RESOLUTION – RDC No. 751, DATED SEPTEMBER 15, 2022

Provides for risk classification, notification and registration regimes, and labeling requirements and medical device use instructions.

The Collegiate Board of Directors of the National Health Surveillance Agency, in the use of the attributions conferred by art. 15, III and IV, combined with art. 7, III and IV of Law No. 9,782, of January 26, 1999, and to art. 187, VI, § 1 of the Internal Regulations approved by the Collegiate Board Resolution - RDC No. 585, of December 10, 2021, decides to adopt the following resolution, as resolved at a meeting held on September 14, 2022, and I, director- President, I determine its publication.

CHAPTER I
INITIAL PROVISIONS

Section I
Objective

Art. 1. This resolution defines the rules of risk classification of medical devices, labeling requirements and instructions for use, and procedures for notification, registration, change, revalidation and cancellation of notification or registration of medical devices.

Section II
Scope

Art. 2. This Resolution applies to the medical devices defined therein, and their notification or registration is mandatory, according to risk classification.

§ 1. The risk classification, procedures and specifications described in this document, for notification and registration purposes, apply to medical devices and their accessories.

§ 2. This resolution does not apply to used or reconditioned medical devices, which are submitted to the specific rules set forth in the Collegiate Board Resolution - RDC No. 579, of November 25, 2021, published in DOU No. 225, of December 1, 2021.

§ 3. This Resolution does not apply to personalized medical devices, which are subject to the specific rules established in the Collegiate Board Resolution - RDC No. 305, of September 24, 2019, published in DOU No. 186, of September 25, 2019, Section 1 , page 69.

§ 4. This resolution does not apply to medical devices for in vitro diagnosis, including the instruments for in vitro diagnosis, which are submitted to the specific rules established in the Collegiate Board Resolution - RDC No. 36, of August 26, 2015 published in DOU No. 164, August 27, 2015, Section 1, p.43.

§ 5. This Resolution does not apply to medicines, cells, tissues, organs or blood of human origin or derivatives, cosmetics, sanitizers, or foodstuffs treated by other regulations.

§ 6. Active devices (equipment) indicated for aesthetic correction and beautification are considered medical devices.

§ 7. Active devices (equipment) specifically intended for cleaning, disinfection or sterilization of medical devices are considered medical devices.

§ 8. The medical provisions intended for clinical investigations are exempt from notification or registration, complying with the legal provisions of the competent health authority to perform this activity, and the commercialization and use for other purposes are prohibited.

§ 9. Notification or registration is the presentations consisting of two or more medical or registered medical devices and in their individual packaging of full presentation,

and should contain in the label the information of the corresponding medical devices, including the notification or registration numbers.

§ 10. The accessories produced by a manufacturer exclusively to integrate the medical devices of their manufacture already notified or registered and whose technical dossiers contain information about these accessories are exempt from notification or registration.

§ 11. New accessories may be included in the notifications or original records, detailing the foundations of operation, action and content.

Art. 3. Anvisa will also grant notification or registration to families, systems and sets (or kits) of medical devices.

Sole Paragraph. Product grouping, with the purpose of notification or registration, will be given according to the rules provided for in specific regulation.

Section III

Definitions

Art. 4. For the purposes of this resolution the following definitions will be applied, which may have different meaning in another context.

I - Accessory (of a medical device): Product intended by your manufacturer to be used in conjunction with one or more specific medical devices, to allow or help in a specific and direct way that the doctor (s) device (s) are used according to the intended purpose;

II - Agglomerate: For the purposes of the definition of nanomaterial, a set of weakly linked particles in which the resulting external surface area is equal to the sum of the surface areas of the individual components;

III - Aggregate: For the purposes of the definition of nanomaterial, a particle that comprises strongly linked or casting particles, where the resulting outer surface area may be significantly lower than the sum of the calculated surface areas of individual components;

IV - Change: Modification of information presented to ANVISA in the process of notification or registration of the medical device and in their respective secondary petitions;

V - Change of Approval Required: Change of greater health relevance, which deals with change to be introduced in the registration process, being authorized in the national territory only after documentary technical analysis and favorable manifestation of ANVISA;

VI - alteration of immediate implementation: change of medium health relevance, which deals with change to be introduced in the notification or registration process, and its implementation is authorized in the national territory after the petition protocol with Anvisa;

VII - non -reportable change: any other change in lower health relevance, resulting from a change that is not classified as required approval or immediate implementation, which does not depend on protocol in ANVISA for implementation;

VIII - holder (notification or registration): legal, public or private entity, manufacturer or importer, responsible for the medical device in the national territory, which holds the grant of commercialization of medical device, issued by ANVISA;

IX - surgically invasive device: invasive device that penetrates the body through its surface, including through the mucous membranes of the body holes within the scope of a surgical intervention; and a device that penetrates the body by way other than a body hole;

X - Medical Device (Medical Product); Any instrument, apparatus, equipment, implant, medical device for in vitro diagnosis, software, material or other article, intended by the manufacturer to be used, isolated or jointly, in humans, for any of the following specific medical purposes, and whose main action intended not to be achieved by

pharmacological, immunological, or metabolic means in the human body, but which can beassisted in their action intended by such means:

a) diagnosis, prevention, monitoring, treatment (or relief) of a disease;

b) diagnosis, monitoring, treatment or repair of an injury or deficiency;

c) Investigation, replacement, alteration of anatomy or a physiological or pathological process or state;

d) support or maintenance of life;

e) control or support for conception; or

f) Supply of information through in vitro examination of samples from the human body, including organ and tissue donations.

XI - Active Medical Device: Any device whose functioning depends on an energy source not generated by the human body for this purpose, or by gravity, and that acts by altering the density or conversion of that energy, except those intended to transmit energy, substances or other elements between an active device and the patient without producing any significant change;

XII - active medical device for diagnosis and monitoring: any active device used in isolation or in combination with other devices to provide information with a view to detection, diagnosis, monitoring, observation or treatment of physiological states, health states, diseases or congenital malformations;

XIII - single -use medical device: a device designed to be used in a person during a single procedure, according to the manufacturer's specification;

XIV - implantable medical device: any device, including those that are partial or fully absorbed, intended to be fully introduced into the human body; or to replace an epithelial surface or the eye surface, through clinical intervention, which is intended to remain in this place after intervention, or to be partially introduced into the human body through clinical intervention and to remain in this place after intervention by a period of at least 30 days;

XV - invasive medical device: any device that partially or fully penetrates in the body, either by one of its holes or through its surface;

XVI - medical device for in vitro diagnosis: reagents, calibers, standards, controls, sample collectors, software, instruments or other articles, used individually or in combination, with intention of use determined by the manufacturer for in vitro analysis of samples derived from the Human body, exclusively or especially to provide information for diagnosis purposes, aid to diagnosis, monitoring, compatibility, screening, predisposition, prognosis, prediction or determination of the physiological state;

XVII - Active Therapeutic Medical Device: Any active device used in isolation or in combination with other devices to maintain, modify, replace or restore biological functions or structures within the treatment or attenuation of a disease, injury or deficiency;

XVIII - Technical Dossier: document describing the elements that make up the product, indicating the characteristics, purpose, mode of use, content, special care, potential risks, production process and additional information;

XIX - legal manufacturer: legal, public, or private entity, with responsibility for the project, manufacturing, packaging, and labeling of a product, with the intention of making it available under its name, being these operations performed by the company itself or by third parties in your name.

