Ministry of Health - MS
National Health Surveillance Agency – ANVISA

RESOLUTION OF THE BOARD OF DIRECTORS - RDC NO. 751, OF SEPTEMBER 15, 2022

(Published in DOU No. 180, of September 21, 2022)

Provides for risk classification, notification and registration schemes, and labeling requirements and instructions for use of medical devices.

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

CHAPTER I

OF THE INITIAL PROVISIONS

Section I

Purpose

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

Section II

Scope

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

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

§° 2º This Resolution does not apply to used or refurbished medical devices, which are subject to the specific rules established in the Resolution of the Collegiate Board of Directors - RDC No. 579, of November 25, 2021, published in DOU No. 225, of December 1, 2021.

§ 3º This Resolution does not apply to custom 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, p. 69.

§ 4 This Resolution does not apply to medical devices for in vitro diagnosis, including instruments for in vitro diagnosis, which are subject to the specific rules set out in the Resolution of the Collegiate Board - RDC No. 36, of August 26, 2015, published in DOU No. 164, Of 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 The active devices (equipment) indicated for aesthetic correction and beautification are considered medical devices.

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

§ 8 Medical devices intended for clinical investigations are exempt from notification or registration, complying with the legal provisions of the health authority competent to carry out this activity, and marketing and use for other purposes is prohibited.

§ 9 Presentations consisting of two or more notified or registered medical devices and in their individual packaging of intact presentation shall be exempt from notification or registration. They shall contain on the label the information of the corresponding medical devices, including the notification or registration numbers.

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

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

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

Single paragraph. The grouping of products, for the purpose of notification or registration, shall take place in accordance with the rules laid down in a specific regulation.

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Section

III

Definitions

Article 4 For the purposes of this Resolution the following shall apply definitions, which can have different meaning in another context.

I - accessory (of a medical device): a product intended by its manufacturer to be used in conjunction with one or more specific medical devices, to permit or assist specifically and directly that the medical device(s) are used for the intended purpose;

II - agglomerate: for the purpose of defining nanomaterial, a set of weakly bound 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 purpose of the definition of nanomaterial, a particle comprising heavily bonded or fused particles, in which the resulting external surface area may be significantly less than the sum of the calculated surface areas of the individual components;

IV - Change: Modification of information submitted to Anvisa in the notification process or registration of the medical device and in its respective secondary petitions;

V - Change of approval required: Amendment of greater sanitary relevance, which deals with change to be introduced in the registration process, being authorized in national territory only after technical documentary analysis and favorable manifestation of Anvisa;

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

VII - Non-reportable change: Any other change of less sanitary relevance, resulting from a change that is not classified as required approval or immediate implementation, and that does not depend on protocol in Anvisa for implementation;

VIII - Holder (notification or registration): Legal entity, public or private, manufacturer or importer, responsible for the medical device in national territory, which holds the concession of marketing 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, in the context of a surgical intervention; and device that penetrates the body by a route 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 articles, intended by the manufacturer to be used, alone or jointly, in human beings, for any of the following specific medical purposes, and whose main intended action is not achieved by pharmacological, immunological or metabolic means in the human body, but that can be assisted in their intended action by such means:

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

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

c) research, substitution, alteration of anatomy or process or physiological or pathological state;

d) support or maintenance of life;

e) control or support to conception; or

f) provision of information through in vitro examination of samples from the human body, including donations from organs and tissues.

XI - active medical device: any device whose operation depends on a source of energy not generated by the human body for that purpose, or by gravity, and which acts by changing the density or by converting that energy, except for 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 alone or in combination with other devices to provide information for the detection, diagnosis, monitoring, observation or treatment of physiological states, health states, diseases or congenital malformations;

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

XIV - implantable medical device: any device, including those which are partially or totally absorbed, intended to be fully inserted into the human body; or to replace an epithelial surface or the ocular surface, by clinical intervention, and intended to remain in this place after the intervention, or that 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;

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

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

XVII - active therapeutic medical device: any active device used alone or in combination with other devices to maintain, modify, replace or restore biological functions or structures in the context of treatment or mitigation of a disease, injury or disability;

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

XIX - legal manufacturer: legal entity, public or private, responsible for the design, manufacture, packaging and labeling of a product, with the intention of making it available for use under its name, these operations being carried out by the company itself or by third parties on its behalf.

XX - family: grouping of medical devices, for the purpose of notification or registration, provided for in a 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, where applicable; and

e) Precautions, restrictions, warnings and special care.

