medical equipment or SaMD, must be presented accompanied by a **critical evaluation** of this bibliography;

- Results of clinical research, specifically developed for the medical equipment or SaMD must be presented. Driving of these surveys shall be based on the provisions determined in specific legislation dealing with the matter **(Resolution - RDC No. 837, of December 13, 2023,** among others).

- The quality of the sterilization process, when carried out, must be evidenced by validation reports of the process employed. No it is advisable to forward all documentation for the validation of this process, These documents must remain at the company and will be evaluated during inspections. of GMP. What is expected is the presentation of a final and conclusive report about the process and quality of product sterilization, including a brief description of the methodology used and the results obtained. Indication of which documents of the company's quality system are associated with the sterilization process, must also be included in the report presented. Factors that may compromise the maintenance of product sterility (e.g. storage, transportation, distribution, packaging, expiration date, etc.) must also be validated and must be taken into account.

- Results of validation and verification tests must be presented of design with regard to basic safety (electrical, mechanical, thermal, unwanted radiation, etc.) and the usability of the equipment. It should be consider the essential performance of the equipment in this evaluation. These tests may be, as appropriate: clinical test results, reports or test reports (issued by first or third-class laboratories) part), certificates of conformity based on technical standards specific, among others.

General Considerations of the Technical Dossier

When the registration request corresponds to a family of medical equipment, the technical dossier must contain the information relating to each model in the family, including a technical comparison between models (technical specifications and accessories, indication specific use, etc.), according to **Resolution - RDC No. 542, of August 30, 2021.**

Proof of Compliance with Technical Regulations

Some medical equipment needs to present the INMETRO Certificate of Conformity or a Consolidated Report of tests, when requesting registration with Anvisa, for equipment that meets the criteria indicated in the **Instruction Normative No. 283, of March 7, 2024** or any other that may come into force replace it. The specific legislation dealing with certification and reporting consolidated is **Resolution - RDC No. 549, of August 30, 2021.**

For certification of conformity of this equipment or issuance of the aforementioned report, the Authorities must be contacted Product Certification – OCP, accredited by Inmetro. Largest information at www.inmetro.gov.br .

For equipment that requires prior evaluation of others government agencies, such as those related to issues metrological (e.g. clinical thermometers, sphygmomanometers, etc.) are previously evaluated by INMETRO) must be evaluated by Product Certification Bodies – OCP, as established by Inmetro Ordinance No. 384, of December 18, 2020; **or** for those medical devices and/or their accessories that they have in their technical characteristics of telecommunications modules, such as wireless communication modules, for example, bluetooth, wifi, cellular interface, etc., must present a document indicating the approval of the equipment

by the necessary government agency, either by reports of tests/assays that prove the security of telecommunications devices or apparatus that use radio frequency and whose emissions produce an electromagnetic field with an intensity within the limits established in the regulations of the National Telecommunications Agency – Anatel, or presenting an Anatel approval certificate.

Authorization of Representation in Brazil

To register imported equipment or SaMD, it must be presented Letter of Authorization for marketing the equipment, issued by its manufacturer to its distributor in Brazil

The document in question must meet the following requirements:

- It must be issued by the legal manufacturer, consularized or apostilled, written in Portuguese, English or Spanish or accompanied by a sworn translation, no more than two years ago when there is no express validity indicated in the document, authorizing the requesting company to represent and market your product(s) in Brazil.
- The Representation Authorization must be granted in favor of of the company that formalized the petition, containing the corporate name identical to that reported in the AFE issued by Anvisa;
- The authorization must explicitly state that the company requesting the registration, you can market the product in Brazil. If they are indicated only certain geographic regions or states of the Brazil, the authorization must explicitly indicate that the company can register the product with Anvisa, although its marketing is restricted to some states or regions.
- When there is an explicit expiration date in the authorization, it must be in force at the time the petition is filed with Anvisa.

- A copy of the consularized document (legalization) must be presented.
consular) or apostilled and accompanied by a sworn translation for
Portuguese language. This requirement is based on art. 13 of the Constitution of the
Federative Republic of Brazil of 1988; in art. 224 of Law No. 10,406, of
January 11, 2002; in art. 129, § 6, of Law No. 6,015, of January 31,
December 1973; in art. 4 of Decree No. 8,742 of May 4, 2016.
In case of doubts, Anvisa may request the presentation of the
original document.

Free Trade Certificate – CLC

The Free Trade Certificate – CLC – must be presented
for registration of imported equipment and SaMD and is issued by
competent health authority of the country where the equipment or SaMD
whether manufactured or marketed.

At a minimum, the following requirements must be indicated in the CLC:

- The name and address of the legal manufacturer of the equipment or
  SaMD, identical to those reported in the registration form
  medical device, product label and instructions for use;
- The name and commercial models of the equipment or SaMD,
  in accordance with the information provided in the registration form
  of medical device;
- Explicit statement that the equipment is freely
  marketed in the country of issue of the certificate;
- Current validity.

For documents issued without an expiration date, the expiration date
issuance of the CLC may not be more than 24 months from the date of
document protocol at Anvisa.

In the event that the free trade declaration is issued by authority other than the health authority, the company must prove that the the authority that issued it has legal competence, according to the legislation that governs your country, to formalize this declaration.

There is no need to present CLC for equipment that have an Inmetro certificate of conformity or a report consolidated tests according to § 1 of art. 3 of **Resolution - RDC No. 549, of August 30, 2021.**

- CE Marking Certificates may be accepted as CLC provided that, in the certificate, explicitly state the name and commercial models of the equipment or SaMD, as declared in the Registration of Medical Device; as well as the name of its legal manufacturer, consistent with the declared on the form. If there is no expiration date on this document, The CE Marking Certificate with up to 2 (two) will be considered valid. years of issue.

- In the event that the medical equipment or SaMD is marketed in Brazil with a commercial name (commercial name and model) different from marketed on the international market, a declaration of the its legal manufacturer certifying that the product listed in the CLC presented faithfully corresponds to the product that one wishes to introduce into the Brazilian market and that its differentiation lies only in its name. The commercial name that will be attributed to the product in Brazil must be clearly stated in this declaration. A copy of the consularized document must be presented (consular legalization) or apostilled, accompanied by a sworn translation for the Portuguese language. This requirement is based on art. 13 of the Constitution of Federative Republic of Brazil of 1988; in art. 224 of Law No. 10,406 of January 11, 2002; in art. 129, § 6, of Law No. 6,015 of December 31, 1973; in art. 4 of Decree No. 8,742, of May 4, 2016. In case of doubt, Anvisa may request presentation of the original document.

Good Manufacturing Practices Certificate – CBPF

The following must be presented in the registration process:

- Copy of the Good Manufacturing Practices Certificate – CBPF, issued by Anvisa, from the manufacturer (manufacturing unit) of the product; or
- Copy of the publication of Good Manufacturing Practices – GMP, of manufacturer (manufacturing unit) of the product, in the Official Gazette of the Union – DOU; or
- Copy of the Certificate request protocol receipt Good Manufacturing Practices;

- These documents must be valid at the time of the registration. request for registration with Anvisa.

It will be accepted for petitioning purposes, as well as for the start of the analysis in the petitions for granting registration, a copy of the proof of request from the CBPF at the time of the request for registration of the equipment or SaMD at Anvisa. The approval of requests for granting of registration is subject to the publication of a Certificate of Valid Good Manufacturing Practices issued by Anvisa and compliance with other requirements for device registration doctors, as established to be observed in Resolution RDC No. 751, of September 15, 2022.

Validity and revalidation of registration

The registration of medical equipment and SaMD will be valid for 10 (ten) years, and may be revalidated successively for the same period, provided that the minimum period required to request the revalidation (up to 6 months before the registration expiration date; as provided for in § 6, Art. 12, of Law No. 6,360/76).

Loading Instructions for Use

As established by RDC No. 751/2022, it is mandatory to carry out the uploading of the product's instructions for use, within 30 days after its publication in the Official Gazette of the Union, which must be carried out by the company responsible for the registration or notification of the product, which certifies that its content complies with current legislation and is consistent with the regularized product.

Loading instructions for use of both Equipment and SaMD, should occur through petition subject 80200 - EQUIPMENT - Instructions for Use are available on the Anvisa Portal, available node portal from the Anvisa; https://consultas.anvisa.gov.br/#/consultadeassuntos/

Uploading instructions for use is the responsibility of the holder of the notification or registration and must be controlled by it to possible audits.

Normalization of symbols and colors

When any information provided on the label or in the instructions of use is presented in the form of symbols or colors, the technical regulation or technical standard that specifies the symbols and colors specific to medical devices, and the same as those described in the instructions for use that accompany the product. If there is no regulation, the symbols and colors must be described in the documentation accompanying the medical device.

Requirements of Regulations and Technical Standards

The printed information on some medical equipment is governed by specific regulations and technical standards, which indicate the locations and content of the information that must be included in the packaging label, indelibly affixed to the body of the equipment and in their instructions for use. These regulatory requirements also must be observed when preparing labels, indelible tags and instructions for use, without prejudice to the provisions of the Technical Regulation approved by RESOLUTION - RDC No. 751/2022.

Change of registration information

The registration holder (manufacturer or importer) who wishes to make modifications to a medical device or SaMD, already registered, must request this change. The requested change will only be authorized after publication of the approval of said change in the Official Gazette of the Union – DOU.

Petitions for amendments must comply with the provisions of **Normative Instruction - IN No. 74, of September 16, 2020,** which details the applicable petitioning topics.

Advertising and marketing of medical equipment or SaMD

Any communication or advertising of the medical device broadcast on the consumer market must be in strict accordance with the information presented to Anvisa. The device advertising physician that contradicts the registration or notification information of the product at Anvisa, are subject to surveillance action and specific ANVISA regulations to prevent the dissemination of inappropriate or fraudulent information and unethical practices of marketing, in accordance with Decree No. 8,077 of August 14, 2013.

Suspension and cancellation of registration of medical equipment or SaMD

As a health action measure and in view of reasons substantiated, Anvisa will suspend the registration of medical equipment in cases where:

- ÿ If suspended, for duly justified security reasons, the validity of any of the documents referred to in the process registration of medical devices;
- ÿ The information is proven to be untrue presented;
- ÿ The equipment or SaMD is under investigation, by competent health authority, regarding irregularity or defect in the product or manufacturing process, which represents risk to the health of the consumer, patient, operator or third parties involved.

Anvisa will cancel the registration of the medical device or SaMD in cases where:

- ÿ False information provided in any case is proven to be false. one of the documents delivered, or one of those is cancelled documents by Anvisa;
- ÿ It is proven that the product or manufacturing process can present a risk to the health of the consumer, patient, operator or third parties involved;
- ÿ If there is proven lack of security or performance inadequate equipment.

Suspension of registration of medical equipment or SaMD will be published in the Official Gazette of the Union - DOU and maintained until the solution of the problem that caused the sanction. Both the suspension and its Cancellation will be communicated through the Official Gazette (DOU). The cancellation of the medical device registration will be published in the Official Gazette (DOU) by Anvisa.

Procedural analysis, requirements and summary rejection of the process

Anvisa will evaluate the documentation presented in the process request for registration and will express its final decision in publication in the DOU. If the information for evaluation is inadequate, Anvisa will send a communication to the interested party (technical requirement) requesting further clarification. The requirements set out must be met as determined in **Resolution - RDC No. 204, of July 6, 2005** and its amendments.

The lack of mandatory documents will result in rejection. summary of the petition for granting, changing or revalidation of registration, there is no room for formulating technical requirements in this case, as per established in § 2, item 2 of art. 2 of **Resolution - RDC No. 204, of 6 July 2005.**

Withhold information or documents requested by Anvisa, within the determined deadlines, subjects the company to the rejection of your request.

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Chapter IV

Registration Change and Notification of Medical Equipment and SaMD

Change of Registration and Notification of Medical Equipment or SaMD

Only after publication in the Official Gazette of the granting of registration or notification to Anvisa is the equipment or SaMD authorized to be marketed throughout the national territory. The product marketed (including its specifications and accessories) must **must necessarily** correspond to what was evaluated and authorized by Anvisa, according to the registration or notification process filed, does not changes to it are permitted without prior authorization from Anvisa, as established in art. 13 of Law No. 6360/1976.

If there is a need to make changes to equipment or SaMD already regularized by Anvisa, petitions for changes must be filed. The documentation presented will be evaluated following the same procedures for granting registration or notification of the equipment or SaMD. The result of the petition analysis of notification and registration change, is published in the Official Gazette. After the date from the publication of the analysis result is that the equipment or SaMD notified or registered may be marketed with the change specified.

The immediate implementation change has its implementation authorized in national territory after filing a petition with the Anvisa, and the non-reportable change does not depend on a protocol at Anvisa for implementation.

Most amendment petitions are subject to collection of fee. The amount of the fee depends on the type of change, the size of the company and the size of the equipment. The procedure for petitioning for request for change of registration or notification complies with the established in Chapter I of this Manual. To decide what type of petition must be presented, the nature of the desired change, in order to avoid incorrect or incomplete.

For each change there is a generating fact and a specific code that can be obtained on the Anvisa website at:

Types of changes that can be requested:

1. Change/inclusion of indication and purpose of use, type of operator or patient or environment of use

It must be requested whenever you wish to change/include:

- Indication/purpose of use of the equipment already approved by Anvisa. In this case, new studies and clinical research for the new indication for use must be presented;
- Type of operator intended to handle (operate) the equipment, if a health professional, lay person with a medical prescription, healthcare professional with manufacturer training, technician, etc.;
- Type of patient (neonatal, pediatric or adult); • Environment in which the equipment will be used (hospital/clinic, home use, outpatient clinic/office, ambulances, laboratory) clinical analyses, hemotherapy services, among others).

Only changes in this sense, encompassing the changes required in the user manual and labeling, are permitted through of this amendment matter.

This change is considered to require approval, that is, change of greater health relevance, which deals with changes to be introduced in the registration process, being authorized in national territory only after technical documentary analysis and manifestation favorable from Anvisa.

2. Change of the Corporate Name of the Foreign Company (Legal manufacturer or manufacturing unit)

This is a change applicable only to equipment or SaMD of foreign origin, in which a change occurred only the legal name of the manufacturer or manufacturing unit, without

occurrence of change of address or legal entity.

National manufacturers who are going through the same situation must change their corporate name only in their Authorization of Operation (AFE), there is no need for changes in each r

company registration. When you change your AFE, all the records and notification under your CNPJ will be changed.

This change is considered to be immediately implemented, or that is, a change of medium health relevance, which deals with a change to be introduced in the notification or registration process, and its implementation authorized in national territory after the filing of petition to Anvisa.

3. Changes in Storage, Transportation and Conditions Operation

Only changes in storage and transportation conditions and operation, including the necessary changes in the manual user and labeling, are permitted through this amendment subject.

This change is considered to be immediately implemented, or that is, a change of medium health relevance, which deals with a change to be introduced in the notification or registration process, and its implementation authorized in national territory after protocolization petition to Anvisa.

4. Change of Contraindications, Adverse Effects, Warnings or Precautions

This change should only be used for changes in contraindications, adverse effects, warnings or precautions of equipment, including the necessary changes in the equipment manual user and labeling.