XX - Family: Grouping of medical devices, for the purpose of notification or registration, provided for in specific regulation, where each product has similar technical characteristics of:

a) indication, purpose of use;

b) operation and action;

c) Technology;

d) content or composition, when applicable; and

e) precautions, restrictions, warnings and special care.

XXI - intended purpose (purpose of use): the use to which a device is intended, according to the information stated by the manufacturer in clinical evaluation;

XXII - importer: legal, public or private entity, responsible for the import activity for the entry of medical provisions from abroad in the national territory;

XXIII - Instructions for Use: Document containing information provided by the manufacturer to clarify the user about the intended purpose of a device, their correct use and eventual precautions to be taken;

XXIV - Reusable Surgical Instrument: An instrument that is intended to cut, drill, scarify, sawing, shaving, remove, staple, remove, trim or perform similar procedures, within the scope of clinical and surgical interventions, and may or may not connect to a active device, and intended by the manufacturer to be reused after the appropriate procedures such as cleaning, disinfection and sterilization have been performed;

XXV - Clinical Research: any systematic research or study in one or more humans, carried out to evaluate the safety, clinical performance and/or effectiveness of a medical device. For the purposes of this regulation, this term is synonymous with "clinical trial" or "clinical research";

XXVI - Kit (set, set or tray): Set of medical devices that, regardless of whether they are recorded or notified individually, are grouped into a unit of sale for a specific use or procedure:

a) For regularization purposes, the set must be from the same manufacturer or manufacturing group; and

b) The components of a medical device kit, in isolation, do not maintain interdependence relationship to obtain the functionality and performance for which it is intended.

XXVII - lot or start: amount of a medical device elaborated in a manufacturing or sterilization cycle, whose essential characteristic is homogeneity;

XXVIII - nanomaterial: natural, incidental, or manufactured material containing particles in non -attached state or in the form of aggregate or cluster, where 50% or more of the number of particles has size distribution within 1 to 100 nm, in one or more of its external dimensions, which may include:

a) fullerenes, graphene flakes and simple wall carbon nanotubes with one or more external dimensions of less than 1 nm are also considered nanomaterials.

b) Materials manufactured with dimensions that go beyond the upper limit of nanoscale (established between 1 and 100 nm), to the landmark of 1000 nm, and which display size or phenomena size distinct from those presented by the same material in macroscale, may be framed in the definition of nanomaterial;

XXIX - Technical Standard: document established by consensus and approved by a recognized organism, which provides for common and repetitive use rules, guidelines or characteristics for activities or their results, aiming to obtain a great degree of ordering in a given context;

XXX - Notification: Act of communicating to Anvisa the intention to commercialize the medical device, intended to prove the right of manufacture and import of medical

device exempted from registration pursuant to § 1 of art. 25 of Law No. 6,360, of September 23, 1976, and classified in risk classes I or II, with the indication of the name, the manufacturer, the purpose and the other elements that characterize it;

XXXI - Body hole: any natural opening of the body, as well as the eye cavity, or any permanent artificial opening such as a stoma;

XXXII - Particle: For the purposes of the definition of nanomaterial, a tiny portion of matter with defined physical boundaries;

XXXIII - skin or injured mucosa membrane: a skin surface or a mucous membrane that has a pathological alteration or caused by disease or injury;

XXXIV - Procedural Revaluation: Procedure performed by ANVISA's technical area in medical devices notifications and records for audit purposes;

XXXV - Registration: Anvisa's private act intended to prove the right to manufacture and import a product submitted to the regime of Law No. 6,360, of September 23, 1976, and classified in risk classes III or IV, with the indication of the name, the manufacturer, the purpose and other elements that characterize it;

XXXVI - documentary repository of medical devices: digital tool for storing and making available documents related to notified and registered medical devices, available on ANVISA's electronic portal;

XXXVII - Legal Responsible: Individual designated in Statute, Social Contract or Minutes, responsible for representing, actively and passively, in the judicial and extrajudicial acts to the requesting legal entity (manufacturer or importer);

XXXVIII - Technical Responsible: Higher level professional, legally qualified, trained in the technologies that make up the product, responsible for the technical information presented by the applicant (manufacturer or importer) and the quality, safety and performance of the marketed product;

XXXIX - label: written, printed or graphic information that contains in the product itself, the packaging of each unit or in the packaging of various devices;

XL - System: set of compatible medical devices, which relate or interact with each other, exclusively in order to fulfill a purpose intended by the manufacturer;

XLI - Central Circulatory System: System that includes the following blood vessels: pulmonary arteries, ascending aorta, aortic arc, descending aortic to aortic bifurcation, coronary arteries, ordinary carotid artery, external carotid artery, internal carotid artery, brain arteries, trunk brachycephalic, coronary veins, pulmonary veins, upper vena and inferior vena cava;

XLII - Central Nervous System: system that includes the brain, meninges and spinal cord;

XLIII - Software as a medical device (AS A AS A Medical Device - SAMD): Product or application intended for one or more purposes indicated in the definition of medical device and performing its functions without being part of the hardware of a medical device, with the following characteristics:

a) SAMD can be executed on a general purpose computational platform (non -medical purpose);

b) The "computational platform" includes hardware and software resources (operating system, processing hardware, storage, database, viewing devices, input devices, programming language, etc.);

c) "Without being part of" means the program does not need the hardware of a medical device to achieve its purpose of use;

d) Software is not considered SAMD if its goal is to control the hardware of a medical device;

e) A SAMD can be used in combination (eg as a module) with other products, including other medical devices;

f) A SAMD may interact with other medical devices, including hardware from other medical devices and another SAMD, as well as general use software; and

g) Mobile applications (apps) that meet the definition are considered SaMD;

XLIV - Applicant: legal, public or private entity, who forwards petitions for notification or registration of medical provisions with the health authority;

XLV - Fabric Unit: place where one or more manufacturing steps occurs, and may be the legal manufacturer itself, contracted manufacturer or original product manufacturer;

XLVI - Short Term Use: Use usually performed continuously for a period between 60 (sixty) minutes and 30 (thirty) days;

XLVII - Long Term Use: Use usually performed continuously for a period exceeding 30 (thirty) days;

XLVIII - Transitional use: Use normally performed continuously for less than 60 (sixty) minutes; and

XLIX - User: Health professional or layman, and may be the patient himself, who uses a medical device, according to the instructions for use.