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

XXII - importer: legal entity, public or private, responsible for the import activity for the entry of medical devices from abroad into 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, its correct use and any precautions to be taken;

XXIV - reusable surgical instrument: an instrument intended to cut, drill, ripple, sawing, scrape, remove, staple, remove, trim or perform similar procedures in the context of clinical and surgical interventions, and may or may not connect to an active device, and intended by the manufacturer to be reused after appropriate procedures have been carried out, such as cleaning, disinfection and sterilization;

XXV - clinical investigation: any systematic investigation or study in one or more human beings carried out to assess the safety, clinical performance and/or efficacy 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 registered or notified individually, are grouped into a sales unit for a specific purpose of use or procedure:

a) for the purpose of regularization, the whole shall be of the same manufacturer or group; and

b) the components of a medical device kit alone do not maintain an interdependence relationship to achieve the functionality and performance it is intended for.

XXVII - lot or departure: the quantity of a medical device prepared in a manufacturing or sterilization cycle, the essential characteristic of which is homogeneity;

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

a) fulerenos, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm are also considered nanomaterials.

b) manufactured materials with dimensions that extrapolate the upper limit of the nanoscale (established between 1 and 100 nm), up to the 1000 nm mark, and that exhibit different size-dependent properties or phenomena 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 body, which provides for common and repetitive use rules, guidelines or characteristics for activities or their results, aiming to obtain an optimal degree of ordering in a given context;

XXX - Notification: Act of communicating to Anvisa the intention to commercialize medical device, intended to prove the right to manufacture and import medical device exempted from registration in the form of §1 of article 25 of Law No. 6,360 of September 23, 1976, And classified in risk classes I or II, with the name, manufacturer, purpose and 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 purpose of nanomaterial definition, a tiny portion of matter with defined physical boundaries;

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

XXXIV - Procedural reassessment: Procedure carried out by Anvisa's technical area in notifications and records of medical devices for audit purposes in the processes;

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

XXXVI - Documentary repository of medical devices: A digital tool for storing and making available documents related to notified and registered medical devices, available on the electronic portal of Anvisa;

XXXVII - legal guardian: a natural person designated by statute, social contract or minutes, responsible for representing, actively and passively, in judicial and extrajudicial acts, the requesting legal entity (manufacturer or importer);

XXXVIII - technical manager: a 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 for the quality, safety and performance of the product marketed;

XXXIX - label: written, printed or graphic information on the product itself, on the packaging of each unit or on the packaging of several devices;

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

XLI - Central Circulatory System: A system that includes the following blood vessels: Pulmonary arteries, ascending aorta, aortic arch, descending aorta to aortic bifurcation, coronary arteries, common carotid artery, external carotid artery, internal carotid artery, cerebral arteries, brachycephalic trunk, coronary veins, pulmonary veins, superior vena cava and inferior vena cava;

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

XLIII - Software as a Medical Device (Software as a Medical Device - SaMD): A product or application intended for one or more purposes indicated in the definition of a medical device and which performs its functions without being part of the hardware of a medical device, having the following characteristics:

a) SaMD can be run on a general purpose computing platform (non-medical purpose);

b) the "computing platform" includes hardware and software features (operating system, processing hardware, storage, database, visualization devices, input devices, programming language, etc.);

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

d) A software is not considered SaMD if its purpose is to control the hardware of a medical device;

e) A SAMD can be used in combination (e.g. 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 other SaMD, as well as general purpose software; and

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

XLIV - Applicant: Legal entity, public or private, that forwards petitions for the notification or registration of medical devices with the health authority;

XLV - manufacturing unit: Place where one or more stages of manufacture takes place, may be the legal manufacturer itself, contracted manufacturer or original manufacturer of product;

XLVI - Short-term use: Use normally performed continuously over a period of 60 (sixty) minutes to 30 (thirty) days;

XLVII - Long-term use: Use normally performed continuously over a period of more than thirty (30) days;

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

XLIX - User: Health professional or layperson, 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 Framework

and Control Regime

Article 5 Medical devices, the object of this Resolution, are framed according to the intrinsic risk they pose 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; E

IV - Class IV: Maximum risk.

§ 1 For framing the medical device in one of these classes, the classification rules set out in this Resolution shall 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 awarded the framework of the medical device.

Article 6 Medical devices falling within risk classes I and II are subject to notification.

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

Section II

Application Rules

Article 8 The application of the classification rules shall be 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 shall apply separately to each device.

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

§ 3 The software that commands 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 independently classified.

§ 5 If the device is not intended to be used exclusively or mainly in a certain part of the body, it shall be considered and classified on the basis of 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, apply the stricter rule and sub-rule leading to higher classification.

§ 7 In the calculation of the duration of use "continuously" one should consider:

a) the entire duration of use of the same device without taking into account temporary interruptions of use during a procedure or temporary removal for cleaning or disinfection of the device, and whether the interruption of use, or removal, it is temporary because of the duration of use prior to and after the period in which use is interrupted or 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 It is considered that a device allows a direct diagnosis when it provides itself the diagnosis of the disease or condition in question, or when it provides decisive information for the diagnosis.