This change is considered to be immediately implemented, or that is, a change of medium health relevance, which deals with a change to be

introduced in the notification or registration process, with its implementation authorized in national territory after the filing of petition to Anvisa.

5. Change/Inclusion of Manufacturing Location (Factory Unit)

This petition serves to change or include the manufacturer of a equipment or SaMD (manufacturing unit), changing only its address.

In the event of a change of address of the manufacturing unit or inclusion of a new manufacturing unit, it must be verified whether this new unit factory requires the presentation of the Good Manufacturing Practices Certificate Manufacturing for the new plant.

This change is considered to require approval, that is, change of greater health relevance, which deals with changes to be introduced in the registration process, being authorized in national territory only after technical documentary analysis and manifestation favorable from Anvisa.

6. Notification Change (risk class I and II)

This petition should be used for any change in Class I and II risk notification processes for equipment.

This change is considered to be immediately implemented, or that is, a change of medium health relevance, which deals with a change to be introduced in the notification or registration process, and its implementation authorized in national territory after protocolization petition to Anvisa.

7. Medical Software Notification Change (class of risk I and II)

This petition should be used for any change in

Software risk class I and II notification processes such as Medical Device - SaMD.

This change is considered to be immediately implemented, or that is, a change of medium health relevance, which deals with a change to be introduced in the notification or registration process, and its implementation authorized in national territory after protocolization petition to Anvisa.

8. Software change (new indications) and features)

This change includes changes involving updates to the equipment software versions or SaMD. In In some cases, software updates may occur due to changes already covered by other amendment subjects, in these cases, there is no need to petition two amendments. This amendment subject should only be used when the update is made to the software is due to changes not covered by other subjects.

With regard to software changes, it is understood that these include those that involve generating a new version of the project plan or changes to functionalities/indications of use.
changes to software versions with mere corrections are not susceptible to changes in registration information, except when are corrections to control some risk.

This change is considered to require approval, that is, change of greater health relevance, which deals with changes to be introduced in the registration process, being authorized in the territory national only after technical documentary analysis and manifestation favorable from Anvisa.

9. Change of trade name and/or denomination name/code (part number) of the commercial model,

component, part or accessory; or visual identity of the software

This subject should be used for name changes.
commercial equipment or SaMD, and system components

equipment, in the denomination of identification codes (part number) or commercial models of the equipment family or SaMD.

This change is considered to be immediately implemented, or that is, a change of medium health relevance, which deals with a change to be introduced in the notification or registration process, and its implementation authorized in national territory after protocolization petition to Anvisa.

10. Change due to Addition of EQUIPMENT in FAMILY Registration of Large, Medium and Small Equipment Port

This petition serves to include a new model in the registry of family of equipment or SaMD, not being allowed, in this petition, request changes to the technical specifications, trade name or commercial model of the equipment or SaMD already registered.

Only the inclusion of a new model in the family will be permitted equipment or SaMD when the initial petition, that is, the petition that originated the parent case, was initially granted as FAMILY OF EQUIPMENT OR SaMD. It is not possible, after the publication of the registry, migrate from equipment registry or single SaMD to registry of equipment family or SaMD.

This change is considered to require approval, that is, change of greater health relevance, which deals with changes to be introduced in the registration process, being authorized in the territory national only after technical documentary analysis and manifestation favorable from Anvisa.

11. Technical Change

Corresponds to changes related to the project of equipment or SaMD with regard to the technical characteristics of the same.

This change is considered to require approval, that is, change of greater health relevance, which deals with changes to be introduced in the registration process, being authorized in national territory only after technical documentary analysis and manifestation favorable from Anvisa.

12. Changing/Including Components in the System

This petition serves to include a new component in the registry of equipment system, regardless of the size of the equipment, does not being allowed, in this petition, to request a change in the specifications techniques, trade name or commercial model of the equipment already registered.

Only the inclusion of a new member in the family will be allowed of equipment when the initial petition, that is, the petition that originated the parent case, was initially granted as SYSTEM OF EQUIPMENT. It is not possible, after publication of the registration, to migrate from single equipment registration to system registration equipment.

This change is considered to require approval, that is, change of greater health relevance, which deals with changes to be introduced in the registration process, being authorized in the territory national only after technical documentary analysis and manifestation favorable from Anvisa.

13. Changing/Including Accessories

This petition serves to change or include accessories in the registry.

of equipment or SaMD (single product, family or system).

This change is considered to require approval, that is, change of greater health relevance, which deals with changes to be introduced in the registration process, being authorized in the territory national only after technical documentary analysis and manifestation favorable from Anvisa.

14. Change/inclusion/exclusion of legal manufacturer, without change in the manufacturing process; and/or exclusion of unit factory

This is a change applicable to equipment or SaMD in the which a change of legal manufacturer occurred, without change in manufacturing process. In this petition, modification/inclusion/exclusion is permitted from legal manufacturer (does not apply to inclusion/change to unit factory). Furthermore, only the exclusion of the manufacturing unit is permitted.

This change is considered to be immediately implemented, or that is, a change of medium health relevance, which deals with a change to be introduced in the notification or registration process, with its implementation authorized in national territory after filing petition to Anvisa.

15. Inclusion/Change of Sterilization Method or Reprocessing and validity

This is a petition that should be used to add or change:

- Sterilization methods for equipment provided sterile or that need to be sterilized before use; or
- Reprocessing methods for equipment that can/should be reprocessed for new use.
- Change in the validity of the sterilization expiration date

This change is considered to require approval, that is,

change of greater health relevance, which deals with changes to be introduced in the registration process, being authorized in the territory national only after technical documentary analysis and manifestation favorable from Anvisa.

16. Deletion of models, system components, accessories, parts, indication of use, method of sterilization

This subject should be used for deletion changes. models, system components, accessories, parts, indication of use, and sterilization method, both for equipment and SaMD.

This change is considered to be immediately implemented, or that is, a change of medium health relevance, which deals with a change to be introduced in the notification or registration process, and its implementation authorized in national territory after protocolization petition to Anvisa.

General Considerations

As established by RDC No. 751/2022, to petition the change in notification or medical device registration, the applicant must proceed with payment of the corresponding fee, if applicable, and submit the **declaration** listing the requested changes and others required documents, according to the subject requested. This statement must be signed by the company's legal and technical managers, where it is stated:

- The new version/date4 of the user manual, post-changes;
- The information being changed or added, informing the pages where this information was contained in the previous manual (inform previous version/date of the manual) and the

[4] The date of the manual corresponds to the date on which the document was approved within the System of Company quality.

pages where this information will be included in the new version of the manual.

Petitioning a particular change only allows the change of the item requested for registration (class III and IV). Any another change inserted, different from the requested change, will be disregarded. For example: if the petition filed is to change the equipment manufacturer, only the information relating to the manufacturer can be changed. If desired, in addition to changing the manufacturer, also change the design of the equipment, two petitions must be requested: change of manufacturer and technical change of equipment, each generating its own case number within the parent process.

As established by **PT Ordinance No. 511, of 30 September 2021,** override the chronological criterion for analyzing petitions relating to the same subject requested by the same interested party and that can be processed together.

For medical devices of risk class I and II, make all changes simultaneously, as long as they are properly identified in the declaration of change that is cited in RDC No. 751/2022.

Only those are subject to the Anvisa protocol changes considered to require approval or implementation immediate.

Those changes considered non-reportable are not protocol objects with Anvisa, and must be controlled by the quality system of the regularization holder and be incorporated into subsequent petitions.

Any non-reportable changes are classified as minor changes not classified as approval required or for immediate implementation, and also: changes to information that do not modify the design of the medical device; software bug fixes; non-technical changes such as images, formatting, layouts, symbols and text adjustments documents without increased risk; information updates Business Operating Authorization; contact changes (e.g. telephone numbers or postal address), technical assistance and website.

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Chapter V

Revalidation of Registration Medical Equipment and SaMD and others secondary petitions

Revalidation of Registration and other secondary petitions

The registration of medical equipment or SaMD is valid for 10 years, according to Resolution of the Collegiate Board - **RDC No. 751, of 15 September 2022,** counted from its publication in the Official Gazette. The its revalidation must, without fail, be filed within the period of one year to six months before its expiration, considering month and year, according to § 6, of art. 12 of Law No. 6,360/1976. Revalidations filed after or before this deadline will be rejected summarily.

Even if the revalidation is published in the Official Gazette before the effective expiration of the registration, there is no problem, since upon publication of the order granting revalidation, the validity period of the registration must be subsequent to the last day of the term of the registration granted or of the last revalidated registration, according to art. 2, § 2, of **Resolution No. 250, of October 20, 2004.** therefore, the revalidation will come into force, only, on the day after the registration expires, not existing, therefore, the possibility of "loss" of effective registration time.

To request registration revalidation, the following must be presented:

I. Medical Device Petition Form, duly completed, indicating in field 1 item 1.3 – Revalidation and informing, in the corresponding field, the process number, and the registration number you wish to revalidate;

II. INMETRO Certificate of Conformity (only for medical equipment subject to such certification 5);

III. Proof of Certification in Good Manufacturing Practices issued by ANVISA, updated. (The protocol of the application for Good Manufacturing Practices Certification will be accepted for effect of petitioning and analysis of revalidation petitions of registration); and

[5] Verify whether, at the time of registration revalidation, the equipment was included in the scope of INMETRO compliance certification.

IV. For imported medical devices: declaration issued by the legal manufacturer, consularized or apostilled, written in Portuguese, English or Spanish or accompanied by translation sworn, for a maximum of two years when there is no express validity indicated in the document, authorizing the company requesting to represent and market its products in Brazil.

NOTE: The name and commercial model of the product, indicated in such documents must be identical to those contained in the application process. equipment registration or SaMD.

When revalidating the registration, no type of change. Revalidation is granted as the equipment or SaMD was registered. Any desired change must be requested by the party, according to the guidelines in Chapter IV of this Manual.

In case of **automatic revalidation, which is also published in the Official Gazette of the Union,** the validity period of the registration, automatically revalidated, is successive to the last day of the term of the registration granted or the last registration revalidated (art. 2, § 4 of the Resolution No. 250, of October 20, 2004) and its duration is subject to the future decision to be made by the administration, according to the conclusion of the analysis to be carried out under the terms of health legislation (art. 2, § 5 of Resolution No. 250, of October 20 2004).

The procedures for filing the request for revalidation follow the same procedures for requesting the registration, as presented in Chapter I of this Manual.

Products subject to the notification regime are exempt from revalidation.

Addendum

As established by **Resolution RDC No. 204, of 6 July 2005,** the addendum is any and all additions to the process, not formally required, which is limited to improving the knowledge of the object of the process, not resulting in a manifestation different from the one requested.

The addendum is used to send any document or communication that the company wishes to attach to the parent case or petition secondary. This petition is exempt from fees and is not subject to publication. in the Official Gazette, having only an informative and complementary character. The petition must be accompanied by a document explaining the reason for the amendment in question. The amendment may also be used for information changes prior to process analysis.
In this case, it will be analyzed together with the open petition to for which it is intended. This petition must be filed with Anvisa, as per current procedure for that subject code.

Amendment - Request for optimized analysis as per Instruction Normative IN No. 290/2024

As established by **Normative Instruction No. 290, of 4 April 2024,** the optimized procedure was implemented for purposes for the analysis and decision of petitions for registration of medical devices, by through the use of analyses carried out by the Authority Equivalent Foreign Regulator (AREE).

This Amendment must be filed by the companies applicants for the equipment registration application or SaMD who wish to that the analysis and decision of the registration request be optimized by the technical area. We note that this procedure only applies to registration requests, not being applied to notification requests, alteration or revalidation of equipment or SaMD.

The Amendment Petition – Request for Optimized Analysis according to Normative Instruction IN No. 290/2024, must be instructed with the following documents:

I. declaration available in the Annex to the Normative Instruction, duly presented with the electronic signatures of the legal and technical managers;

II. document proving registration or authorization issued by AREE, which must refer to the medical device essentially identical to what is intended to be registered in the territory national and include information regarding indications of use/intended use and manufacturers, and must be consularized or apostilled, and accompanied by a sworn translation when not written in Portuguese, English or Spanish;

and

III. instructions for use of the medical device adopted and in force within the jurisdiction of AREE, accompanied by translation sworn when not written in Portuguese, English or Spanish.

This petition is exempt from fees and is not subject to publication. in the Official Gazette, having only an informative and complementary character. This petition must be filed with Anvisa, according to the procedure in effect for that subject code.

Cancellation

The holder of notification or registration of a medical device that intend to no longer sell it in the Brazilian market must petition your cancellation. The reason for cancellation must be stated.

This is a fee-free petition and must be filed with Anvisa, according to the procedure in force for this subject code.

The cancellation petition must consist of:

I. Document stating the reason for cancellation;

Cancellation is a petition subject to approval by Anvisa, whose opinion is published in the Official Gazette. Cancel the registration or notification of a medical device with Anvisa does not exempt the company (manufacturer or importer) of the technical and legal responsibilities associated with products that were placed on the market during the validity period of the registration. Even if the registration or notification is canceled, the provisions of Law No. 8,078/90 (Consumer Protection Code) apply.

Transfer of Ownership

The transfer of ownership serves to transfer the ownership of the registration of one company to another. It can only be petitioned in cases of merger, spin-off, incorporation, or commercial operation, with or without changing the company's corporate name, as long as the original technical requirements of the equipment or SaMD already registered/notified. The terms and conditions necessary for the transfer of ownership, can be found in **Resolution - RDC No. 903, of September 6, 2024.**

Companies must update data relating to the registration of Equipment or SaMD, through a transfer petition ownership and cancellation of registration, whenever it occurs corporate or commercial transaction that involves a change in ownership of product registration.

Petitions for transfer of ownership and cancellation registration must be filed in parallel with Anvisa, respectively by the successor and succeeded companies, within a period of up to one hundred and eighty days. The two petitions, although in separate proceedings, will be analyzed and published jointly in the DOU. Thus, in DOU in which the transfer of ownership is published will also be published the cancellation of the registration.

Equipment or SaMD subject to notification are not subject to transfer of ownership, and the successor company must make a new notification.

The validity of the registration remains exactly the same, regardless from the date of publication of the transfer of ownership, although it occurs change in registration number, to comply with the training process of registration number presented in the Introduction of this Manual.

The petition for transfer of registration ownership must be instructed with the following documents:

I. duly completed and signed petition form;

II. proof of payment or exemption from the Tax Health Surveillance Inspection - TFVS, through the Union Collection Guide - GRU;

III. declaration of the corporate or commercial transaction carried out, as provided in Annex I of Resolution **RDC No. 903, of September 6, 2024;** and

IV. copy of the operating license or health permit issued by the competent body, duly updated after the corporate or commercial transaction.

Publication Rectification

The rectification of publication must be requested whenever the company observes discrepancies in information between what is presented in the documentation of the request for registration or notification, and what was published in the Official Gazette (e.g.: commercial name of the equipment, corporate name of the manufacturer, models, origin of the product, etc.). Exception is made with relation to the health classification (rule and class) and the technical name of the equipment, because in cases where the company informs this data erroneously, Anvisa corrects them without the need to issue technical requirement to the company.