CHAPTER II

RISK CLASSIFICATION OF MEDICAL DEVICES

Section I

Framing and control regimes

Art. 5. The medical devices, object of this Resolution, are classified according to the intrinsic risk they represent to the health of the user, patient, operator or third parties involved, in Classes I, II, III or IV:

I - Class I: low risk;

II - Class II: medium risk;

III - Class III: high risk; and

IV - Class IV: maximum risk.

§ 1. In order to classify the medical device in one of these classes, the classification rules established in this Resolution must be applied.

§ 2. In case of doubt as to the classification resulting from the application of the rules established in this Resolution, Anvisa will be responsible for the classification of the medical device.

Art. 6. Medical devices classified in risk classes I and II are subject to notification.

Art. 7. Medical devices classified in risk classes III and IV are subject to registration.

Section II

Application Rules

Art. 8. The application of classification rules is governed by the intended purpose of medical devices, with the exception of in vitro diagnostic devices, which are governed by specific classification rules.

§ 1. If the device in question is intended to be used in combination with another device, the classification rules apply separately to each of them.

§ 2. The accessories of a device must be classified by themselves, separately from the device with which they are used.

§ 3. Software that controls a device or influences its use is classified in the same

class as that device.

§ 4. If the software (SaMD) is independent of any other device, it must be classified independently.

§ 5. If the device is not intended to be used exclusively or primarily on a particular part of the body, it should be considered and classified based on the most critical use.

§ 6. If several rules apply to the same device or, within the same rule, several sub-rules, based on their intended purpose, the most stringent rule and sub-rule that lead to the higher classification apply.

§ 7. When calculating the duration of use "on an ongoing basis" the following must be considered:

a) the entire duration of use of the same device without regard to temporary interruptions of use during a procedure or temporary removal for purposes of cleaning or disinfection of the device, and it shall be determined whether interruption of use, or removal, is temporary depending on the duration of previous and future use to the period when the use is interrupted or that the device is removed; and

b) The accumulated use of a device intended by the manufacturer to be replaced immediately by another of the same type.

§ 8. A device is considered to allow a direct diagnosis when providing, by itself, the diagnosis of the disease or the condition in question, or when it provides decisive information for the diagnosis.

SECTION III

Classification Rules

Art. 9. Medical devices are classified according to the risk, according to the rules set forth in Annex I of this Resolution.

CHAPTER III

NOTIFICATION OR REGISTRATION REQUEST AND ITS MAINTENANCE

Section I

Procedures for notification or registration of medical devices

Art. 10. The applicant must submit to Anvisa the documents for notification, registration, change, revalidation or cancellation of notification or registration of the medical provision, related to this Resolution.

§ 1. Anvisa shall evaluate the documentation presented for registration, alteration or revalidation of the registration and will manifest by official means.

§ 2. The evaluation of the documentation shall be carried out within the deadlines and legal conditions provided for in the Brazilian health legislation.

§ 3. For technical reasons, in order to prove the safety and performance of the product, due to potential risk to public health, Anvisa may determine the presentation of additional documents and information.

§ 4. The petition with no documents, forms and statements, provided for in the list of procedural instruction documents, incompletely or with missing or unreadable information, or obsolete, without certificate of compliance, shall not be subject to a technical requirement. No clinical evidence for products with technology or innovative indication, giving non -consent or rejection of the petition.

§ 5. There will be no technical analysis of notification and notification petitions so that the products are considered regularized, without prejudice to the realization, at any time, documentary or tax assessments on notification processes and their changes, and, if necessary, requesting information or additional clarifications.

§ 6. The processing of the medical device notification shall occur routinely within 30 (thirty) days after the protocol by the applicant.

§ 7. The maintenance of notification and registration is linked to compliance with the requirements of good manufacturing practices, essential security and performance requirements and specific regulations, when existing.

§ 8. The granting of the registration is subject to the publication of the certificate of good manufacturing practices issued by ANVISA.

§ 9. The forms of petition, instructions for use or manuals of the user/operator and labeling models shall be presented in the Portuguese language.

§ 10. The other documents, not mentioned in the previous §, which make up the petitions of medical devices may be presented in the Portuguese, Spanish or English languages, according to rules defined in specific regulation.

Art. 11. The registration of medical devices will be valid for 10 (ten) years, counted from the day of its publication in the Federal Official Gazette, and may be revalidated successively for the same period, pursuant to section V of this Resolution.

Art. 12. Medical devices subject to certification of compliance within the Brazilian Conformity Evaluation System (SBAC) may only be imported and marketed if manufactured during the compliance certificate.

Section II

Notification of Medical Devices

Art. 13. The applicant to petition the notification of a medical device must proceed with the payment of the corresponding fee and submit to Anvisa, the following documents:

I - Form for notification of duly completed medical device available on Anvisa's electronic portal;

II - for imported medical devices: statement issued by the legal, consular or apostilated manufacturer, written in Portuguese, English or Spanish or accompanied by sworn translation, at most 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;

III - copy of the certificate of compliance issued within the Brazilian Conformity Evaluation System (SBAC), applicable only to the medical provisions with compulsory certification, related by ANVISA in specific regulations; and

IV - proof of compliance with legal provisions determined in technical regulations, pursuant to legislation regulating specific medical provisions. Sole Paragraph. The statement referred to in item II must contain the corporate name and full address of the legal manufacturer and the requesting company, the express authorization for the requesting company to represent and market its products in Brazil, and the affirmation about knowledge and service to the service Good Health Product Manufacturing Practice Requirements established in the Collegiate Board Resolution - RDC No. 665, of March 30, 2022, or regulation that will replace it.

Section III

Registration of Medical Devices

Art. 14. The applicant to petition the medical device registration must proceed with the payment of the corresponding fee and submit to Anvisa, the following documents:

I - Duly completed medical device registration form available on Anvisa's electronic portal;

II - technical dossier, as provided in Chapter VII of this Resolution;

III - for imported medical devices: statement issued by the legal, consular or apostilled manufacturer, written in Portuguese, English or Spanish or accompanied by sworn translation, at most 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;

IV - for imported medical devices: proof of registration or certificate of free trade or equivalent document, granted by the competent authority of the country where the medical device is manufactured and marketed or only marketed, issued at most two years when there is no express validity indicated in document, and must be consularized or apostille consularized, and accompanied by sworn translation when not written in Portuguese, English or Spanish;

V - certificate of good manufacturing practices issued by ANVISA or proof of protocol of request for certificate of good manufacturing practices;

VI - copy of the certificate of compliance issued within the Brazilian Conformity Evaluation System (SBAC), applicable only to the medical devices with compulsory certification, related by ANVISA in specific regulations; and

VII - proof of compliance with legal provisions determined in technical regulations applied to specific medical devices.

§ 1. The declaration referred to in item III shall contain the corporate name and full address of the legal manufacturer and the requesting company, the express authorization for the requesting company to represent and market its products in Brazil; and the affirmation of knowledge and compliance with good health manufacturing practices requirements established in the Resolution of the Collegiate Board - RDC No. 665, of March 30, 2022, or regulation that will replace it.