Section III

Classification Rules

Article 9 Medical devices are classified according to risk, as per
The rules set out in Annex I to this Resolution.

CHAPTER III.

REQUEST FOR NOTIFICATION OR REGISTRATION 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, alteration, revalidation or cancellation of notification or registration of the medical device, related in this Resolution.

§ 1 Anvisa will evaluate the documentation submitted for registration, alteration or revalidation of the registration and will manifest itself through official means.

§ 2º The evaluation of the documentation will 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 without documents, forms and declarations, provided for in the list of documents of procedural instruction, completed in incomplete form or with missing or illegible information, or obsolete, without certificate of conformity where applicable, shall not be subject to technical requirement. or without clinical evidence for products with innovative technology or indication, giving rise to non-consent or summary rejection of the petition.

§ 5 There shall be no technical analysis of the requests for notification and amendment of notification so that the products are considered regularized, without prejudice to the carrying out, at any time, of documentary or fiscal evaluations on the notification procedures and their amendments, and, if necessary, request for additional information or clarifications.

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

§ 7 Maintaining notification and registration is bound by compliance with the requirements of Good Manufacturing Practices, essential safety and performance requirements and specific regulations where they exist.

§ 8 The approval of the registration is conditional on the publication of the Certificate of Good Manufacturing Practices issued by Anvisa.

§ 9 Petition forms, instructions for use or user/operator manuals and labeling models should be presented in the Portuguese language.

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

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

Art. 12. Medical devices subject to conformity certification under the Brazilian Conformity Assessment System (SBAC) can only be imported and marketed if manufactured during the validity of the Certificate of Conformity.

Section II.

Notification of medical devices

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

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

II - For imported medical devices: A statement issued by the legal manufacturer, consulted or apostilated, 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 its product(s) in Brazil;

III - Copy of the certificate of conformity issued under the Brazilian System of Conformity Assessment (SBAC), applicable only to medical devices with compulsory certification, related by Anvisa in specific regulations; and

IV - proof of compliance with the legal provisions determined in technical regulations, in the form of legislation regulating specific medical devices.

Single paragraph. The statement that it deals with item II shall contain the social reason 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 the knowledge and compliance with the requirements of Good Manufacturing Practices of Health Products established in the Resolution of the Collegiate Board - RDC No. 665, of March 30, 2022, or regulation that will replace - la.

Section III.

Registration of medical devices

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

I - Form for registration of medical device, duly completed, available on the electronic portal of Anvisa;

II - Technical Dossier, as provided for in Chapter VII of this Resolution;

III - For imported medical devices: A statement issued by the legal manufacturer, consulted or apostilated, 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 its 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 for a maximum of two years when there is no express validity indicated in the document, must be consulted or apostilated, 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 application for Certificate of Good Manufacturing Practices;

VI - Copy of the certificate of conformity issued under the Brazilian System of Conformity Assessment (SBAC), applicable only to medical devices with compulsory certification, related by Anvisa in specific regulations; and

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

§ 1 The statement that it deals with item III shall contain the social reason 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 the requirements of Good Manufacturing Practices of Health Products established in the Resolution of the Collegiate Board - RDC No. 665, of March 30, 2022, or regulation that will replace it.

§ 2º The protocol of the Application for Certification of Good Manufacturing Practices will be accepted for the purpose of petitioning, as well as the beginning of the analysis in the petitions for granting registration.

§ 3º The approval of applications for granting registration is conditional on the publication of a certificate of good manufacturing practice issued by Anvisa and the fulfillment of the other requirements for registration of medical devices.

Section IV.

Change of notification or Medical Device Registration

Art. 15. In order to request the alteration of the notification or registration of medical device, the requester must proceed with the payment of the corresponding fee, if applicable, and present the declaration relating the changes requested and other required documents, according to the subject requested.

Art. 16. Changes to information presented in the medical device notification or registration process are classified under:

I - amendment of approval required;

II - Immediate implementation change; and

III - Non-reportable change.

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

§ 2º Any minor changes not classified as required approval or immediate implementation are classified as non-reportable changes, and also: Changes in information that do not modify the medical device design; bug fixes in software; Non-technical changes such as images, formatting, layouts, symbols and text adaptations of documents without additional risk; updates of company operating authorization information; changes of contact (e.g. telephone numbers or postal address), technical assistance and website.

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

§ 4º The change petitioning for medical devices of risk classes I and II will be performed by the immediate implementation regime, except when it is a non-reportable change.

Art. 17. The subjects of petition for change of notification or registration of medical devices are provided by Normative Instruction - IN No. 74, of September 16, 2020, which identifies the changes that are considered as required approval or immediate implementation.