The petition for rectification of publication must be included in the following documents:

I. Justification of the reason for the rectification;

II. Documents proving that the information presented in the registration/notification application documents differs those published in the Official Gazette.

There are 2 (two) types of Rectification petition; the one used to request a correction of a publication error by ANVISA, which is exempt from fees. And the one used to request correction of an error caused due to incorrect information given by the company in the original petition, to which involves fee.

Presentation of new Certificate of Conformity INMETRO

This petition was created exclusively for the presentation of new INMETRO certificate of conformity for the equipment, always that the certificate presented to Anvisa is updated in time of granting of registration/notification or change of registration/notification. These updates may be due to: change of the OCP, change of versions of technical standards, inclusion/exclusion of technical standards, etc.

The petition for Submission of a new Certificate of Conformity INMETRO must include the following documents:

I. New INMETRO certificate of conformity for the equipment;

II. Declaration, signed by the legal and technical representatives, indicating the reason for presenting a new certificate of compliance for the equipment.

It is important to highlight that, in case of updating the Certificate of Conformity has already been presented through a secondary petition (amendment, revalidation), there is no need for the company register the subject “Presentation of new Certificate of Conformity INMETRO”.

Declaration of intent to keep the line active

Reconditioning

This petition was created exclusively to comply with Resolution RDC No. 579, of November 25, 2021. For equipment that have been discontinued by the manufacturer, but they want to maintain the line of active production for refurbished products, the company must file this matter linked to the process number of the registration/notification of the equipment.

Remembering that refurbished equipment is equipment or in vitro diagnostic instrument resulting from an industrial process carried out by the original manufacturer of the new product, by company belonging to the same corporate group or by a qualified company and authorized by the original manufacturer specifically for this process, involving, when necessary: a) repair, rework, replacement of worn parts and software/hardware upgrades of used products, in extent necessary to determine the state of conservation of their components, parts and pieces; and b) the replacement of components critical and/or worn by new or refurbished components,

so that the resulting refurbished good presents conditions of

operation, functioning and performance equivalent to the specifications of the original new property, including in terms of warranty.

Refurbished equipment should not be confused with equipment sent for technical assistance. The assistance technique is the maintenance or repair of a finished product in order to return it to its specifications to the **same customer.** Now the refurbished equipment will be repaired and sold again for the Brazilian market as “new” equipment.

The petition for Declaration of Intention to keep the line active Reconditioning must be included in the following documents:

I. Declaration by the company holding the registration/notification, signed by the legal and technical managers, indicating the models of the equipment that will be submitted to the process reconditioning;

II. Legal manufacturer's statement stating which manufacturing unit will carry out the reconditioning activity. Note: If the manufacturing unit is not properly regularized with the equipment registration/notification, the company must request change of registration/notification. Subjects: 80220 EQUIPMENT – Registration change – Approval required – Change/ inclusion of manufacturing location unit factory or 80270 EQUIPMENT – Change notification Class II – Immediate implementation or 80224 EQUIPMENT – Class I notification change – Immediate implementation.;

III. For equipment with risk class III or IV, present the Valid Good Manufacturing Practices Certificate - CBPF issued by ANVISA in accordance with the established requirements of RDC No. 751/2022;

IV. Model of the indelible equipment label, indicating that the device is refurbished and the Year that the reconditioning was carried out, in accordance with article 18 of RDC No. 579/21.

Medical Device Petition Form (Class III and IV)

The Medical Device Petition Form contains the minimum information necessary for the equipment or SaMD can be identified as to its type, name and commercial model, manufacturer, company holding the registration, responsible parties, origin and sanitary framework. Its model is available on the portal from the Anvisa: https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/produtos-para-a-saude/formularios-1

You must always be aware of the information that is indicated in this Form, as these will serve as references for all other documents in the process. For example, if the trade name of the equipment indicated on the form is “NAME A, MODEL m-PLUS”, then this will be the trade name and model commercial that must appear in ALL other documents of the process. Not even small variations, such as “NAME A, MODEL PLUS-m”, are allowed. It is understood that **MODEL m-PLUS IS NOT SAME AS PLUS-m MODEL!**

The information contained in this form is practically identical to those required to complete the electronic petition (see Chapter I). Therefore, it is suggested that the Form be completed before, to provide subsidies in filling out the petition electronic.

Copy of the Form, duly completed and signed by the legal and technical responsible, must be attached to each petition filed, whether it is a primary or secondary petition. The indication of the The need to send the form must be observed in Chapters II, III and IV of this Manual.

Below, you will find details of each of the FFIPM items:

1. Process Identification

1. Identificação do Processo	
1.1 Identificação do Processo (n°)	
1.2 Número do Registro do Produto (Para petições secundárias)	
1.3 Código e Descrição do Assunto da Petição	

In item 1.3, the corresponding type of petition must be informed. the documentation accompanying the Form. Primary petitions correspond to items 1.1, and item 1.2 for secondary petitions.

This form only applies to equipment or SaMD subject to registration. Products subject to notification, as well as your changes are made using a specific form.

The “Petition Subject Code and Description” fields must be completed for all petitions, whether primary or secondary. The subject code and its description must be obtained from the list of Subjects, available on the Anvisa website at: https://consultas.anvisa.gov.br/#/consultadeassuntos/

2. Registration Holder Data (National Manufacturer) or Importer)

2. Dados do Detentor do Registro (Fabricante Nacional ou Importador)	
2.1 Razão Social	
2.2 Nome Fantasia	
2.3 CNPJ	
2.4 Endereço	
2.5 Cidade/UF	
2.6 CEP	
2.7 Telefone (com código de área)	
2.8 E-mail	
2.9 Sítio Eletrônico (URL)	
2.10 Autorização de Funcionamento na Anvisa (nº)	

The information presented in this item must always correspond to the registration information of the company requesting the registration, which are constant in the publication of your AFE – Authorization Company Operating Instructions - issued by Anvisa.

3. Origin of the Medical Device

3. Origem do Dispositivo Médico	
☐ Brasil	
☐ Externa	
ATENÇÃO: se houver mais de um fabricante legal, estes devem ser do mesmo grupo fabril e a empresa deverá apresentar documento comprobatório.	
3.1 Identificação do Fabricante Legal:	
1. Nome:	
Endereço – Cidade e País:	
Número da AFE (somente para fabricante nacional)	
2. Nome:	
Endereço – Cidade e País:	
Número da AFE (somente para fabricante nacional)	
3.2 Identificação da(s) Unidade(s) Fabril(is):	
1. Nome:	
Endereço – Cidade e País:	
Número da AFE (somente para fabricante nacional)	
2. Nome:	
Endereço – Cidade e País:	
Número da AFE (somente para fabricante nacional)	
3. Nome:	
Endereço – Cidade e País:	
Número da AFE (somente para fabricante nacional)	

In this field the company must indicate whether the product is of origin National or External (imported).

3.1 Legal Manufacturer Identification

This item provides information about the Legal Manufacturer of equipment or SaMD, that is, the person responsible for the product, formally recognized by the health authority of your country of origin origin. Accurate information about this data is extremely important, especially for imported products, as it is essential data.
to facilitate customs clearance of the equipment or SaMD. It is not allowed entry into the country of products whose origin is countries with manufacturers other than those declared in this field of the form.

In this field you must enter the name of the legal manufacturer of the product, in Brazil (national product) or abroad (imported product), and your address.

For legal manufacturers in Brazil, the AFE number granted by Anvisa must be provided, with the activity of manufacturing related products (medical devices).

The manufacturer declared in this field must correspond to the legal manufacturer informed in ALL other documents of the process (label, indelible label, instructions for use, technical dossier etc.).

3.2 Identification of the Actual Manufacturer (Factory Unit)

This field must include the company responsible for the manufacturing of the product, which may be the same legal manufacturer, or, in cases of partial or total outsourcing, another authorized company by the legal manufacturer. Depending on the type of partial outsourcing of the product, there may be more than one manufacturing unit, which must be indicated in this field. However, only the following can be indicated: manufacturing unit(s) if they meet the definition of a manufacturing unit according to **Resolution RDC No. 687, of May 13, 2022.**

For the manufacturing unit located in Brazil, the following must be informed:

AFE number granted by Anvisa, with manufacturing activity

related (medical devices).

4. Medical Device Data

4. Dados do Dispositivo Médico	
4.1 Nome Técnico	
4.2 Código do Nome Técnico	
Consulta de nomes técnicos disponível em: https://consultas.anvisa.gov.br/#/nomes-tecnicos/	
4.3 Regra de Classificação	
4.4 Classe de Risco do Dispositivo Médico	☐ Classe III ☐ Classe IV
4.5 Nome Comercial	
4.1.6 Modelo(s) Comercial (is)	
4.1.6.1 Para Família: Informar os códigos referentes aos modelos comerciais, quando aplicável. 4.1.6.2 Para Sistema: Informar códigos referentes ao sistema bem como de seus componentes, quando aplicável. 4.1.6.3 Para Conjunto (kit, bandeja ou set): Informar códigos referentes ao conjunto bem como de seus materiais e respectivas partes, quando aplicável.	
4.1.7 Acessórios – produto destinado pelo seu fabricante a ser utilizado em conjunto com um ou vários dispositivos médicos específicos, para permitir ou ajudar de forma específica e direta que o(s) dispositivo(s) médico(s) sejam usados de acordo com a finalidade pretendida (se aplicável).	

4.1 Technical Name

The technical name is the name commonly used in the “medical field”

to identify the equipment or SaMD. Do not confuse the technical name

with the commercial name of the product. The list of technical names can be found

available, to consultation, on the Anvisa website at:

https://consultas.anvisa.gov.br/#/nomes-tecnicos/

It may happen that the technical name of the equipment or SaMD, which

the company wishes to register does not exist on the aforementioned list. In this case, the

company must use the technical name that most closely resembles its

equipment or SaMD. When the process reaches the technical area,

Anvisa, it will be verified whether there really is no technical name

corresponding name, if it does not exist, it will be created by the technical area. It is Anvisa's

prerogative to create and define the technical name that will be applied

to the product.

4.2 Technical Name Code

The identification code is the code corresponding to the name technician indicated in the list of technical names already mentioned.

4.3 Classification Rule

This item on the Form corresponds to the framework of the equipment or SaMD. The equipment or SaMD must be classified in accordance with its rule, as per the provisions of Annex I of the Resolution RDC No. 751/2022. Annex C of this Manual contains a medical equipment and SaMD classification guide.

It is Anvisa's prerogative to determine whether the rule conferred by company to its product, is correct.

4.4 Product Risk Classification

This item on the Form corresponds to the framework of the equipment or SaMD. The equipment or SaMD must be classified according to its risk class (in the case of class III registration or IV), as per the provisions of Annex I of Resolution RDC No. 751/2022. In Appendix C of this Manual you will find a classification guide for medical equipment and SaMD.

It is Anvisa's prerogative to determine whether the class conferred by company to its product, is correct.

4.5 Business Name

Still in item 4, the commercial identification of the equipment. Corresponds to the name with which it will be sold in the Brazilian market. This item consists of two fields:

• **Trade name**

It is the name by which the company, requesting registration, wants its equipment or SaMD to be known and marketed in the market. Brazilian. It does not necessarily need to have the technical name incorporated in this identification, although the company, in many cases, chooses to incorporate it to facilitate the identification of your equipment or SaMD by users.

The trade name indicated must correspond to the name commercial that will appear in ALL other documents in the process (labels, instructions for use, technical dossier, certificates of conformity, test reports, etc.).

An exception allowed is in relation to imported products that will be marketed in Brazil under a different trade name than that practiced in your country of origin. In this case, together with the CLC – Free Trade Certificate, a declaration of the manufacturer of the product, indicating the name under which your product will be marketed in Brazil. It should be possible to verify in this declaration the correlation between the commercial name of the product abroad and what will be practiced in Brazil. The same is expected of the product models, as explained below.

• **Commercial Model(s)**

The commercial model corresponds to the versions or variations of the equipment or SaMD that you wish to register. It must always be completed for Equipment Family Registration cases (see Chapter 1 of this Manual), where for the **SAME TRADE NAME there is more than one MODEL (variation of the same equipment or SaMD),** with its own identification that differentiates it from the others family models (e.g., A, B, AB, FULL, etc.). The indication of equipment family classification must comply with the requirements established in Resolution - RDC No. 542/2021.

Single product registrations must also have indications in this field, the product model. For example:

ÿ Commercial name of the Product: **YYYYYYYYY Equipment**

ÿ Product Commercial Model: **X1**

The choice of name and commercial model of equipment is free for the company requesting registration. However, Anvisa may interfere in the choice of the name and/or commercial model of the product, in cases of misinterpretation by users, as established in article 5 of Law No. 6,360/1976.

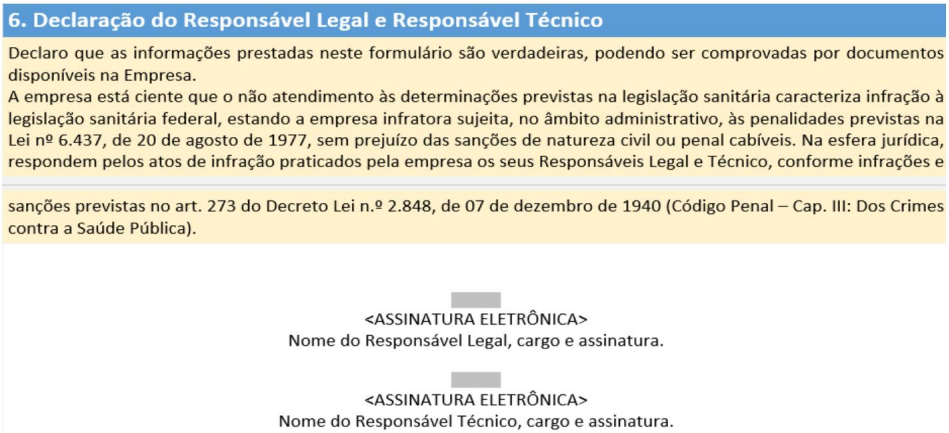
5. Legal and Technical Responsibility

5. Responsabilidade Legal e Técnica	
Nome do Responsável Legal:	
Cargo:	
Nome do Responsável Técnico:	
Conselho de Classe Profissional:	
Número Conselho/UF:	

The penultimate item of the Form identifies the legal and technician for the equipment or SaMD in Brazil. The names provided these items must correspond to the professionals indicated in the AFE approved. The position indicated for each person in charge must correspond to the position he occupies within the hierarchical structure-organizational structure of the company.

For the technical manager, the following must also be informed: Professional Class Council, along with the council number and region.

6. Declaration of the Legal Guardian and Responsible Person Technical



6. Declaração do Responsável Legal e Responsável Técnico

Declaro que as informações prestadas neste formulário são verdadeiras, podendo ser comprovadas por documentos disponíveis na Empresa.
A empresa está ciente que o não atendimento às determinações previstas na legislação sanitária caracteriza infração à legislação sanitária federal, estando a empresa infratora sujeita, no âmbito administrativo, às penalidades previstas na Lei nº 6.437, de 20 de agosto de 1977, sem prejuízo das sanções de natureza civil ou penal cabíveis. Na esfera jurídica, respondem pelos atos de infração praticados pela empresa os seus Responsáveis Legal e Técnico, conforme infrações e

sanções previstas no art. 273 do Decreto Lei n.º 2.848, de 07 de dezembro de 1940 (Código Penal – Cap. III: Dos Crimes contra a Saúde Pública).