§ 2. The protocol of the request for certification of good manufacturing practices shall be accepted for the purpose of petition, as well as the beginning of the analysis in the registration grant petitions.

§ 3. The granting of registration grant requests is subject to the publication of a valid manufacturing certificate of good manufacturing issued by ANVISA and compliance with the other requirements for the registration of medical devices.

Section IV

Change of notification or registration of medical devices

Art. 15. To petition the change in the notification or registration of the medical device, the applicant must pay the corresponding fee, if applicable, and submit the declaration relating the pleaded changes and other required documents, as provided for.

Art. 16. Changes in information presented in the notification process or registration of medical devices are classified as:

I - change of approval required;

II - alteration of immediate implementation; and

III - non -reportable change.

§ 1. The petitioning of the amendments contained in items I and II of this article shall comply with the provisions of Normative Instruction - IN No. 74, of September 16, 2020, published in DOU No. 180, of September 18, 2022, Section 1, Pag. 111, which details applicable petition issues.

§ 2. Any changes of less relevance not classified as required approval or immediate implementation are classified as non -relevant changes, as well as: changes in information that does not modify the project of the medical device; Bug corrections in software; Non

-technical changes such as images, formatting, layouts, symbols and text adjustments of documents without increased risk; Company Operating Authorization Information Updates; Contact changes (eg phones or postal address), technical assistance and website.

§ 3. The amendments listed in §2 shall be controlled by the regularization holder quality system and be incorporated into subsequent petitions.

§ 4. The petitioning of change to medical devices of risk class I and II shall be performed by the immediate implementation regime, except when it comes to non -reportable change.

Art. 17. Affairs for amending notification or registration of medical provisions are provided by normative instruction - IN No. 74, of September 16, 2020, which identifies the changes that are considered of approval or immediate implementation.

Art. 18. The petition of information alteration shall be accompanied by the supporting documentation of the modification to be implemented, observing the current health legislation.

Art. 19. The alteration of immediate implementation that has interdependence with change of approval required shall be petitioned together with it, incorporating its contents to it.

Art. 20. The changes arising from field action notified to ANVISA to ensure the safety and performance of the device in relation to the user and patient will have their priority analysis.

Sole Paragraph. To request a prioritization of analysis cited in the caput the company must file the claim, presenting evidence of sending the notification of the field action to Anvisa.

Art. 21. The change of approval required will only take effect after published the final decision in the Federal Official Gazette and, when applicable, updated data will be advertised on Anvisa's electronic portal.

Art. 22. Immediate implementation changes will be published in the Federal Official Gazette and, when applicable, updated data will be publicized on the Anvisa Electronic Portal, observing the period of up to 30 (thirty) days, from the completion of the protocol of the respective petition, regardless of documentary analysis by Anvisa.

Art. 23. The immediate implementation petition may be the subject of documentary or tax assessment at any time by ANVISA and, if necessary, additional information or clarification may be requested.

Sole Paragraph. ANVISA may suspend the commercialization, import and/or use of the product until its regularization, in the event that there is inconsistency in the petitioning of immediate implementation alteration that justifies such a sanitary measure.

Art. 24. The granting of changes in alteration/inclusion of manufacturing unit or change of manufacturing unit or inclusion of products or models in family/system/set of products framed in risk classes III and IV is conditioned to the publication of the certificate. good manufacturing practices issued by ANVISA and compliance with the other requirements corresponding to each type of petition.

Sole Paragraph. The protocol of the request for good manufacturing practices certification will be accepted for the purpose of petition, as well as the beginning of the analysis in the petitions.

Art. 25. If there is a need for inventory depletion of finished products due to a change, the importation and simultaneous marketing of the versions involved is allowed until the end of the expiration date or useful life of the product.

Sole Paragraph. Changes made to solve safety and product performance problems do not fit the caput permission.

Art. 26. It is allowed to exhaust the stock of packaging, labels and instructions for use for a period of 120 (one hundred and twenty) days from the publication of the change.

Sole Paragraph. Changes made to solve safety and product performance problems do not fit the caput permission.

Section V

Medical device registration revalidation

Art. 27. To petition the revalidation of the medical device registration, the applicant must proceed with the payment of the corresponding fee and submit the following documents:

I - For imported medical devices: Declaration issued by the consular or apostille notarized legal manufacturer, written in Portuguese, English or Spanish or accompanied by a sworn translation, for a maximum of 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.

II - certificate of good manufacturing practices issued by ANVISA valid.

§ 1. The declaration referred to in item I shall contain the corporate name and full address of the legal manufacturer and the requesting company, the express authorization for the requesting company to represent and market its products in Brazil, and the statement about knowledge and compliance with good health manufacturing practices requirements established in the Collegiate Board Resolution - RDC No. 665, of March 30, 2022, published in DOU No. 62, of March 31, 2022, Section 1, p. 334, or regulation that will replace it.

§ 2. The request for revalidation shall be submitted within the period provided for in the Resolution of the Collegiate Board - RDC No. 250, of October 20, 2004.

§ 3. The protocol of the request for certification of good manufacturing practices shall be accepted for the purpose of petitioning and analysis of registration revalidation petitions.

Art. 28. Products submitted to the notification regime are exempt from revalidation.

Section VI

Cancellation of notification or registration of medical devices

Art. 29. The holder of notification or registration of a medical device who wants to no longer market it in the Brazilian market must petition its cancellation.

Section VII

Compliance of information

Art. 30. The changes made by the manufacturer in the information related to the medical device contained in the notification or registration shall be communicated by the holder to Anvisa, as required by Section IV of this Resolution.

Art. 31. Changes for a medical device that require prior approval by ANVISA may only be disclosed to the market after publication of that change in the Federal Official Gazette and Anvisa Electronic Portal.

Art. 32. All communication or advertising of medical device conveyed on the market shall keep strict agreement with the information presented by the notification holder or registration to Anvisa.

Section VIII

Documentary Repository of Medical Devices

Art. 33. Loading instructions for use in the documentary repository of medical devices corresponds to the insertion and updating of these documents linked to the medical device notification or registration processes.

§ 1. In the case of a medical device that has no instructions for use (such as specific document), the labeling model in the field of instructions for use should be loaded, also included the information provided for in Chapter VI.

§ 2. The loading of instructions for use shall occur through applicable petition issues, identified as "availability of use instructions on the Anvisa Portal".

§ 3. The loading of instructions for use is the responsibility of the holder of the notification or registration and shall be controlled by the notification for any audits.

§ 4. The loading of instructions for use is mandatory and must be executed by the company responsible for the notification or registration of the product, which attests that its content holds agreement with the current legislation and consistency with the regularized product.

§ 5. For the new products notified or registered and for the changes of those previously notified or registered products, the petition, and the respective loading of instructions for use shall be performed within 30 (thirty) days after publication in the Federal Official Gazette.

§ 6. For the non -reportable changes of those previously notified or registered products, the petition, and the respective loading of instructions for use shall be performed within 180 (one hundred and eighty) days after the implementation of the change that implies change in the instructions for use.

Art. 34. The availability of instructions for use will be performed exclusively on the Anvisa electronic portal, immediately after the completion of the protocol of the respective petition, regardless of documentary analysis by the agency.

§ 1. The update is performed through a new insertion of instructions for use.

§ 2. If there is a new load of instruction of use in the process of notification or registration will be held public only those recently loaded.

§ 3. The instructions for use charged over time shall be kept in the database for control and audit by ANVISA.

Art. 35. The instructions for use loaded or their absence under the terms of this resolution may be the subject of documentary or tax assessment at any time by ANVISA and, if necessary, the agency may:

I - request from the company, information, additional clarification or loading of the appropriate use instructions; and/or

II - Remove the instructions for use or restore a previous version when there is justification for such measurements.

Art. 36. The penalties provided for in Law No. 6,437, of August 20, 1977, are subject to companies that insert information in the documentary repository of medical provisions that do not agree with current legislation and consistency with the regularized product.

Sole Paragraph. In the event of non -compliance with current legislation or inconsistency that justifies a sanitary measure, Anvisa may suspend the commercialization, import and/or use of the product until the loading of the instructions for use appropriate to the terms of this Resolution, subject to the provisions of art. 15 of Law No. 6,437, of August 20, 1977.

Section IX

Procedural re-evaluation procedure

Art. 37. Notification and registration processes of medical devices are subject to procedural evaluation and revaluation, audit, market monitoring and inspection by the competent sanitary authority.

Art. 38. In cases where inconsistencies or need to complement information are evidenced, holders will be instituted to adapt their processes.

§ 1. The adjustments referred to in the caput shall be answered by the notification or registration holder within 30 (thirty) days from the date of confirmation of their receipt.

§ 2. The situations that give correction of previously presented information shall be dealt with through specific petition.

§ 3. The absence of response to the notification of adequacy referred to in the caput within 30 (thirty) days from its issuance, will result in the cancellation of the notification, registration or change.

CHAPTER IV

ADMINISTRATIVE SANCTIONS

Art. 39. Anvisa may suspend the manufacture, import, marketing and use of the medical device in cases where:

I - is suspended, due to properly justified security, the validity of any of the documents referred to in Articles 13 and 14 of this Resolution;

II - the non -compliance with any requirement of Chapter III, Section VII of this Resolution is proven; or

III - The product is under investigation by a competent health authority, regarding the irregularity or defect of the product or manufacturing process, which represents a risk to the health of the user, patient, operator or third parties involved, duly justified.

Art. 40. The suspension of manufacturing, importation, marketing and use of medical device will be published in the Federal Official Gazette and will be maintained until the problem that caused the sanction and its cancellation is communicated.

Art. 41. Anvisa may cancel the notification or registration of the medical device in cases where:

I - the falseness of information provided in any of the documents requested in this Resolution, or any of these documents by the competent health authority is proven;

II - in case of proof that the product or manufacturing process may present a risk to the health of the user, patient, operator or third parties involved;

III - absence of information or documents in the proceedings of products subject to notification is identified;

IV - error is identified in the sanitary framework in the notification processes; or

V - when there is no meeting, the procedural reevaluation demands presented by ANVISA.

Art. 42. ANVISA may determine the cancellation of changes that cause incorrect information or irregularity of medical device.

Art. 43. ANVISA may at your discretion and at any time request information or clarifications before the decision to cancel the irregular medical provision.

Art. 44. The cancellation of the notification or registration of a medical device will be published in the Federal Official Gazette.

CHAPTER V

INFORMATION FORMS OF THE APPLICANT AND HIS MEDICAL DEVICES

Art. 45. Applicable forms on the applicant and product information subject to notification or registration process shall be completed electronically on Anvisa's electronic

portal.

Sole Paragraph. When applicable, the forms must be presented with the signatures of the legal and technical responsible.

CHAPTER VI

LABELS AND INSTRUCTIONS FOR USING MEDICAL DEVICES

Section I

Information requirements on labels and instructions for use

Art. 46. Information on labels and instructions for the use of medical devices shall meet the following general requirements:

I - The information contained in the labels and instructions for use shall be written in the Portuguese language;

II - all medical devices shall include instructions for use in their packaging or refer to the way they access these documents;

III - Exceptionally, these instructions may not be included in the packaging of the medical devices framed in classes I and II, provided that the safety of these products may be guaranteed without such instructions;

IV - The information necessary for the use of the medical device with full security, should be, whenever possible, in the medical device itself or on the label of its individual packaging, or, in the impossibility of this, on the label of its commercial packaging;

V - If it is not possible to pack each unit individually, this information should be included in the instructions of use that accompanies one or more medical devices;

VI - when appropriate, the information may be presented in the form of symbols or colors, which must comply with current regulation or technical standards;

VII - If there is no regulation, the symbols and colors must be described in the documentation that accompanies the medical device; and

VIII - If in a specific technical regulation of a medical device there is a need for complementary information due to the specificity of the product, it will be incorporated to the label or instructions for use, as applicable;

Art. 47. The label model should contain the following information:

I - Company name and address of the legal manufacturer, preceded by the term "manufacturer" or equivalent symbolism;

II - Company name and address of the notification or registration holder;

III - the necessary information for the user to identify the medical device and the content of their packaging;

IV - when applicable, the word "barren" and the sterilization method;

V - the lot code, preceded by the word "lot", or the serial number, as appropriate;

VI - as applicable, date of manufacture and expiration date or date before which the medical device must be used;

VII - when applicable, the indication that the medical device is for unique use;

VIII - the specific conditions of storage, conservation and handling of the product;

IX - special instructions for operation and/or use of the medical device;

X - all warnings and precautions to be adopted;

XI - name of the technical responsible legally qualified for the function;

XII - notification number or registration of the medical device, preceded by the Anvisa identification acronym.