<ASSINATURA ELETRÔNICA>
Nome do Responsável Legal, cargo e assinatura.

<ASSINATURA ELETRÔNICA>
Nome do Responsável Técnico, cargo e assinatura.

Finally, both those responsible, technical and legal, must sign the form, in which all information is stated as true presented in this document.

The applicant must submit digitally signed documents by legal and technical managers, as required by regulations applicable or when indicated in the list of instruction documents procedural. In digitized documents, the electronic signature qualified, which uses a digital certificate issued by ICP-Brasil, must be used. In native-digital documents, a signature must be used qualified electronics, which uses a digital certificate issued by the ICP-Brazil, or advanced electronic signature, such as gov.br https://www.gov.br/governodigital/pt-br/assinatura-eletronica . It is recommended that the applicant confirm the validation of the signatures of the Legal and Technical Managers through the link https://validar.iti.gov.br/.

Annex B

Essential Device Security and Performance Requirements
Doctors

The applicable essential safety and performance requirements to medical equipment and SaMD, which must be met, are indicated in Resolution - **RDC No. 848, of March 6, 2024.**

To establish which requirements are applicable, an assessment (Risk Management) based on the inherent characteristics of the product and its production process must be carried out. The requirements essential indicate the basic controls and care that must be observed by the manufacturer, in the design and manufacture of the product and are grouped as follows:

- ÿ Chemical, physical and biological properties;
- ÿ Infection and microbial contamination;
- ÿ Environmental and manufacturing properties;
- ÿ Products with measurement and diagnostic functions;
- ÿ Radiation protection;
- ÿ Requirements for medical equipment connected to, or equipped with an electrical power supply;
- ÿ Protection against mechanical risks;
- ÿ Protection against risks associated with energy management and substances to the patient;
- ÿ Protection against risks associated with self-service equipment administration;
- ÿ Information provided by the manufacturer (precautions, warnings, indications for use, instructions for use, etc.);
- ÿ Performance evaluation presenting, evaluation and clinical investigation of the medical device.

It is up to the manufacturer to identify, among the essential requirements, which are relevant to your product, documenting the justifications to exclude those considered irrelevant. Anvisa, during the petition evaluation process, will verify the justifications presented, and may request additional information, if the presented are not satisfactory.

The essential safety and performance requirements **GUIDE** the manufacturer regarding the possible risks, which require be controlled. **This does not mean that only the risks indicated in this Manual exist and that others, although not indicated here, cannot and should not be managed. It is the manufacturer's EXCLUSIVE responsibility to analyze, evaluate and control (when necessary) the risks associated with its product.**

Therefore, all associated risks, whether indicated or not in this Manual, must be adequately analyzed, evaluated and controlled (when necessary) by the manufacturer, considering the entire **product life cycle.** Therefore, the manufacturer must establish a Risk Management for each of your products, so you can determine the associated risks and the best ways to control them risks. In this way, the definition of which risk factors are relevant and which are excluded, must be justified by the results of the Risk Management carried out by the manufacturer. Risk Management Medical device risk should be performed based on the prescriptions of the technical standard ABNT NBR ISO 14971, as this is the national normative reference that deals with the topic in question.

With the risk factors identified, the following must be verified: correlation of these with each of the items of Resolution - RDC No. 848/2024. The table below shows some of the risk requirements that must be verified:

ITEM	Fatores de Risco	Requisitos Essenciais de Segurança Associados aos Fatores de Risco (RESOLUÇÃO - RDC nº848/24)[1]
1	Toxicidade	Art. 20
2	Inflamabilidade	Art. 20 / Art. 34
3	Incompatibilidade biológica	Art. 20 / Art. 68
4	Contaminantes residuais	Art. 21 / Art. 66
5	Incompatibilidade com outros materiais, substâncias ou gases	Art. 69
6	Infecção e contaminação microbiana	Art. 24 / Art. 25 / Art. 26 / Art. 27 / Art. 28 / Art. 29 / Art. 30 / Art. 31
7	Incompatibilidade de combinação ou conexão com outros produtos	Art. 32
8	Instabilidade e limitações de características físicas e ergonômicas	Art. 33 / Art. 38 / Art. 40 / Art. 41
9	Sensibilidade a condições ambientais	Art. 29 / Art. 33
10	Interferência recíproca com outros produtos	Art. 33 / Art. 47 / Art. 48
11	Impossibilidade de calibração e manutenção	Art. 35
12	Imprecisão ou instabilidade de medida	Art. 54
13	Controle inadequado das radiações	Art. 56 / Art. 58 / Art. 59
14	Proteção inadequada das radiações	Art. 60 / Art. 61
15	Controle inadequado de energias ou substâncias administradas	Art. 76 / Art. 77
16	Proteção inadequada de energias ou substâncias administradas	Art. 76
17	Inteligibilidade de sistemas digitais programáveis	Art. 49 / Art. 50
18	Instabilidade de sistemas digitais programáveis	Art. 52
19	Falhas da fonte de energia para funcionamento	Art. 44
20	Inadequação de alarmes para alerta	Art. 45 / Art. 46
21	Susceptibilidade a choques elétricos	Art. 47

(1) The correlation presented in this table is for guidance only. It is possible that the items in Resolution - RDC No. 848/24 have a direct or indirect correlation with more than one risk factor presented, and it is up to the manufacturer to carry out a detailed analysis to verify the correlation that best suits their needs. product.

Proof of compliance with the essential requirements should not be limited to a statement from the manufacturer stating that the item has been met. For each risk factor identified, the manufacturer must effectively prove compliance with the provisions of the Resolution - RDC No. 848, of March 6, 2024, clearly indicating which actions were taken so that the item has been met, taking as a basis justification of the results of the product's Risk Management. Each action taken must be adequately validated so that it remains ensuring compliance with the essential requirements, in order to controlling the overall residual risk, keeping it within the risk limits considered acceptable.

Where relevant, certificates, reports, test reports, verification and validation results, process control, information on design features, comparative studies, specifications of raw materials, among others, can be presented as part of the proof of compliance, provided that, the relationship of the document to the risk can be clearly identified that it proposes to control.

All documents presented to prove the compliance with the essential requirements must be supported by technical-scientific to be accepted as valid justification. For example, if compliance with a specific item can be proven through specification and control of raw materials, must be clearly indicated which technical-scientific references (articles academics published in indexed journals, technical standards Brazilian or international etc.) that indicate such specification for the intended function; or, if these do not exist, what studies and research were carried out by the company which resulted in the specification in question. A summary of the results of these studies and research should be presented in the justification.

However, often the mere adequate specification of a raw material is not sufficient to guarantee control of the risk that this imputes to the product, since the manufacturer must have guarantees that the raw material will be purchased and received as specified, will arrive to the production line with the required specifications and the process will end productive within the established specifications, respecting the changes expected and necessary as a result of the process productive. Therefore, procedures involving project specification, supplier qualification, purchasing control, and testing receipt, storage and handling of raw materials, testing finished product, among other related products, must be referenced as part of proof of attendance.

It is worth noting that there is no need to send a copy of the company procedures and work instructions, as it is sufficient that these are available to health surveillance whenever necessary necessary. Reference these documents with a description summary of what is covered in them and what their participation in the final objective, which is risk control, reflecting in the final quality and safety of the product is sufficient. If Anvisa deems it necessary, it will request copies of such documents or carry out an evaluation of the same during a Good Manufacturing Practices inspection, *in loco* at the manufacturer.

Annex C

Guidelines for the Sanitary Classification of Medical Devices

The following guidelines are part of a group of rules related to issues of sanitary classification of devices doctors, defined in accordance with the provisions of Resolution - RDC Anvisa No. 751/2022.

This Annex is based on the Medical Device Coordination Group Document – MDCG 2021-24, version October/2021, established by Article 103 of European Regulation 2017/745, however, amendments significant changes were incorporated so that the text can reflect the health classification of MEDICAL EQUIPMENT OR SaMD in the context of Brazilian Health Legislation.

THE INFORMATION CONTAINED IN THIS ANNEX DOES NOT NECESSARILY REFLECT THE HEALTH FRAMEWORK OF MEDICAL DEVICES OTHER THAN THESE MEDICAL EQUIPMENT OR SaMD. In this way, the information presented here are solely for registration purposes or notification of medical equipment and SaMD.

Purpose and Logic of the Sanitary Classification of Equipment Doctors or SaMD

During the structuring of the health regulation of the devices doctors, it was found that it is not economically viable, nor justifiable in practice, subject all medical devices to the most rigorous sanitary controls available. Therefore, a system was structured control graduate.

In such a system, the level of control corresponds to the level of potential hazard inherent in the type of product. Consequently, the established medical device classification system, classifies medical devices according to a roadmap appropriate to the health framework.

In this sanitary framework model, manufacturers must assess which risk class and classification rule your product falls into inserted. In order to prevent the framing from being carried out in a random, which would make the framing process quite complex, considering the wide range of medical devices, it was decided if a health framework system is defined in which products can be classified, based on pre-defined rules and risk classes.

It was found that structuring framing rules based on the technical characteristics of medical devices was impossible, due to the diversity of products and the constant increase technological sector. However, the human body is an element relatively immutable in the “medical device X human being” relationship. In this way, the concept of framing was based, essentially, the potential hazards related to the indication for use, the consequences of possible product failure, and the technology used. This approximation, in turn, allows the use of a small selection of criteria that can be combined in various ways: duration of contact with the body, degree of invasiveness and local versus systemic effect.

It is recognized that although existing rules classify adequately the vast majority of existing products, a number small of products can be found on the dividing line between two rules, because of their nature or unusual situations to which are submitted. In these cases, the classification will be in the rule that present the highest risk class.

The registration/notification holder (manufacturer or importer) must first identify whether your product is equipment medical device, accessory to a medical device, or a SaMD.

Basic definitions:

Classification rules are based on related deadlines the duration of contact with the patient, the degree of invasiveness and the part of the body affected by the use of the product. These terms are defined in the Glossary of this Manual and reproduced below, together with some additional guidance.

DURATION:

ÿ TRANSITORY USE - use normally carried out continuously for less than 60 (sixty) minutes.

ÿ SHORT TERM USE - use carried out normally in a continuous for a period between 60 (sixty) minutes and 30 (thirty) days.

ÿ LONG TERM USE - use carried out normally in a continuous for a period exceeding 30 (thirty) days.

THE CONCEPT OF CONTINUOUS USE:

The concepts of duration such as TRANSITORY, SHORT TERM and LONG TERM are defined in terms of continuous use. Continuous use must be understood as a REAL, uninterrupted USE for the INTENDED PURPOSE. For example, a blood pressure monitor can be used on the same patient during a medical procedure that may last several hours. However, uninterrupted use for the intended purpose indicated, that is, measuring the pressure, normally does not last more than a few seconds at a time. Consequently, a device pressure is a product for temporary use.

However, where use of a product is interrupted by a short period (for example: stopping an infusion pump for replacement) of the equipment) or replaced by another identical product (for example: replacement of a cardiac pacemaker), this will be considered a extent of continued use of the product.

INVASIVITY:

INVASIVE MEDICAL DEVICE :

Any device that partially or totally penetrates the body, either through one of its holes or through its surface.

BODY ORIFICE :

Any natural opening of the body, as well as the cavity ocular, or any permanent artificial opening such as a stoma.

SURGICALLY INVASIVE MEDICAL DEVICE:

Invasive device that penetrates the body through its surface, including through the mucous membranes of the orifices bodies, within the scope of a surgical intervention; and device that enters the body by a route other than a bodily orifice.

For the purposes of this Manual, products that penetrate the body through a natural orifice or cavity are not considered as surgically invasive products. However, it should be noted that, in case where there is a surgically created stoma, for example, the used in colostomy in ileostomy or permanent tracheostomy, for the purposes of applying this Manual, are considered as a hole natural of the body. Consequently, the products introduced into such stoma are not surgically invasive. However, an opening surgically created to allow access to the circulatory system, on the contrary, it should not be considered as "a natural orifice of the body". Products introduced into such an opening are surgically invasive.

Any product that, in whole or in part, penetrates the body, through a natural body orifice or through the surface of the body is an invasive product. A surgically invasive product involves

whenever it enters through an artificially created opening. This it may be a large opening, such as a surgical incision, or it may be an opening of a sting created by a needle-like electrode.

A product that delivers energy to the body should not be considered invasive if only the energy penetrates the body and not the product itself. Energy itself is not a product and, consequently, it cannot be classified. Only the product that generates the energy must be classified. However, if a medical device administers a substance, and whether it is a pharmaceutical or a another medical device, the substance in question must be evaluated individually, considering the specific applicable health legislation the same.

IMPLANTABLE MEDICAL DEVICE:

Any device, including those that are partially or wholly absorbed, intended to be introduced completely into the human body; or to replace an epithelial surface or the ocular surface, by means of clinical intervention, and is intended to remain in this location after the intervention, or even one intended to be partially introduced into the human body through clinical intervention and to remain in this place after the intervention for a period of at least 30 days.

The product is indicated to be partially introduced into the body human with surgical intervention and indicated to remain in place after the procedure for at least 30 days, it is also considered an implantable product.

One of the key elements in defining what a product is implantable is the concept of "procedure". Thus, a product implantable must remain in the patient after the procedure. A "procedure" includes the surgical act during which the implant is placed in the body, and the associated post-operative care. The "procedure" does not extend to the completion of therapeutic treatment, for example, the removal of an implant should be considered another "procedure". Thus, an implantable infusion pump used to

chronic pain control is an implant, even if it is removed after patient healing. In this case, placing the infusion pump implantable and its removal are two different surgical procedures

Some partially implemented products are considered implants. For example, if a surgical procedure is performed with the aim of placement of a cardiac pacemaker electrode in the body and this remain in the patient for at least 30 days after the procedure, the said electrode will be considered an implant. However, an electrode or other active product, which is removed before 30 days is not a implant.

ACTIVE MEDICAL DEVICE:

Any device whose operation depends on a source of energy not generated by the human body for this purpose, or by gravity, and which acts by changing the density or by conversion of this energy, except those intended to transmit energy, substances or other elements between an active device and the patient without producing any significant change.

However, those that use energy directly generated by the human body or by the force of gravity, even though they act by converting these energies into other types of energy. For example, the ECG electrode that Its operating principle is based on the conversion of the cardiac activity signal (ionic current) into an electrical signal (current electrical), through a physical-chemical reaction at the electrode-electrolyte, is not considered an active device. Considering that the "energy to be converted" is energy generated by the human body (sign of cardiac activity), the product in question is not classified as an active medical device.

Medical devices indicated to transmit energy, substances or other elements between an active medical device and the patient, without any significant changes, are not considered active medical devices. The concept of "significant changes" includes changes in the nature, level, and density of energy. For example, the electrical resistance in a connecting cable of a medical equipment, which causes small changes between input and the energy output (energy loss due to the *Joule Effect)* does not promote "a significant change" in the transmitted energy, to the point of consider the cable as an active medical device.