Art. 48. The model of instruction of use must contain the following information, as applicable:

I - The information indicated in art. 47 of this Resolution, except those contained in items "V", "VI" and "XI";

II - the purpose of use attributed by the manufacturer as well as any eventual undesirable side effects;

III - If a medical device must be installed or connected to other medical devices to function according to the intended purpose, sufficiently detailed information should be provided about its characteristics to identify the medical devices that can be used with the product, so that it is obtained A safe combination;

IV - All information that makes it possible to prove if a medical device is well installed and can work correctly and in complete security, as well as the information related to the nature and frequency of maintenance and calibration operations to be performed to ensure the good permanent operation and safety of the medical device;

V - useful information to avoid certain risks arising from the implementation of the medical device;

VI - information regarding the risks of reciprocal interference arising from the presence of the medical device in investigations or specific treatments;

VII - the necessary instructions in case of damage to the protective packaging of sterility, and, when applicable, the indication of the appropriate methods of resterilization;

VIII - If the medical device is reusable, information on the appropriate procedures for reuse, including cleaning, disinfection, packaging and as appropriate, the sterilization method, if the product has to be rewrite, as well as any restrictions on the number possible reuse;

IX - If the medical device must be sterilized before its use, the instructions on cleaning and sterilization must be formulated so that, if correctly performed, the product meets the requirements provided by the manufacturer as to the essential security and performance requirements (or effectiveness);

X - information on treatment or additional procedure that should be performed before the medical device is used;

XI - If a medical device issues radiations for medical purposes, information regarding nature, type, intensity and distribution of such radiation, shall be described;

XII - the instructions for use should include information that allows the health professional to inform the patient about contraindications and precautions to be taken;

XIII - the precautions to be adopted in case of alteration of the operation of the medical device;

XIV - the precautions to be adopted regarding exposure, under reasonably predictable environmental conditions, magnetic fields, external electrical influences, electrostatic discharges, pressure or pressure variations, acceleration and ignition thermal sources, among others;

XV - adequate information about the medicine (s) that the medical device is intended to administer, including any restrictions on choosing these substances;

XVI - the precautions to be adopted if the medical device has a specific risk -specific risk associated with its elimination;

XVII - the mention of medicines incorporated in the medical device as an integral part of it; and

XVIII - the level of precision attributed to medical measurement devices.

Art. 49. Equipment under health surveillance regime notified or registered shall have posted indelible label, which indicates:

I - commercial name of the product, indicating the model, when applicable;

II - name of the legal manufacturer or brand;

III - number of notification or registration with ANVISA; and

IV - serial number or other identifier that allows the equipment to trace.

§ 1. For the equipment of reduced and/or implantable size, where it is not possible to fix such label, manufacturer or brand identification registration and traceability elements will be required.

§ 2. In cases of systems, all its components shall be identified as members of the system to which they are associated.

§ 3. The provisions of the unique use equipment is excluded from the caput.

Section II

Use instructions in non -printed format

Art. 50. Used instructions in non -printed format may be provided in physical media or available on the Internet or in another format that includes all the requirements of this Resolution.

Art. 51. These are requirements for the provision of utilized instructions in non -printed format:

I - inform on the external label the mode of obtaining the correlation between the supplied product and the version of the corresponding use instruction;

II - indicate in the label a consumer service where the printed format of the instructions of use may be requested at no additional cost (including shipping);

III - ensure the availability of instructions for use throughout the period in which the product provided is on the market; and

IV - specify the resources required to read the user's instructions.

§ 1. When the external labeling dimensions do not allow, the information required in this article may be included in a document attached to the product.

§ 2. The manufacturer or holder of the notification or registration of equipment shall consider the period indicated in item III as the shelf life specified for the product, from the last marketed unit of the product.

Art. 52. Usage instructions provided in non -printed format must contain:

I - all information required in this Chapter and, when applicable, in regulations dedicated to specific medical devices;

II - identification of the version of the instructions of use corresponding to the respective product;

III - an alert to the user to observe the correlation of the version of the instructions for use indicated with the product purchased, as provided by the manufacturer; and

IV - the indication of how to obtain, at no additional cost (including shipping), the product use instructions in printed format.

Art. 53. For the supply of instructions for use over the internet, in addition to the established in arts. 51 and 52, the following requirements should also be met:

I - Provide with the product clear guidance on how to find the corresponding and up -to -date use instructions at the email address available on the Internet;

II - guarantee the basic security requirements of the email address;

III - make available the file of the instructions of use at the electronic address in non -editable reading format;

IV - make available at the email address free access to the tool required to read the instructions for use; and

V - Ensure that the file made available and printed by this way is identical to that provided by the manufacturer or holder of the notification or registration, when requested, in printed format.

Art. 54. The exclusive availability of non -printed format instructions for the following products is prohibited:

I - health use equipment that has an indication of:

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

b) Lay operation, regardless of the place of use.

II - health use materials used by lay public.

CHAPTER VII

TECHNICAL DOSSIER

Art. 55. Legal and technical guardians of the requesting company are responsible for the information and documents presented.

Art. 56. It is the responsibility of the holder of the medical device notification to keep the technical dossier updated, containing all the documents and information indicated in this Resolution, for supervisory purposes by the National Health Surveillance System.

§ 1. This technical dossier shall not be filed with Anvisa as part of the product notification request, and shall remain in possession of the company holding the notification.

§ 2. The technical dossier does not need to correspond to a physical or electronic file containing all the information described below, and may be composed of references to documents and information that makes up other files or records of the company's quality system, which must be available to Inspection of the National Sanitary Surveillance System.

§ 3. In specific cases, when investigations and investigations are necessary, the technical dossier may be requested to Anvisa.

Art. 57. The technical dossier must include the following information, which must be structured as described in Annex II of this Resolution:

I - detailed description of the medical device, including the fundamentals of its operation and action, its content or composition, when applicable, as well as list of accessories intended to integrate the product;

II - indication, purpose or use to which the medical device is intended, as indicated by the manufacturer;

III - precautions, restrictions, warnings, special care and clarification on the use of the medical device, as well as its storage and transportation;

IV - forms of presentation of the medical device;

V - labels and instructions for use, according to arts. 46 to 49 of this Resolution;

VI - flow diagram containing the steps of the manufacturing process of the medical device with a description of each step of the process, until the finished product is obtained, with the indication of the manufacturing units and their respective steps;

VII - description of the safety and performance of the medical device, in accordance with the current regulation that provides for the essential security and performance requirements of medical devices.

§ 1. Proof of the safety and performance of the medical device shall meet the requirements established in applicable technical standards.

§ 2. If necessary, the health authority may request additional information or clarifications, as well as presentation of complementary documentation, including specifically designed clinical study report and conducted for investigation of the medical device object of interest.

Art. 58. The information of the technical dossier shall be organized in accordance with the product's sanitary risk class, as provided in Annex II of this Resolution.

CHAPTER VIII

FINAL AND TRANSITORY PROVISIONS

Art. 59. The notification regime applies the same typification of sanitary infractions and the associated combinations in force for the medical device registration regime.

Art. 60. Notifications and records of medical devices, their changes and other acts will be published in the Federal Official Gazette and will remain available for consultation on Anvisa's electronic portal.

§ 1. Products subject to notification and registration may only be industrialized, imported, exposed for sale or delivered to consumption after the publication of that number of notification or registration.

§ 2. Products made in national territory exclusively for export purposes do not require notification or registration with ANVISA.

Art. 61. Protocols of medical device registration petitions will be accepted with the structuring of a technical report provided for in Collegiate Board Resolution - RDC No. 185, of October 22, 2001, filed until February 28, 2023.

Sole Paragraph. For records granted during the effectiveness of RDC No. 185 of October 22, 2001, the maintenance of the technical report will be maintained until any amendment of a change in the registration of approval required, which shall include the new technical dossier structure.

Art. 62. The period of 365 (three hundred and sixty -five) days, counted from the entry into force of this Resolution, is established so that the holders of medical device notifications foster fictions of sanitary reframing of products that had their regime modified notification for registration as a function of updating the classification rules.

§ 1. The petition shall be instructed with the same documentation required for new product registration.

§ 2. The protocol of the request for certification of good manufacturing practices shall be accepted for the purpose of petition, as well as the beginning of the analysis in the sanitary reframing petitions.

§ 3. The granting of the sanitary re -combination requests is subject to the publication of a valid manufacturing certificate of good manufacturing issued by ANVISA and the fulfillment of other requirements for the registration of medical devices.

§ 4. Failure to comply with the caput will lead to cancellation of product notification.

Art. 63. The registration processes whose products had their regularization regime registration regime for notification depending on the updating of the classification rules will be treated by means of ANVISA rectification file.

Art. 64. The Collegiate Board Resolution - RDC No. 270, of February 28, 2019, published in DOU No. 43, of March 1, 2019, Section 1, p. 68, starts to be in force with the following change:

“Art. 5. Notifications of medical devices, their changes and other acts will be published in the Federal Official Gazette and will remain available for consultation on Anvisa's electronic portal.”

Art. 65. The Collegiate Board Resolution - RDC No. 340, of March 6, 2020, published in DOU No. 48, of March 11, 2020, Section 1, p. 56, starts to be in force with the following change:

“Art. 9º The immediate implementation changes will be published in the Federal

Official Gazette and, when applicable, the updated data will be publicized on the Anvisa Electronic Portal, observing the period of up to 30 (thirty) days, from the finalization of the protocol of the respective petition, regardless of of documentary analysis by Anvisa."

Art. 66. are revoked from the date of entry into force of this Resolution:

I - the Collegiate Board Resolution - RDC No. 185, of October 22, 2001;

II - Resolution - RE No. 1554, of August 19, 2002;

III - the Collegiate Board Resolution - RDC No. 207, of November 7, 2006;

IV - items I and II of article 2., and item II of article 5 of Normative Instruction - IN No. 4, of June 15, 2012;

V - Collegiate Board Resolution - RDC No. 15 of March 28, 2014;

VI - the Collegiate Board Resolution - RDC No. 40, of August 26, 2015.

Art. 67. This Resolution enters into force on 1. March 2023.

ANTONIO BARRA TORRES
Chairman

ATTACHMENT I

Medical device risk classification rules

Noninvasive devices

Rule 1

All noninvasive devices are classified in class I unless one of the following rules is applied.

Rule 2

All non -invasive devices intended for blood conduction or storage, fluids, cells or body tissues, liquids or gases with a view to eventual perfusion, administration or introduction to the body are classified in class II:

a) If they may be connected to an active device of classes II, III or IV; or

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 cells and body tissues, except for blood pockets and blood components, which are classified in Class III.

In all other cases, these devices are classified in class I.

Rule 3

All non -invasive devices designed 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 in the body are classified in class III, unless the treatment in which the device It is used to consist of filtration, centrifugation or change of gas or heat, in which case they are classified in class II. All non -invasive devices consisting of substance or mixture of substances to be used in vitro in direct contact with cells, tissues or human organs taken from the human body or used in vitro with human embryos, before its implantation or administration in the body, are classified in class IV.

Rule 4

All noninvasive devices that come into contact with skin or injured mucosa membrane are classified:

a) in class I, if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;

b) in class III, if they are intended to be used mainly in skin lesions that have

produced the dermis or mucous membranes and which can only heal by second intention;

c) in class II, if mainly intended to control the microenvironment of the skin or injured mucosa membrane; and

d) in class II in all other cases.

This rule also applies to invasive devices that come into contact with an injured mucosa membrane.

Invasive devices

Rule 5

All invasive medical devices applicable to body holes except surgically invasive devices, which are not intended to be connected to an active device or intended to be connected to an active class I device are classified:

a) in class I, if transient use is intended;

b) in Class II, if the use of short term is intended, except if used in the oral cavity to the pharynx, the ear canal to the eardrum or in the nasal cavity, in which case they are classified in class I; and

c) in class III, if long -term use is intended, except if used in the oral cavity to the pharynx, the ear canal to the eardrum or in the nasal cavity, and if they are not susceptible to absorption by the mucosa, in which case they are classified in class II.

All invasive medical devices applicable to body holes except surgically invasive devices, which are intended to be connected to an active medical device of Class II, III or IV, are classified in Class II.

All invasive medical devices applicable to body orifices, except surgically invasive devices, which are intended to be connected to a class II, III, or IV active medical device, are classified in class II.

Rule 6

All surgically invasive devices intended for transient use are classified in class II unless:

a) 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 in class IV;

b) they are reusable surgical instruments, in which case they are classified in class I;

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 they are classified in class IV;

d) are intended to supply energy in the form of ionizing radiation, in which case they are classified in class III;

e) have a biological effect or are absorbed, in whole or in large part, in which case they are classified in class III; or

f) are intended for the administration of drugs through a delivery system, when performed in a potentially dangerous way, considering the mode of application, in which case they are classified in class III.

Rule 7

All surgically invasive devices intended for short-term use are classified in class II unless:

a) 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 in class IV;

b) are specifically intended to be used in direct contact with the heart, the central

circulatory system or the central nervous system, in which case they are classified in class IV;

c) are intended to supply energy in the form of ionizing radiation, in which case they are classified in class III;

d) have a biological effect or are absorbed, in whole or in large part, in which case they are classified in class IV;

e) are intended to undergo a chemical change in the body, in which case they belong to class III, unless they are placed on the teeth; or

f) are intended to administer medication, in which case they are classified in class III.

Rule 8

All implantable devices and surgically invasive devices intended for long-term use are classified in class III unless:

a) are intended to be placed on the teeth, in which case they are classified in class II;

b) are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified in class IV;

c) have a biological effect or are absorbed, in whole or in large part, in which case they are classified in class IV;

d) are intended to undergo a chemical transformation in the body, in which case they are classified in class IV, unless they are placed on the teeth;

e) are intended to administer drugs, in which case they are classified in class IV;

f) are active implantable devices or their accessories, in which case they are classified in class IV;

g) are breast implants or surgical meshes, in which case they are classified in class IV;

h) are total or partial joint prostheses, in which case they are classified in class IV, with the exception of auxiliary components such as screws, wedges, plates and instruments; or

i) are intervertebral disc replacement implants or implantable devices that come into contact with the spine, in which case they are classified in class IV, with the exception of components such as screws, wedges, plates and instruments.

Active Devices

Rule 9

All active therapeutic devices intended to supply or exchange energy are classified in class II, unless, by their characteristics, they can supply energy to the human body or exchange energy with it in a potentially dangerous way, taking into account the nature, the density and the place of energy application, in which case they are classified in class III.