"Energy conversion" includes the conversion of energy into product or at the interface between the product/fabrics or in the fabrics. For example, the electrodes used in electrosurgical equipment for tissue cutting or cauterization are active medical devices because its operation depends on the energy supplied by a generator and its action is achieved by converting electrical energy into thermal energy in the tissue. That is, unlike the ECG electrode, which converts energy coming from the human body into electrical energy, the electrode to electrosurgery converts electrical energy into thermal energy.

As explained, the direct application of energy from the human body does not make a product "active" unless that energy is stored in the product for subsequent release. For example, the energy generated by human muscle and applied to the piston of a syringe, which causes a substance to be infused into the patient, does not makes the syringe "an active product". However, if a system application of substance depends on the manual winding of a spring that is subsequently released to apply it, then the product that incorporates the spring is "an active product". In this case, it is observed that the product makes use of the elastic potential energy, stored in the spring, to carry out your activity.

Medical devices that use gases or vacuum, stored as an energy source, are considered as active products. For example: vacuum-powered suction pumps,

dental micromotors driven by gas compressor,
among others.

Heating/cooling products intended to release only stored thermal energy are not active products because do not act by converting energy. However, the products of heating/cooling that act by chemical action (e.g., endothermic or exothermic reaction) or electrical are active products, a since they are converting chemical or electrical energy into energy thermal.

The radioactive sources indicated to deliver the radiation ionizing devices are considered active medical devices unless that are classified as radiopharmaceuticals or implantable radioactive sources.

ACTIVE IMPLANTABLE MEDICAL DEVICE:

Implantable active medical devices correspond to all active medical devices intended to be introduced wholly or partially in the body, by surgical or other means medical act, and which are intended to remain on site after the procedure.

Considering the “deployable” and “active” characteristics of a medical device, it is concluded that:

- ÿ A hydrocephalic valve intended for the control of hydrocephalic pressure is not considered an active medical device. implantable, even if the adjustment of the same can be carried out by electromagnetic means. Although the product in question is implantable, is not characterized as active, since the medical function of the product, relief of hydrocephalic pressure by drainage of cerebrospinal fluid, is not exercised by means active, that is, by the conversion of energy. Therefore, the product is, only, implantable.

- ÿ An implantable infusion pump intended for the administration of medicines through a previously energy stored (battery, gas, etc.) is an active medical device implantable;
- ÿ An intravascular catheter that contains a fiber-optic catheter connected to an external light source, intended to measure a certain characteristic of blood, it is not considered a device active physician. Although every system depends on a source external energy to achieve its purpose, the catheter in question is not considered active, as it performs nothing more than conduct light, without performing any significant conversion of this energy;
- ÿ Cochlear implant powered by an external battery is considered an active implantable medical device, as it is easily characterized the performance of their medical function through an energy conversion: sound energy into electrical energy and, later, into mechanical energy, to necessary stimulation of certain areas of the brain responsible for identification of sounds.

The integral parts of active implantable medical devices (electrodes, cables, adapters, programmers, software, controllers, etc.), are, by convention, classified as devices implantable active doctors, even if they do not present necessarily “active” or “implantable” characteristics. These must be classified under the same rule and risk class as the equipment indicated for joint use.

MEDICAL DEVICE WITH MEASUREMENT FUNCTION:

Medical devices with a measuring function are the indicated by the manufacturer to perform quantitative measurements and qualitative characteristics of physiological or anatomical parameters and, furthermore, the indicated to measure a qualifying quantity or characteristic of energy or substance delivered to or removed from the human body.

Being a measurable quantity, the result must be indicated using the unit of measurement of the International System of Units – SI applicable to it, as established in Resolution CONMETRO No. 12, October 1988, of the National Council of Metrology, Standardization and Industrial Quality – CONMETRO.

Examples of products with a measuring function: thermometer clinical, products that indicate whether the body temperature is above or below a certain value, biochemical analyzers, sphygmomanometers, multiparametric monitors, among others.

Application of the Framing Rules

The manufacturer must take into account all the rules in order to establish the appropriate classification for its product.
completely conceivable, for example, that one of the general rules that is not specific to active products, applies to such product; for such evaluation, all product characteristics must be taken into account consideration. The characteristic, or combination of characteristics that, according to the intended function informed by the product manufacturer, results in the highest class and determines the classification of the product as a whole.

As for the application of classification rules, they must be considered that:

- It is the purpose indicated by the manufacturer (intended function) that determines the rule and risk class of the product.

- If a medical device performs intended functions that can be classified into different risk classes, then it must be adopt the most critical risk class.

- Medical equipment accessories, when registered or notified separately, fall under the category of considering its characteristics and purposes of use. Except in the if they are accessories for implantable active medical equipment.

- It is the indicated use and not the accidental use of the product that determines its sanitary classification. For example, a transducer ultrasonic blood flow, which is indicated to monitor the flow patient's blood and, during normal use, should be kept out of the reach of children. patient (as indicated by the manufacturer), should not be considered as an invasive product even if, during the surgical procedure, the doctor decide to use it invasively. This way, if a healthcare professional health to use the product in a way not indicated by the manufacturer, this does not changes the classification rule and risk class of the same for purposes of health framework.

- It is the indicated purpose of the product, assigned by the manufacturer, which determines the risk class of the product and not the risk class attributed to other similar products.

- A product that is part of a system, such as, a module of a multiparameter monitor, can be classified as a product in its own rule. However, if it is incorporated into the system, it will receive the same risk class and classification rule. of the most critical part of the system, that is, the system must be classified as a whole.

- If the product is not indicated for use in a specific part of the body, must be considered and framed based on in the most critical use. The product's classification will have to be determined based on the indications contained in the instructions for use supplied with the product. The manufacturer must be sufficiently specific in this consideration. If the manufacturer wants to avoid a highest particular classification, must clearly define in the instructions for use for the intended purpose, in such a way that the product stay in the lowest class. The manufacturer must provide, as a minimum requirement, appropriate positive or negative indications for the use of your product.

- For a product to be specifically indicated for the purpose referenced in a particular classification rule, the manufacturer must clearly state in the instructions for use that the product is indicated for a specific purpose. Otherwise, it will be judged that it is indicated for use and purposes accepted in general medical practice.

- Multi-application equipment, such as printers laser and identification cameras, which can be used in combination with medical devices, are not medical devices unless their manufacturer places them on the market for the specific purpose of medical device. For example, a camera used in obtaining intraoral imaging during dental procedures.

- Software as a Medical Device, SaMD, is classified under your own rule.

Problems of interpretation

In case the manufacturer is not sure how their products must be classified, the latter must forward a query to Anvisa, through the Anvisa Call Center, on the portal https://www.gov.br/anvisa/pt-br/canais_atendimento/formulario-eletronico

General Explanation of the Rules - Examples

Rule 1 – Medical devices that do not come into direct contact with the patient or come into contact only with intact skin.

This is a recurrence rule that applies to all medical devices that are not covered by a more stringent rule specific. In general, it applies to devices that come into contact only with intact skin or that does not touch the patient.

RULE 1	EXAMPLES
All non-invasive devices are in Class I unless one of the following rules applies.	- Products for collecting liquids of the body indicated to be used so that a flow of return is unlikely (for example, to collect excretions of the body, such as bottles of urine collection, ostomy bags, incontinence pads or the collectors used with products wound drainage). - Products used to immobilize body parts or apply force or compression on them (e.g., non-sterile dressings used to help in the healing of a twist, plaster of Paris, necklaces cervical, traction products by gravity, hose of compression). - Products in general indicated for the external support of the patient (e.g. hospital beds non-active, non-active cranes patients, walkers, wheelchairs non-active wheels, tensioners, chairs of patients non-active dental services). - Non-active stethoscopes for the diagnosis, plasters for occlusion of the eye, fields non-sterile surgical gels drivers, electrodes no invasive and non-active (electrodes for EEG or ECG). - Permanent magnets for removal of intraocular residues.

Observations:

Note 1: Some non-invasive medical devices are indirectly in contact with the body and can influence processes internal physiological systems for storing, channeling or treating fluids (blood, other body fluids, or substances) that return or are infused into the body, or products that generate energy to be supplied to the body. These products are not covered by this rule and must be supported by another classification rule, since that its indirect influence on the body can cause specific dangers.

Note 2: Ultrasound gels must not be absorbed or dispersed locally in the body at the site of action to achieve the desired function. intended.

Rule 2 – Channeling or storage for eventual administration.

This rule applies to non-invasive devices intended for channeling or storage of blood, body fluids, cells or tissues, liquids or gases for specific purposes. Invasive devices, except surgically invasive devices intended for the administration of inhaled medicines, fall under Rule 20.

These types of products should be considered separately. of Rule 1 contactless products because they can be indirectly invasive. They channel or store the substances that will be eventually administered into the body; they are typically used in transfusion, infusion, in extracorporeal circulation, in the administration of anesthetic gases and oxygen.

In some cases, the products covered by this rule are products very simple, like gravity-activated administration.

RULE 2	EXAMPLES
All non-invasive devices intended for driving or storage of blood, fluids, body cells or tissues, liquids or gases with a view to eventual infusion, administration or introduction node body they are classified in class II: a) if they can be connected to a Class II active device, III or IV; or	- Syringes for infusion pumps; - Products indicated to be used as channels for medication administration in active systems. For example, equipment indicated for use with an infusion pump. - Products used for channeling gases, for example, circuits respiratory for anesthesia, indicator of pressure (pressure gauges), circuits of patient used in systems anesthesia by breathing and pressure limiters, piping antistatic for anesthesia.
(b) if they are intended to be used for the conduction or storage of blood or other body fluids or for the storage of organs, parts of organs or body cells and tissues, - with the exception of blood bags and blood components, which are classified in class III;	- Products intended for channeling blood, for example, in transfusion, circulation extracorporeal. - Non-active products indicated for long-term storage term of substances and tissues biologicals, such as: corneas, sperm, human embryos, etc. - Refrigerators and freezers for blood conservation and blood components. - Blood bags without a substance that, if used separately, he can to be considered a medicine.

In all other cases, these devices are classified as Class I.	- Products that provide a simple channeling function, with gravity providing the force to transport the liquid, by example: serum equipment. - Syringes without needles.

Observations:

Note 1: If a product, for example, equipment, can be used for a purpose that requires a connection to an active medical device, will automatically be in Class II unless the manufacturer clearly state that it should not be connected to a device active physician.

Note 2: The expression "can be connected to a medical device" active" represents the possibility of connection between a medical device non-active and an active medical device, where the non-active device forms a link for the transfer of substances between the patient and the active medical device, and the safety and performance of one of the products are influenced by each other. For example, the piping of a extracorporeal circulation system, responsible for conducting the flow blood between the patient and the pump falls into this situation.

Rule 3 – Devices that modify the biological composition or chemistry of human tissues or cells, blood, other body fluids, or other fluids intended for implantation or administration in the body.

These products should be considered separately from the non-contact products of Rule 1, since they are indirectly invasive, intended to treat or modify the substances that will be eventually administered into the body. This rule covers, for the most part, the most sophisticated elements of circulation systems extracorporeal, dialysis systems and autotransfusion systems; and also products for extracorporeal liquid treatment bodily substances that may or may not be immediately reintroduced into the body,

including situations in which the patient is not in a circuit closed with the device.

This rule also covers substances in direct contact with human cells, tissues or organs *in vitro* prior to their implantation or administration, without substances derived from human or animal origin, like human albumin.

RULE 3	EXAMPLES
All non-invasive devices intended to alter the biological or chemical composition of tissues or cells of human origin, blood, other body fluids, or other liquids for implantation or administration into the body are classified as Class III.	- Products indicated for removal unwanted substances from the blood by concentration gradient between solutions, such as hemodialyzers. - Products indicated for separating cells by physical means, for example, average gradient for separation of sperm. - Hemodialysis concentrates
except if the treatment in which the filtration device is used consists of centrifugation or gas or heat exchange, in which case they are classified in class II.	- Specific products for filtration of blood particles, used in a extracorporeal circulation system. They are generally used in the removal of particles and blood embolisms. - Centrifugation of blood for prepare it for transfusion or autotransfusion, excluding centrifuges for manufacturing a product medicinal. - Products for removing carbon dioxide blood carbon or addition of oxygen. - Heating products or blood cooling in a system extracorporeal circulation

All non-invasive devices consisting of a substance or mixture of substances intended for use in vitro in direct contact with human cells, tissues or organs taken from the human body or used in vitro with human embryos, prior to their implantation or administration into the body, are classified in class IV.	- Substances or mixtures of substances for transport, perfusion, storage of intended organs transplant that do not reach the main action intended by means pharmacological, immunological or metabolic. - *In vitro* fertilization products or art without principle action pharmacological/metabolic (substance or mixture of substances) - Cell culture media for albumin-free *in vitro* fertilization human

Observations:

Note 1: These products are normally used together with an active medical device covered by Rule 9 or Rule 12.

Note 2: Filtration and centrifugation must be understood, in the context of this rule, as exclusively mechanical methods.

Rule 4 - Medical devices in contact with the skin or membrane damaged mucosa

This rule applies to non-invasive devices as well as invasive devices that come into contact with skin or membrane damaged mucosa.

This rule is indicated to cover, primarily, dressings for wounds, regardless of the depth of the wound. The types traditional of these products (for example, those used as protection by mechanical barrier) present technology already mastered and not result in no major risk. However, rapid technological developments in this area have been observed with the emergence of new types of dressings, such as influence directly into the micro-surroundings of the wound to reinforce its mechanism natural healing process.

Other innovative claims relate to the mechanism of healing by secondary intention, such as influencing the mechanisms of granulation or epithelial formation or, even, prevent the wound contraction.

Some devices used on damaged dermis may even have the purpose of sustaining life or saving life, for example, when there is a full thickness destruction of the skin over a large area or a systemic effect.

Dressings that incorporate a substance that, if used separately, it can be considered a medicine and that it has a accessory action to that of the dressing, fall into class III of Rule 14. Devices composed of other substances that are absorbed or dispersed locally in the human body fall under Rule 21.

RULE 4	EXAMPLES
All devices do not invasive that come into contact with skin or mucous membrane injured are classified:	
a) in class I, if they are intended for be used as a barrier mechanical, for compression or for absorption of exudates;	- Wound dressings such as absorbent compresses, wool cotton, strip dressings absorbent pads and gauze to act as a barrier or to maintain the positioning of the wound or to absorb excretions from it. - Ostomy bags.
b) in class III, if intended to be used mainly in skin lesions that have produced rupture of the dermis or of the mucous membranes and that can only heal by the second intention;	- Products indicated for use in severe injuries, which ruptured substantially and extensively to dermis, and where the healing process it can only be by intention secondary, such as:

	ÿ wound dressings extensive and chronic ulcers; ÿ burn dressings severe that broke the dermis and cover an area extensive; ÿ dressings for severe wounds from the decubitus; ÿ dressings that incorporate means of increasing tissue and to provide a replacement temporary for the skin.
c) in class II, if intended mainly to control the skin microenvironment or damaged mucous membrane; and	- They have specific properties for help in the healing process, controlling the humidity level in the wound during the healing process, and to regulate the micro-environment of the area damaged, in terms of humidity, temperature, oxygen levels and other gases, and pH values; or influencing the process by others physical means. - These products may specify additional therapeutic properties private individuals, as long as they are not indicated for extensive wounds that require intention therapy secondary. - Adhesives for topical use. - Polymer film dressings, moisturizing gel dressings and dressings of gauze not impregnated with medicines.
d) in class II in all others cases.	