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 in Class III.

All active medical devices intended to emit ionizing radiation for therapeutic purposes, including medical devices that control or monitor these devices or that directly influence their performance, are classified in class III.

All active medical devices intended to control, monitor, or directly influence the performance of active implantable devices are classified in class IV.

Rule 10

Active devices for diagnosis and monitoring are classified in class II in cases where:

a) are intended to provide energy that will be absorbed by the human body, with the exception of devices intended to illuminate the patient's body in the visible spectrum, in which case they are classified in class I;

b) are intended to visualize in vivo the dissemination of radiopharmaceuticals; or

c) are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended to monitor or observe vital physiological parameters and the nature of variations in these parameters is likely to result in immediate danger to the patient, as is the case with variations in heart rate, breathing and central nervous system activity, or are intended for diagnosis in clinical situations in which the patient is in immediate danger, cases in which they are classified in class III.

Active devices intended to emit ionizing radiation for diagnostic or therapeutic radiology, including interventional radiology devices and those that control or monitor these devices, or that directly influence their performance, are classified in class III.

Rule 11

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 could cause:

a) the death or irreversible deterioration of a person's state of health, in which case it is classified in class IV; or

b) a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified in class III.

Software intended to monitor physiological processes is classified in class II, except when it is intended to monitor vital physiological parameters, when the nature of variations in these parameters could result in an immediate danger to the patient, in which case it is classified in class III.

Any other Software as a Medical Device (SaMD) is classified in class I.

Rule 12

All active medical devices intended to deliver drugs, body fluids or other substances into or from the human body are classified in class II, unless this is done in a potentially dangerous manner, taking into account the nature of the substances or part of the body involved and the mode of application, in which case they are classified in class III.

Rule 13

All other active medical devices not covered by the previous rules are classified in class I.

Special Rules

Rule 14

All devices that include, as an integral part, a substance which, if used separately, could be considered a medicinal product, including a medicinal product derived from human blood or plasma, and which has an action complementary to that of the devices, are classified in class IV.

Rule 15

All devices used in contraception or in the prevention of transmission of sexually transmitted diseases are classified in class III, except when they are implantable or invasive devices intended for long-term use, in which case they are classified in class IV.

Rule 16

All medical devices specifically intended to be used to disinfect, clean, wash or, where applicable, moisturize contact lenses are classified in class III.

All devices specifically intended to be used to disinfect or sterilize medical devices are classified in class II, except in the case of washing and disinfecting machines specifically intended to be used to disinfect invasive devices, as a final step in processing, in which case

they are classified in class III.

This rule does not apply to devices intended for cleaning, solely by physical action, of devices other than contact lenses.

Artificial tears and ophthalmic lubricants, when classified as medical devices, are classified in class III.

Rule 17

Devices specifically intended to record diagnostic images generated by X-rays are classified in Class II.

Rule 18

All devices manufactured using non-viable cells, tissues, or their 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 the intact skin.

This rule does not apply to advanced therapy products, which are dealt with by specific regulation.

Rule 19

All devices that incorporate nanomaterials or consist of nanomaterials are classified:

a) in class IV, if they present a high or medium potential for internal exposure;

b) in class III, if they present a low potential for internal exposure; and

c) in class II, if they present an insignificant potential for internal exposure.

Rule 20

All invasive devices applicable to body orifices, except surgically invasive devices, intended for the administration of drugs by inhalation are classified in class II, unless their mode of action has a significant impact on the efficacy and safety of the drug administered. or are intended to treat life-threatening conditions, in which case they are classified in class III.

Rule 21

The medical devices consisting of substances or combinations of substances that are intended to be introduced into the human body through a body hole or applied to the skin and are absorbed or disseminated by the human body or locally dispersed in it are classified:

a) in class IV if devices, or their metabolism products, are absorbed or systemically disseminated by the human body to achieve the intended purpose;

b) in class IV if they reach the intended purpose in the stomach or lower gastrointestinal tract and whether devices, or their metabolism products, are absorbed or systemically disseminated by the human body;

c) in class II if they are applied to the skin or if they are applied to the nasal or oral cavities to the pharynx, and if they reach the intended purpose in these cavities; and

d) in class III in all other cases.

Rule 22

Active therapeutic devices with integrated or incorporated diagnostic function that significantly direct patient management, such as closed-circuit systems or external automatic defibrillators, are classified in class IV.

ATTACHMENT II

Technical dossier structure of medical devices subject to notification and registration with ANVISA

Medical Device Technical Dossier[1]	**Notification**		**Registration**	
	Class I	**Class II**	**Class III**	**Class IV**
Chapter 1				
Administrative and technical information (forms available on the Anvisa Portal)	X	X	X	X
List of devices (Models / Components / Variants)	X	X	X	X
Chapter 2				
Detailed description of the medical device and grounds of operation and action	X	X	X	X
Description of the packaging and device presentation ways	X	X	X	X
Intended purpose (purpose of use); Purpose of use; Intended user; Indication of use	X	X	X	X
Environment / context of intended use	X	X	X	X
Contraindications of use	X	X	X	X
Global History of Commercialization	-	X	X	X
Chapter 3				
Risk Management	X	X	X	X
List of essential security and performance requirements	-	X	X	X
List of Technical Standards	X	X	X	X
Physical and Mechanical Characterization	X	X	X	X
Material/Chemical Characterization	X	X	X	X
Electrical Systems: Safety, Mechanical and Environmental Protection, and Electromagnetic Compatibility	X	X	X	X
Software / Firmware Description	X	X	X	X

Biocompatibility Assessment	X	X	X	X
Pyrogenicity Assessment	X	X	X	X
Safety of Materials of Biological Origin	X	X	X	X
Sterilization Validation	X	X	X	X
Residual Toxicity	X	X	X	X
Cleaning and Disinfection of Reusable Products	X	X	X	X
Usability / Human Factors	X	X	X	X
Product Shelf Life and Packaging Validation / Stability Study	X	X	X	X
Chapter 4				
General Summary of Clinical Evidence[2]	X	X	X	X
Relevant Clinical Literature	-	X	X	X
Chapter 5				
Product Labeling / Packaging	X	X	X	X
Instructions for Use / User Manual	X	X	X	X
Chapter 6				
General Manufacturing Information (Addresses of Manufacturing Units)	X	X	X	X
Manufacturing Process (Flowchart)	X	X	X	X
Design and Development Information	X	X	X	X

Notes:

1) The Medical Devices Technical Dossier Structure is aligned with the document issued by the International Medical Device Regulators Forum - IMDRF/RPS WG/N9 (Edition 3) FINAL:2019 - Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC) and may be updated considering possible future editions.

2) Applicable only when clinical evidence is required as a result of demonstration of safety and performance, technological innovations and new indications for use. In compliance with current health legislation for clinical trials conducted in Brazil, and the Specific Special Notice must be presented.