This rule also applies to invasive devices that enter in contact with a membrane damaged mucosa.	- Dressings for nosebleeds (a The purpose of the dressing is not to control the microenvironment) - Dental dressings that do not contain material derived from animals

Observations:

Note 1: The classification of products covered by this rule is extremely sensitive to the indications and purposes of use of the product. For example, a polymeric film dressing would be in Class II if the indicated use was to control the wound microenvironment, and in Class I, if its indicated use were limited to retaining an invasive cannula in the site of the wound. Consequently, it is impossible to say, a priori, that a particular type of dressing is in a specific class, without knowing its use indicated and defined by the manufacturer. If there is an indication for use that the device is interactive or active with respect to the healing process the wound is generally Class II

Note 2: Most dressings that are indicated for one use that classifies it in Class II or III, it also performs the functions that are in Class I, for example, a mechanical barrier. Such products, nevertheless, they are classified in the highest class

Note 3: For products that incorporate a substance that, if used separately, it can be considered a medicine, or a derived from human blood, or animal tissues or derivatives made infeasible, see Rule 14; or Rule 18, respectively

Note 4: In the injured dermis, the wound exposes, at least in part, the subcutaneous tissue

Note 5: In healing by secondary intention, the healing of the wound is completed with a protective scab; then the epithelium grows behind this scab and the wound contracts. In contrast, first intention implies that the edges of the wound are close enough quite or can be placed close together, for example, by suturing, to allow the wound to close and heal.

Rule 5 - Invasive devices in body orifices

Invasiveness through body orifices (ear, mouth, nose, eye, anus, urethra and vagina) must be considered separately from invasiveness arising from a cut in the body surfaces (invasiveness surgical). For short-term use, a more complete distinction should be made be made between invasiveness (related to the anterior parts less vulnerable: the ear, mouth and nose) and other anatomical sites that can be reached through the body's natural orifices.

The devices covered by this rule tend to be instruments diagnostics and therapeutics used in private specialties (ophthalmology, dentistry, proctology, urology, gynecology).

RULE 5	EXAMPLES
All medical devices invasive applicable to orifices bodies, except devices surgically invasive, which are not intended to be connected to a device active or intended to be connected to a device Class I assets are classifieds:	
in class I, if they are intended for transitory use;	- Hand mirror used in dentistry to aid in diagnosis and surgery dental; dental materials printing; cannulas used for stomach pumping, products for enema, examination gloves.
b) in class II, if intended for short-term use,	- Contact lenses, urinary catheters, tubes tracheal, products to urinary incontinence and pelvic suspension, prolapse containment products vaginal.

except if used in the cavity oral to the pharynx, in the ear canal to the eardrum or in the nasal cavity, in which case are classified in class I; and	- Plastic syringe used to measure a quantity of medicine before use. oral administration to the patient.
c) in class III, if intended for long-term use term,	- Ureteric stents. - Long-lasting corrective contact lenses term - Urinary catheters intended for use by long term
except if used in the cavity oral to the pharynx, in the canal auditory to the eardrum or in the nasal cavity, and if they are not susceptible to absorption by mucosa, in which case they are classified in class II.	- Orthodontic wire. - Fixed dental prostheses.
All medical devices invasive applicable to orifices bodies, except devices surgically invasive, which are intended to be connected to a active medical device class II, III or IV, are classified in class II.	Tracheostomy or tracheal tubes connected to a ventilator, cannulas nasopharyngeal, some feeding tubes enteral, optical fibers used with endoscopy systems, catheters suction or tubes for drainage of the stomach, dental suction tips. Electric nasal irrigators. Endoscopes that use a light source in the spectrum visible.

Observations:

Note 1: In relation to devices intended for connection to a active device: the strictest rule and sub-rule will apply result in a higher rating. For example, a cannula tracheal for prolonged use should be classified as class IIb

Note 2: Devices composed of substances that are absorbed or dispersed locally in the human body can also be covered by Rule 21.

Rule 6 – Surgically invasive devices for transient use (<60 min)

This rule covers three main groups of medical devices: products that are used to create a channel through the skin (needles, cannulas, etc.), surgical instruments (scalpels, saws, etc.) and various types of catheters and suction cups.

RULE 6	EXAMPLES
All surgically implanted devices invasive intended for temporary use are classified in class II, unless be that:	- Suture needles, syringe needles, lancets, aspirators, single-use scalpels, single-use scalpel blades, ophthalmic surgery support products, surgical swabs, drills and saws used with active medical products, surgical gloves, heart valve tester.
a) are specifically intended for control, diagnose, monitor or correct cardiac or central circulatory system through direct contact with these parts of the body, in which case they are classified in class IV;	- Cardiovascular catheters (for example, balloon catheters for angioplasty), including guide wires related and instrumental surgical cardiovascular dedicated disposables2 , put example, electrodes for the electrophysiological diagnosis and ablation. - Catheters containing or incorporating radioisotopes sealed, where the radioactive isotope in itself is not intended to be administered into the body, if used in the central circulatory system
b) are surgical instruments reusable, in which case they are classified in class I;	- Scalpels, scalpel handpieces, drill and saw sets (not intended for connection to an active medical product), forceps, scrapers.

c) are specifically intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case which are classified in class IV;	- Neuroendoscopes, Spatulas cerebral, stimulation cannulas direct, Spinal Needles, Guide to skull for use in craniotomy. - Cryoablation of the heart or column - Cannula of drainage cardiovascular designed specifically to circulate the blood while located in the heart or vascular system central
d) are intended to supply energy in the form of ionizing radiation, in which case they are classified in class III;	- Catheters containing or incorporating sealed radioisotopes, where the radioactive isotope itself is intended to be released into the body. Excluding the central circulatory system.

Observations:

Note 1: The expression "correct dysfunctions" does not cover products used to assist cardiac procedures such as *clamps.*

Note 2: The “dedicated” feature means that the function intended purpose of the product is to diagnose, monitor or correct a defect in the heart or central circulatory system.

Note 3: The concept of "potentially dangerous form" is related to the characteristics of the product and not to the competence of the user.

Rule 7 – Surgically Invasive Devices for Short-Term Use term (>60min <30days)

These are mostly medical devices used in the context of surgery or post-operative care (e.g., staples, drains, etc.), infusion devices (e.g., cannulas, needles) and the catheters of various types.

RULE 7	EXAMPLES
All surgically invasive devices intended for short-term use are classified as Class II unless: a) they are specifically intended to control, diagnose, monitor or correct cardiac or central circulatory system dysfunctions through direct contact with these parts of the body, in which case they are classified as Class IV;	- Clamps, infusion cannulas, products for skin closure, materials of provisional fillings. - Cardiovascular catheters, cables provisional pacemaker implants. - Thoracic catheters indicated for cardiac drainage, including the pericardium. - Carotid artery shunts
b) if specifically used in the direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified in class IV;	- Neurological catheters, cortical electrodes
c) are intended to supply energy in the form of ionizing radiation, in which case they are classified in class III;	- Brachytherapy Products.
d) have a biological effect or are absorbed, in whole or in large part, in which case they are classified in class IV;	- Absorbable sutures and biological adhesives.
e) are intended to undergo chemical transformation in the body, in which case they are in class III, unless they are placed in the teeth; or	- Vascular closure devices Hemostatic foams
f) are intended to administer medications, in which case they are classified in class III.	- Temporal dialysis catheter
c) are intended to supply energy in the form of ionizing radiation, in which case they are classified in class III;	- Brachytherapy Products.

Observations:

Note 1: The administration of medications goes beyond the channeling, also involves storage and influence of volume and the rate of medication administered. The capsules implanted to slow release medications are medications, not devices doctors.

Rule 8 - Implantable devices and surgically inserted devices invasive for long-term use (>30 days)

These are mostly implants from orthopedic fields, dental, ophthalmic and cardiovascular procedures, as well as implants used in plastic surgery.

RULE 8	EXAMPLES
All implantable devices and surgically inserted devices invasive intended for use long term are classified in the class III, unless:	- Common prosthetic replacements, ligaments1 , derivations, stents, nails, plates, intraocular lenses, internal products for closing, implants for tissue augmentation, infusion ports, vascular grafts peripherals, implants penile, non-absorbable sutures, cements bone and maxillofacial implants, viscoelastic surgical products specifically indicated for the anterior segment surgery ophthalmic1 .
a) are intended to be placed on the teeth2 , in which case they are classified in class II;	Bridges, crowns, materials and pins dental fillings, dental alloys, ceramics and polymers.

b) are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case that are classified in the class IV;	- Prosthetic heart valves, aneurysm clamps, prostheses vascular, stents spinal, vascular stents, electrodes of the central nervous system - CNS and cardiovascular sutures. - Permanent vein filters dig;
c) have a biological effect or are absorbed, in whole or largely, in which case are classified in class IV;	- Absorbable sutures, adhesives and implantable products intended to be bioactive through surface coating. such such as phosphorocholine. - Biodegradable bone cements
d) are intended to undergo a chemical transformation3 in the body, in which case they are classified in class IV, unless they are placed on the teeth;	- Peritoneal dialysis.
e) are intended to administer medicines, in which case they are classified in class IV;	- Non-active rechargeable systems for administering medication;
f) are implantable devices assets or their accessories, if in which they are classified in class IV;	- Pacemakers cardiac implantables, their cables and electrodes; gastric pacemakers implantables, their cables and electrodes; - Defibrillators and Cardioverters implantable. - Cochlear implants
g) are breast implants or surgical screens, in which case they are classified in class IV;	- Breast implants - Breast tissue expanders - Surgical meshes for hernia repair

h) are joint prostheses total or partial, in which case are classified in class IV, with the exception of components auxiliaries such as screws, wedges, plates and instruments; or	- Hip, knee, shoulder, ankle
i) are replacement implants of the intervertebral disc or implantable devices that come into contact with the column vertebral, in which case they are classified in class IV, with exception of components such as screws, wedges, plates and instruments.	- Disc replacement implants spinal - Spinal implants: hooks that fix the rod to the spine - Implantable rods in contact with the spine - Device placed in the space of the disk

Observations:

Note 1: These devices are implants because, under normal conditions, normal, a significant amount of the substance remains in place surgical after the procedure. If these products contain tissues of of animal origin or its derivatives are covered by Rule 18.

Note 2: Implants without bioactive coatings intended for attaching teeth or prostheses to the maxillary or mandibular bones are in Class III, following the general rule.

Obs.3: The clause on chemical transformation under this rule does not apply to products such as bone cements in which the change chemistry occurs during placement and does not continue long term.

Rule 9 - Active therapeutic devices intended to administer or exchange energy, as well as active devices intended to directly control/monitor/influence certain devices.

Devices classified by this rule are, for the most part, electrical equipment used in surgery such as lasers, generators surgical devices, stimulation devices, devices intended to emit ionizing radiation2 for therapeutic purposes, including devices that control or monitor such devices, or that directly influence in their performance, devices intended to control, monitor or directly influence the performance of implantable devices assets.

Active implantable devices are covered by Rule 8.

Rule 22 may also apply to therapeutic devices assets.

RULE 9	EXAMPLES
All active therapeutic devices intended to deliver or exchange energy are classified as class II,	- Electrical, magnetic or electromagnetic: Stimulators muscle and bone growth, TENS wave equipment and electro acupuncture equipment - Thermal energy: Equipment cryosurgery, heat exchangers. - Mechanical energy: Dermatomes energized, parts of hand dental, electric drills. - Light: Phototherapy for the treatment of skin and neonatal care, Photo dental whitening. - Sound: Hearing aids - Ultrasound: Equipment for physiotherapy.
unless, due to their characteristics, they supply energy may to the human body or exchange energy with it in a potentially dangerous way1 , taking into account the nature, density and place of application of the energy, in which case they are classified in class III.	- Thermal Energy: Incubators for babies; electric blankets and blankets, blood warmers; blood exchangers electrically energized heat. - Energy Electrical: Generators high frequency electrosurgical, electrocautery equipment,

	including their electrodes, pacemakers external, external defibrillators without integrated diagnostic function or incorporated. - Light: Surgical lasers - Ultrasound: Lithotripters, equipment surgical ultrasounds. - Energy Kinetics: Fans Pulmonary
All active medical devices intended to control or monitor the performance of Class III active therapeutic devices, or to directly influence the performance of such devices, are classified as Class III.	- External feedback systems for active therapy
All active medical devices intended to emit ionizing radiation for therapeutic purposes, including medical devices that control or monitor devices that directly influence their performance, are classified as those class III. or	- Brachytherapy devices, therapeutic cyclotrons, linear accelerators, therapeutic X-ray sources
All active medical devices intended to control, monitor or directly influence the performance of active implantable devices are classified as class IV.	- Programming units and systems analyzers stimulation. - Cardioscopes with indicators stimulation pulse specifically conceived to monitor active implantable devices. - Programmer for: Pulse Generator Implantable Cardioverter Defibrillator Implantable.

Observations:

Note 1: The concept of "potentially dangerous" depends on the type of technology involved and the intended function of the equipment and does not alleviated as a result of the measures adopted by the manufacturer, in view of of equipment risk control. For example, all devices indicated to emit ionizing radiation and lithotriptors must be in the Class III, regardless of safety controls and conditions adopted by its manufacturer in the development of the project. However, the unchanged risk classification does not exempt the manufacturer from complying with the mandatory requirements and adopt necessary solutions, such as the use of technical standards or other relevant risk control measures, to meet the safety and effectiveness requirements of the equipment.

Rule 10 - Active devices for diagnostics and monitoring or intended for diagnostic or therapeutic interventional radiology

This rule mainly covers equipment used in ultrasound diagnostic fields and capture of physiological signals, as well as those associated with diagnostic and therapeutic radiology2 interventionist.

Please note that devices for recording X-ray images for diagnosis are covered by Rule 17. Devices specifically intended for monitoring active implantable devices fall under Rule 8 or Rule 9.

RULE 10	EXAMPLES
Active devices for diagnostics and monitoring are classified as class II in cases where:	
a) are intended to provide energy that will be absorbed by the human body,	Magnetic resonance equipment, devices for pulp diagnosis, evoked potential equipment, ultrasound for diagnosis.
with the exception of devices designed to illuminate the patient's body in the visible spectrum, in which case they are classified as class I;	Examination lamps, Surgical microscopes designed to illuminate the patient's body in the visible spectrum, Dermatoscopes with integrated light sources.

b) are intended to visualize *in vivo* the dissemination of radiopharmaceutical products;	- Gamma cameras, positron emission tomography and single photon emission computed tomography.
c) are intended to allow the direct diagnosis or the process monitoring vital physiological,	- Electrocardiographs; electroencephalographs; Electronic thermometers; Electronic stethoscopes; Electronic blood pressure measuring equipment; CAD/CAM type optical system (topography) for dental use.
unless they are specifically intended for monitoring or to the observation of vital physiological parameters1 and the nature of the variations in these parameters is likely to result in immediate danger to the patient, as is the case with variations in heart rate, respiration and central nervous system activity, or if they are intended for diagnosis in clinical situations in which the patient is in immediate danger, these are cases in which they are classified in class III.	- Multiparametric monitors; sensors of physiological signals; analyzers of blood gases used in surgery cardiac; apnea monitors, including apnea monitors used at home. - Implantable or detachable glucometer continuous monitoring.
Active devices intended to emit ionizing radiation for diagnostic or therapeutic radiology, including interventional radiology devices2 and those that control or monitor3 such devices, or that directly influence their performance, are classified as class III.	- X-ray equipment for diagnosis; - Surgical arches; - Hemodynamic equipment.

Observations:

Note 1: Vital physiological processes and parameters include, for example, respiration, heart rate, functions brain, blood gases, blood pressure and body temperature.

Medical devices indicated for use in observation continuous interruption of vital physiological processes in anesthesia, intensive care, or emergency care are in Class III.

Medical devices indicated for obtaining signal readings
vital physiological factors in routine checking or self-monitoring are in the
Class II. A thermal imaging device intended to monitor the
blood flow is not considered a product of measurement of
temperature.

Note 2: The indicated radiotherapeutic equipment
correspond to the radiological equipment used in
interventional procedures. For example: equipment
diagnostic tests used during a surgical procedure (e.g., rainbow
surgical).

Note 3: This refers to active devices for control,
monitoring or influencing the emission of ionization and not to
subsequent processing, recording or viewing of the image
resulting.

**Rule 11 - Software intended to provide information to
to support decisions for diagnostic or therapeutic purposes or
software designed to monitor physiological processes.**

This rule describes and categorizes software risk based on the
combination of the importance of the information provided by the software
for the health care decision and the health care situation
or patient condition.

This rule also distinguishes between SaMD intended to monitor
vital and non-vital physiological processes (the sub-rule applies only to
software intended for monitoring purposes only).

Software used in conjunction with medical devices that merely records,
stores, or displays information generally does not
are considered devices. For example, software analogous to diaries
for recording insulin doses are not considered devices,
unless an analysis is performed on the data or the device
change in any way the treatment, prescription, doses, etc. of the
patient.

RULE 11	EXAMPLES
Software intended to provide information used for decision-making for therapeutic or diagnostic purposes is classified in Class II, unless such decisions have an impact that may cause:	- SaMD aims to classify therapeutic suggestions for a healthcare professional with based on the patient's history, imaging test results and patient characteristics, by example, SaMD which lists and ranks all options of chemotherapy available for individuals with BRCA genes positive; - SaMD cognitive therapy, where a specialist determines therapy necessary cognitive based on the result provided by SaMD
a) death or irreversible deterioration of a person's health, in which case it is classified in class IV	- SaMD aims to perform diagnoses through image analysis to enable treatment
b) a serious deterioration in a person's health or a surgical intervention, in which case it is classified as class III.	- A mobile application intended for analyze heartbeats of user, detect abnormalities and report a doctor properly. - SaMD is intended for diagnosis of depression with based on a score resulting from entered data about the patient's symptoms (e.g., anxiety, patterns sleep, stress, etc.)
Software designed to monitor physiological processes is classified as class II,	- SaMD aims to monitor physiological processes that are not considered vital.

	- Devices intended to be used to obtain readings of vital physiological signs in routine examinations, including home monitoring
except when intended for monitoring vital physiological parameters, when the nature of the variations in these parameters may result in immediate danger to the patient, in which case it is classified in class III.	- Medical devices, including SaMD, intended for use for continuous monitoring of vital physiological processes in anesthesia, emergency intensive care. or service
Any other Software as a Medical Device (SaMD) is classified in class I.	- The SaMD app aims to assist in conception by calculating the user's fertility status based on a validated statistical algorithm. The user enters health data, including basal body temperature.

Observations:

Note 1: For software classification, it is necessary to consider the intended purpose, the intended population (including, for example, diseases to be treated and/or diagnosed, speed of disease progression, severity of health consequences), the context of use (e.g., intensive care, emergency care, use domestic) of the software and information provided by the software, as well as as the possible decisions to be made.

Rule 12 - Active devices to manage and/or remove medicines, body fluids and other bodily substances human or out of it.

This rule predominantly covers administration systems of medications and anesthesia equipment. If the route of intended drug delivery by the device for pulmonary, rule 20 applies.

RULE 12	EXAMPLES
All active medical devices intended to administer to or remove from the human body medications, other body fluids or substances are classified as class II,	- Suction equipment, pumps enteral feeding; - Sodium bicarbonate jet for dentistry. - Nebulizers intended for patients breathing consciously and spontaneously, where the administration of the dosage is not potentially dangerous.
unless this is done in a potentially dangerous way, taking into account the nature of the substances or the part of the body involved and the method of application, in which case they are classified in class III.	- Parenteral infusion pumps, lung ventilators, machines anesthesia, anesthetic vaporizers, dialysis equipment, pumps blood for heart machines lung, hyperbaric chambers, medical gas mixers, moisture exchangers in circuits respiratory when used in unconscious or breathing patients non-spontaneously; - Nebulizers where administration dosage can be dangerous.

Rule 13 - All other active medical devices.

This is a coverage rule for all active devices.
not covered by the preceding rules.

RULE 13	EXAMPLES
All other active medical devices, not covered by the previous rules, are classified as class I.	- Active products intended for external support of the patient (e.g. hospital beds, patient hoists, patient chairs wheels, dental chairs). - Dental and surgical focus.

Rule 14 – Medical devices incorporating, as part of an integral part, an auxiliary medicine and derivative medicines of human blood or blood plasma.

This rule is intended for devices that incorporate, such as an integral part, a substance which, if used separately, can be considered a medicine, with the purpose of helping in operation of this device. However, this rule does not cover devices incorporating medicinal substances solely for the purpose of maintaining certain characteristics of the device and which are not responsible for acting on the body. For example: agents for the preservation of contact lens solutions.

In summary, it can be stated that the medical device falling under Rule 14 does not have its intended function supported by the pharmacological effect of the drug, although it has medication incorporated into its structure.

RULE 14	EXAMPLES
All devices that include, as an integral part, a substance that, if used separately, could be considered a medicinal product, including a medicinal product derived from human blood or plasma, and that has a complementary action to the devices, are classified in class IV.	- Cements bone antibiotics, condoms with spermicides, heparin-coated catheters, materials endodontics with antibiotics. - Dressings incorporating an agent antimicrobial. blood-releasing stents pharmaceuticals, Intra-Uterine Devices (IUD) containing substances medicinal.

Rule 15 - Devices used for contraception or prevention of sexually transmitted diseases.

This rule covers two types of products with intended functions very different: those intended for contraception and those intended for prevention of sexually transmitted diseases. Some products can perform both functions, such as condoms.

Products indicated to prevent sexual transmission of the HIV virus (Human Immunodeficiency Virus) are also covered by this rule.

RULE 15 All	**EXAMPLES**
devices used for contraception or to prevent the transmission of sexually transmitted diseases are classified as class III, except when they are implantable or invasive devices intended for long-term use, in which case they are	- Condoms, contraceptive diaphragms
classified as class IV.	- Intrauterine contraceptive products (IUDs).

Rule 16 – Specific devices for disinfection, cleaning, rinsing or sterilization of medical devices.

This rule is intended to cover several products used specifically with contact lenses, such as solutions intended for storage of contact lenses and solutions used to support contact lenses placed on the ocular surface.

The rule also covers substances and equipment specifically intended for the disinfection or sterilization of medical devices that the manufacturer intends to sterilize or disinfect before use.

This rule does not apply to physical means for cleaning medical devices, such as ultrasound and general-purpose brushes. Such products will only be considered medical devices if they are specifically intended for cleaning, disinfecting or sterilizing medical devices. Devices specifically intended for cleaning contact lens physics are covered by this rule.

RULE 16	EXAMPLES
All medical devices specifically intended to be used to disinfect, clean, wash or, where applicable, moisturize contact lenses are classified as class III.	- Lens storage solutions contact. - Contact lens cleaners. - Ultraviolet, vibrating or ultrasonic to cleaning and disinfection of contact lenses
All devices specifically intended to be used to disinfect or sterilize medical devices are classified as class II,	- Washer-disinfectors designed specifically to disinfect non-invasive medical devices. - Sterilizers intended the sterilization of medical devices in a medical setting.
except in the case of washing and disinfecting machines specifically designed to be used to disinfect invasive devices, as the final stage of processing, in which case they are classified in class III.	- Specific washing and disinfection equipment for disinfecting endoscopes or other invasive devices at the end point of processing (e.g. dental equipment)
This rule does not apply to devices intended for cleaning, solely by physical action, devices other than contact lenses.	- Brushes specifically designed for cleaning of medical devices by action mechanics - Ultrasonic devices (for devices other than contact lenses)
Artificial tears and ophthalmic lubricants, when classified as medical devices, are classified in class III.	

Observations:

Note 1: Equipment that only performs washing (cleaning) of medical devices (e.g., instruments), without disinfection activity and sterilization, fall under Rule 13.

Rule 17 - Devices for recording diagnostic images by x-rays

This rule covers stand-alone X-ray detectors and sensors. as recording devices used in various types or modalities of medical imaging procedures, each of which uses different technologies and techniques. Includes non-active devices and active devices used to record diagnostic images by X-rays of the human body. The rule is intended to cover primarily digital devices and analog recording media, but not media (including digital media) used for processing and subsequent storage of images.

RULE 17	EXAMPLES
Devices specifically intended to record diagnostic images generated by X-rays are classified as class II.	X-ray films, photostimulable phosphor plates, X-ray detectors for image recording

Observations:

Note 1: Devices designed to emit ionizing radiation to diagnostic and/or therapeutic purposes are not covered by this rule. See Rule 9 or 10.

Rule 18 - Devices using tissues or cells of origin human or animal or their derivatives

This rule is intended for devices that use fabrics of animal origin or its derivatives rendered inert, that is, in which there is no longer any capacity for cellular metabolic activity on their part fabrics.

RULE 18	EXAMPLES
All devices manufactured using cells, tissues, or their non-viable derivatives (without the capacity for metabolism or multiplication) or made non-viable, are classified in class IV, unless they are devices intended to come into contact only with intact skin.	- Biological heart valves, xenograft dressings from pigs, catgut sutures , implants and dressings made of collagen.
This rule does not apply to advanced therapy products, which are covered by specific regulations.	

Observations:

Note 1: Derivatives are products that are processed from tissues of animal origin and exclude products made by animals such as milk, silk, wax, hair, lanolin.

Note 2: Products made from inert animal tissue that only come into contact with intact skin (e.g., leather components of orthopedic products), are in Class I - Rule 1. Intact skin includes the skin around an established stoma, excluding cases where the skin is broken.

Rule 19 – Devices incorporating or consisting of nanomaterial

The concept of internal exposure is a key element for the classification of nanomaterials that incorporate or consist of nanomaterials. The potential risk of using nanomaterials in devices doctors is mainly associated with the possibility of releasing nanoparticles free from the device and the duration of exposure. It estimates the external and internal exposure based on device type, type of application, type (location) of contact and duration of contact.

RULE 19	EXAMPLES
All devices incorporating or consisting of nanomaterials are classified:	
a) in class IV, if they present a high or medium potential for internal exposure;	- Fillings bone with nanomaterials in its formulation (not polymerized before contact blood/tissue and degradable) - Non-polymer intravascular catheter degradable, with nano-coating
b) in class III, if they present a low potential for internal exposure; and	- Bone fixation screws/plates with a highly bonded, high-potency nano-coating
c) in class II, if they present an insignificant potential for internal exposure.	Intravascular catheter for short-term use made of degradable non-polymer material, with nanomaterial incorporated into the polymer matrix

Observations:

Obs.1: The high, medium, low or insignificant potential of internal exposure is based on the combination of different factors, such as the site of application of a medical device, the type of contact (e.g., tissue, cells, or body fluids), the time of contact, and the type incorporation of the nanomaterial(s), (free, fixed, incorporated). When the nanomaterial is applied as a coating on the surface of the device, it is important to consider the type of interaction with the material (chemisorption versus physisorption). When the nanomaterial is incorporated in a matrix, it will be important to consider the degradability of the material

Note 2: Internal exposure: exposure may occur through damaged skin or mucous membrane, devices (surgically) invasive and implantable devices

Note 3: Dental materials that are placed on the teeth of the patient in paste form, where they are cured to a solid form, can release nanomaterials during a very long exposure time short. For most of the exposure time, these devices contain tightly bound nanomaterials.

In many cases, grinding and/or polishing occurs during application of the device and may also lead to exposure to nanomaterials. These nanomaterials do not necessarily contain the nanomaterials present in the paste formulation. It is very important to include this aspect in the risk assessment of these devices. For the purposes of classification, the potential internal exposure to nanomaterials of these devices can generally be considered insignificant. The classification of this type of material should be based on the first state, in this example, the short exposure to the paste form, which has greater release potential than cured material.

Note 4: Devices with components that incorporate nanomaterials that have no intended direct or indirect contact with users or patients, such as wheelchair or walker tires made of rubber reinforced with carbon black nanomaterials, shall be exempt from classification under Rule 19.

Note 5: Medical devices that do not incorporate or consist of in nanomaterials may still have potential for exposure internal to nanomaterials due to degradation or wear processes. Although it is very important to include this aspect in the risk assessment of such devices, it is not a factor to be considered when deciding the classification under Rule 19, as it applies only to medical devices that incorporate or consist of nanomaterials.

Rule 20 - Invasive devices intended for the administration of inhalation medications

This rule covers active and non-active medical devices with respiratory medication administration.

Unlike other rules that cover devices that administer medications, Rule 20 is also intended specifically to cover medical devices whose impact on efficacy and safety of the administered drug is critical.

The rule also covers drug delivery products
intended for the treatment of potentially fatal conditions.

RULE 20	EXAMPLES
All invasive devices applicable to body orifices, surgically invasive devices, which are intended for the administration of drugs by inhalation are classified in class II,	- Spacer for inhalers measured dose (connected to the inhaler), unless it is to treat life-threatening conditions. - Inhalers for replacement therapy of nicotine (nicotine not included) - Oxygen supply system with nasal cannula, unless it is treating life-threatening conditions - Inhalers and nebulizers, if your mode of action does not have probably essential impact on drug efficacy and safety administered or that are not intended for treat potentially fatal conditions
unless their mode of action has a significant impact on the efficacy and safety of the drug administered or they are intended to treat life-threatening conditions, in which case they are classified in class III.	- Nebulizers (not pre-loaded) with a specific medication) where failure to provide the characteristics of dosage adequate can be dangerous; - Spacer for inhalers measured dose attached to the inhaler.

Observations:

Note 1: 'Essential impact' includes management systems
medications in which the device has a significant impact on
factors that influence the deposition of inhaled medication in the airways
airways, including inhalation flow, aerosol velocity,
particle size of the inhaled drug and the amount of
medicine that reaches the patient.

Rule 21 - Devices composed of substances that are introduced through a bodily orifice or applied to the skin

This rule covers a wide range of medical devices exclusively based on substances. In this context, "substance" means any material that forms part of the medical device.

The classification takes into account the place of application of the medical device, as well as the location where the medical device performs its action on the human body. For the purposes of this rule, nails also are considered to belong to the "skin".

Manufacturers of substance-based devices must provide clear information that supports the mode of action through which the substance achieves the specific medical purpose intended as a basis for the application of this rule, including the place of application, as well as the place where the action is achieved within or on the body.

RULE 21	EXAMPLES
You devices doctors consisting of substances or combinations of substances that are intended to be introduced into the human body through a bodily orifice or applied to the skin and that are absorbed or disseminated by or in the human body scattered locally they are classifieds:	
a) in class IV if the devices, or its products metabolism, are absorbed or disseminated systemically by human body to achieve intended purpose;	- Na/Mg alginate, xyloglucan - Fat absorbers that are absorbed systemically, they themselves or their metabolites

b) in class IV if they reach the intended purpose in the stomach or in the lower gastrointestinal tract and if the devices, or their products of metabolism, are absorbed or disseminated systemically by the human body;	- Na/Mg alginate, xyloglucan - Fat absorbers that are absorbed systemically, they themselves or their metabolites
c) in class II if they are applied in skin or if they are applied to the nasal or oral cavities up to the pharynx, and if they achieve the purpose intended in these cavities; and	- Formulations based on substances for the treatment of skin - Salt water used, for example, in the nose or throat sprays - Oral treatments for cough that achieve the intended objective in oral cavity to the pharynx
d) in class III in all others cases.	- Simethicone preparations for oral administration - Activated charcoal for administration oral - Vaginal hydration gel/ vaginal lubricants - Eye drops for hydration

Observations:

Note 1: Products that act in the nasal or oral cavity can be ingested or inhaled to some extent. These products will be considered class II devices if they achieve the intended purpose intended only in these cavities, and not in the respiratory tract, stomach or lower gastrointestinal tract.

Note 2: In most cases, the drops penetrate the ear only up to the eardrum. This is considered as applied to the skin. The outer layer of the tympanic membrane is the epithelium; therefore, if there is intact tympanic membrane, the drops are applied only to the skin and have local action, and, consequently, the device would be class II.

This will occur unless the eardrum (tympanic membrane) is perforated. and the product should be used on perforated eardrums.

Rule 22 - Active therapeutic devices, with a therapeutic function built-in diagnostics.

This rule applies to therapeutic devices whose intended functionality depends, to a significant degree, on a diagnostic function. integrated or incorporated.

Automated or "closed-loop" therapeutic systems are systems in which relevant biological conditions are automatically monitored (using feedback from physiological sensors) and are used to adjust a therapy in order to maintain or achieve a state specific physiological. Such devices are typically used in precision medicine and/or personalized therapies to achieve efficacy ideal therapy. This rule covers systems such as autonomic pharmacological (drug administration) and neuromodulation.

RULE 22	EXAMPLES
Active therapeutic devices with integrated or built-in diagnostic function that significantly direct patient management, such as closed-loop automated external defibrillator systems, are classified in class IV. or you	Automatic external defibrillators (AED) including their pads/electrodes; semi-automatic external defibrillators; Automated closed-loop insulin delivery system; Automated external infusion pumps with integrated sensors for adapting infusion therapy; Closed-loop systems for deep brain stimulation (DBS) treatment of various neurological conditions;

Observations:

Note 1: 'Integrated or built-in diagnostic function' means the functionality of a system that includes physiological sensors, for example, AED electrodes/paddles using a feedback control to process and record changes in the patient's physiological state to continually adjust therapy. The diagnostic function can be physically integrated or a component of an external subsystem.

Annex D

Reference Legislation

All legislation cited in this Manual is available at Anvisa portal, www.anvisa.gov.br in Content Hubs > Legislation > Thematic Libraries > Health Products.

Health Product Theme Library

In the link above you can access the Library in PDF, with documents that bring together all the current regulations of a given macro-theme, divided by themes. The objective is to facilitate access and understanding of the Regulatory Stock to internal and external audiences, as well as how to improve the process of preparing and reviewing regulations.

The technical area also provides Technical Notes with the aim of clarify certain matters relating to the regularization of medical devices. These documents are available on the website of Anvisa, www.anvisa.gov.br in Regulated Sector > Regularization of products and services > Health products > Technical notes.

Technical Notes - Medical Devices

Below we inform you of some of the main regulations mentioned in this Manual.

- ÿ Law 6,360/1976 - Provides for the Health Surveillance to which the Medicines, Drugs, Pharmaceutical Inputs are subject and Related Products, Cosmetics, Sanitizing Products and Other Products.
- ÿ Decree 8.077/2013 – Regulates the conditions for the operation of companies subject to health licensing, and registration, control and monitoring, within the scope of surveillance sanitary, of the products covered by Law No. 6,360, of 23 September 1976.

- ÿ RDC 204/2005 – Procedure for petitions submitted for analysis by the technical sectors of Anvisa Amended by: RDC 23/2015.
- ÿ RDC 250/2004 - Revalidation of registration of products subject to Health Surveillance.
- ÿ RDC 903/2024 - Procedures for the transfer of ownership of registration of products subject to health surveillance, global transfer of responsibility for clinical trials and updating of registration data relating to the operation and certification of companies, as a result of operations corporate or commercial operations.
- ÿ IN 74/2020 - Establishes the subjects for changes to information presented in the process of regularizing medical devices at ANVISA, under RDC 340/2020.
- ÿ Guide No. 44, version 3, dated 12/06/2023 - Guide on the Specification of the Documentation for Electronic Petitioning of Medical Devices.
- ÿ RDC 545/2021 - Electronic protocol for issuing a Certificate Product (Notification Certificate or Device Registration) Physician) and Certificate for Foreign Government (Certificate of Notification or Registration for Export of Medical Device).
- ÿ RDC 549/2021 - Procedures for compulsory certification of equipment under Health Surveillance.
- ÿ PRT 511/2021 - Chronological criteria for analysis or approval of the registration or notification processes for defined products as medical devices, within the scope of the National Agency of Health Surveillance.
- ÿ RDC 751/2022 - Risk classification, notification regimes and registration, and the labeling requirements and instructions for use of medical devices.
- ÿ RDC 848/2024 - Essential safety requirements and performance applicable to medical devices and devices doctors for in vitro diagnostics (IVD).

- ÿ RDC 837/2023 - Conducting clinical investigations with medical devices in Brazil.
- ÿ Guide No. 29, version 1, dated 12/17/2019 - Evidence Guide Medical Device Clinics: Concepts and Definitions.
- ÿ Guide No. 30, version 1, dated 12/17/2019 - Investigation Guide Medical Device Clinic.
- ÿ Guide No. 31, version 2, dated July 9, 2020 - Clinical Evaluation Guide of Medical Devices.
- ÿ RDC 591/2021 - Identification of medical devices regularized at Anvisa, through the Unique Identification of Medical Devices (UDI) system.
- ÿ RDC 542/2021 - Defines "group of products" to which the item 5.3 of Annex II of Law 9,782 of January 26, 1999
- ÿ Guide No. 38, version 1, dated September 14, 2020 - Guide on Principles and Cybersecurity Practices in Medical Devices.
- ÿ RDC 657/2022 - Regularization of software as a medical device (Software as a Medical Device - SaMD).
- ÿ IN 290/2024 - Establishes, under the terms of the Board Resolution Collegiate - RDC No. 741, of August 10, 2022, optimized procedure for the purposes of analyzing and deciding on petitions for registration of medical devices, through the use of analyses carried out by an Equivalent Foreign Regulatory Authority (AREE).
- ÿ IN 283/2024 - List of Technical Standards for the certification of compliance of equipment under Surveillance regime Sanitary.
- ÿ INMETRO Ordinance 384/2020 - Approves the Requirements for Conformity Assessment for Equipment under Health Surveillance Regime – Consolidated.
- ÿ RDC 924/2024 - Standardization of declaration phrases of natural rubber latex content on device labels doctors.

- ÿ RDC 665/2022 - Good Manufacturing Practices for Products Doctors and In Vitro Diagnostic Products.
- ÿ RDC 687/2022 - Criteria for granting or renewing the Good Manufacturing Practices Certification for Devices Doctors.
- ÿ RDC 579/2021 - Import, commercialization and donation of used and refurbished medical devices.

Defined Terms

Risk Analysis Systematic use of available information to identify hazards and estimate risks.

Risk Assessment Risk comparison process estimated in relation to the risk criteria, to determine the risk acceptability.

Risk Control Process in which decisions are made and measures are implemented to reduce or maintain risks within the specified levels.

Damage Injury or harm to the health of people, or harm to property or the environment

Risk Determination General process comprising a risk analysis and a risk assessment.

Accompanying Document Document that accompanies a medical device and contains important information for the user, operator, installer or assembler of the product, mainly relating to safety, indication and purpose of use and instructions for use.
Note: The accompanying document may be a set of documents that indicate all the information described above.

Primary Packaging Packaging wrapper, intended for package and protect the product, usually for transportation purposes and storage, which maintains direct contact with it.

Secondary Packaging Casing destined to the packaging of the product in its primary packaging, generally for transportation and storage purposes, which does not maintain contact directly with it.

Medical Equipment Equipment for use in health, with the purpose medical, dental, laboratory or physiotherapy, used directly or indirectly for diagnosis, therapy, rehabilitation or monitoring of human beings, and even those for beautification and aesthetic purposes.

Self-Administration Equipment Medical equipment asset intended to be used and operated primarily by laypersons, allowing the administration of substances or energy to patients. It has therapeutic purposes.

Accuracy of a Measuring Instrument Fitness of one measuring instrument to give answers close to a value of reference. Measurement accuracy indicates the degree of agreement between the result of a measurement and the true value of the measured object.

Note: The term precision should not be used as accuracy.

Contract Manufacturer : Duly established third-party company as a legal entity, which carries out the industrialization of a product doctor under the responsibility of a Legal Manufacturer, under contract legally established.

Note: Contract Manufacturer derives from the English term Contract Manufacturer (CM).

Legal Manufacturer Legal entity, public or private, with responsibility for the design, manufacture, packaging and labeling of a product, with the intention of making it available for use under your name, these operations being carried out by the company itself or by third parties in your name.

NOTE: when referring to “Manufacturer” in this Manual, the definition of “Legal Manufacturer” must always be considered.

Intended Function It is the indication and purpose of use of medical equipment.

Risk Management Systematic application of policies, management procedures and practices for analysis tasks, risk assessment and control

Gravity Measure of the possible consequences of a hazard

Indication and Purpose of UseIndication of use of a product, process or service, according to its specifications, instructions and information provided by your manufacturer

Consumable Material Material that qualifies as a device doctor or not, who accompanies the medical equipment in his/her packaging and needs to be replaced periodically. They are generally disposable products.

Note: “Tracking medical equipment” does not necessarily mean being entered in the registration/notification of this equipment.

Body Orifice Any natural opening of the body, as well as the eye socket, or any permanent artificial opening such as, for example, example, a stoma.

Danger Potential source of damage.

Accuracy of Measurement Results Difference between successive results of the same measurand. The greater the agreement between the successive values obtained, the greater the precision of the instrument of measurement.

Medical Device Any instrument, device, equipment, implant, medical device for in vitro diagnostics, software, material or other article, intended by the manufacturer to be used, alone or in combination, in humans, for any of the following specific medical purposes, and whose primary intended action is not achieved by pharmacological, immunological or metabolic means in the human body, but which can be assisted in their intended action by such means: a) diagnosis, prevention, monitoring, treatment (or alleviation) of a disease; b) diagnosis, monitoring, treatment or repair of an injury or disability; c) investigation, replacement, alteration of anatomy or of a physiological process or state or pathological; d) support or maintenance of life; e) control or support of

conception; or f) provision of information by means of in vitro examination of samples from the human body, including donations of organs and tissues.

Active Medical Device Any device whose functioning depends on an energy source not generated by the body human for this purpose, or by gravity, and which acts by altering the density or by conversion of that energy, except those intended to transmit energy, substances or other elements between an active device and the patient without producing any change significant.

Medical Device with Any **Measurement Function** device doctor indicated by the manufacturer to perform quantitative measurements of physiological or anatomical parameters and, also, those indicated for measuring a qualifyable quantity or characteristic of energy or substance delivered to or removed from the human body.

Implantable Medical Device Any device, including those that are partially or totally absorbed, intended to be introduced entirely in the human body; or replacing an epithelial surface or ocular surface, through clinical intervention, and which is intended to remain in this place after the intervention, or even the one intended for be partially introduced into the human body through intervention clinic and to remain in this location after the intervention for a period of, at least 30 days.

Invasive Medical Device Any device that partially penetrates or completely in the body, either through one of its orifices or through the its surface.

Surgically Invasive Device Invasive device that penetrates in the body through its surface, including through membranes mucous membranes of the body's orifices, as part of a surgical intervention; and device that penetrates the body by a route other than an orifice body.

Indexed Publications Scientific and academic articles with results of research and studies on a given topic,

recognized by the scientific community through publication in journals indexed to specific databases (e.g. SciELO, LILACS, Medline, etc.) and that are included in the Journal Portal of CAPES - Coordination for the Improvement of High-Level Personnel Superior of the Ministry of Education.

Product Master Record Compilation of documents containing specifications, instructions and procedures for obtaining a finished product, as well as for its installation, technical assistance and maintenance.

Risk Combination of the probability of damage occurrence and the severity of that damage.

Residual RiskRemaining risk after risk control measures have been implemented.

Security Absence of unacceptable risk.

Health service Activity in which there is provision of assistance to the individual or human population that may alter their health status, aiming at the prevention and diagnosis of diseases, the treatment, recovery, aesthetics or rehabilitation, carried out must be carried out by a health professional or under their supervision.

Note: Health services include hospitals, nursing homes, health care facilities, limited health facilities, clinics, medical and dental offices, and centers mobile or permanent outpatient clinics, but not limited to these.

Quality System Structure organizational, responsibilities, procedures, specifications, processes and resources necessary for quality management.

Equipment System Set of equipment designed to be used in association, where the lack of hair less than one member of the system makes the entire system inoperative.

Short-Term Use Use normally carried out continuously for a period between 60 (sixty) minutes and 30 (thirty) days.

Long-Term Use Use normally carried out continuously for a period exceeding 30 (thirty) days.

Use of Transitional Term Normally used

continuously for less than 60 (sixty) minutes.

Validation Confirmation by analysis and objective evidence that the requirements defined for a given purpose lead, in a consistently, to the expected result.

Verification Confirmation by analysis and presentation of evidence objective evidence that the specified requirements have been met, including the process of examining the results of an activity to determine the compliance with established specifications

Acronym

ABNT	Brazilian Association of Technical Standards
AFE	Company Operating Authorization
ANVISA	National Health Surveillance Agency
GMP	Good Manufacturing Practices
CBPF	Good Manufacturing Practices Certificate
CLC	Free Trade Certificate
GQUIP	Equipment Technology Management Doctors
GGTPS	General Management of Product Technology for Health
IN	Normative Instruction
INMETRO	National Institute of Metrology, Standardization and Industrial Quality
LF	Operating License
MS	Ministry of Health
OCP	Product Certification Body
RBC	Brazilian Calibration Network
DRC	Collegiate Board Resolution
RE	Special Resolution
VISA	Local Health Surveillance (municipal or state)
SaMD	Software as a Medical Device
SI	International System of Units

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