Art. 18. The request to change information must be accompanied by documentation proving the modification to be implemented, in accordance with the current health legislation.

Art. 19. The immediate implementation change that is interdependent with the required approval change should be requested in conjunction with this amendment, incorporating its content.

Art. 20. Changes resulting from field action notified to Anvisa in order to ensure the safety and performance of the device in relation to the user and the patient will have their analyzes prioritized.

Single paragraph. To request the prioritization of the analysis cited in the caput the company must protocol the claim, presenting evidence of sending the notification of the field action to Anvisa.

Art. 21. The required approval change will only take effect after the final decision is published in the Official Gazette and, where applicable, the updated data will be published in the electronic portal of Anvisa.

Art. 22. Changes in immediate implementation will be published in the Official Gazette and, where applicable, the updated data will be published in the electronic portal of Anvisa, observing the period of up to thirty (30) days, counted from the completion of the protocol of the respective petition, regardless of document analysis by Anvisa.

Art. 23. The request for immediate implementation may be subject to documentary or fiscal evaluation at any time by Anvisa and, if necessary, additional information or clarification may be requested.

Single 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 change that justifies such sanitary measure.

Art. 24. The acceptance of requests for modification/inclusion of a manufacturing plant or change of the factory address or inclusion of products or models in the family/system/set of products framed in risk classes III and IV, It is conditioned to the publication of the Certificate of Good Manufacturing Practices issued by Anvisa and to the fulfillment of the other requirements corresponding to each type of petition.

Single paragraph. The protocol of the Application for Certification of Good Manufacturing Practices will be accepted for the purpose of petitioning, as well as the beginning of the analysis in the petitions.

Art. 25. If the stock of finished products needs to be exhausted as a result of a change, the simultaneous import and commercialization of the versions involved is allowed until the end of the shelf life or shelf life of the product.

Single paragraph. Changes made to troubleshoot product security and performance issues do not fall under the caput permission.

Art. 26. It is allowed to deplete 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.

Single paragraph. Changes made to troubleshoot product security and performance issues do not fall under the caput permission.

Section V

Medical Device Registration Revalidation

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

I - For imported medical devices: Declaration issued by the legal manufacturer consulted or apostilated, written in Portuguese, English or Spanish or accompanied by 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 its product(s) in Brazil.

II - Certificate of Good Manufacturing Practice issued by valid Anvisa.

§ 1 The statement that the item I deals with must contain the social reason 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 the requirements of Good Manufacturing Practices of Health Products established in the Resolution of the Collegiate Board - 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.

§ 2º The request for revalidation must be submitted within the time limit set by the Resolution of the Collegiate Board - RDC No. 250, of October 20, 2004.

§ 3º The protocol of the Application for Certification of Good Manufacturing Practices will be accepted for the purpose of petitioning and analysis of registration revalidation petitions.

Art. 28. The products submitted the notification regime is exempted from revalidation.

Section VI.

Cancellation of Notification or Registration of Medical Devices

Art. 29. The holder of notification or registration of medical device that intends no longer to market it in the Brazilian market must request its cancellation.

Section VII Compliance

of Information

Art. 30. Changes made by the manufacturer in the information relating to the medical device contained in the notification or registration shall be communicated By the holder to Anvisa, in accordance with the requirements set out in Section IV of this Resolution.

Art. 31. Changes relating to a medical device that require prior approval by Anvisa may only be disclosed to the market after publication of the said change in the Official Gazette and electronic portal of Anvisa.

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

Section VIII.

Document repository of medical devices

Art. 33. The loading of instructions for use in the Medical Device Documentary Repository corresponds to the insertion and updating of these documents linked to the processes of notification or registration of medical devices.

§ 1 In the case of a medical device that does not have instructions for use (as a specific document), the labeling model must be loaded in the field of instructions for use, including the information provided for in Chapter VI.

§ 2º The loading of instructions for use should occur through the applicable petitioning subjects, identified as "provision of instructions for use on the Anvisa Portal".

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

§ 4º The loading of instructions for use is mandatory and must be carried out by the company responsible for the notification or registration of the product, which certifies that its content complies with the current legislation and consistency with the regularized product.

§ 5º For new products notified or registered and for changes to those products previously notified or registered, the petitioning and the respective loading of instructions for use shall be carried out within thirty (30) days of publication in the Official Gazette.

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

Art. 34. The provision of instructions for use will be carried out exclusively on the electronic portal of Anvisa, immediately after the completion of the protocol of the respective petition, regardless of document analysis by the Agency.

§ 1 The update is performed by means of a new insertion of instructions use.

§ 2. There is a new loading of instructions for use in the process of notification or registration will be kept public only those recently uploaded.

§ 3 The instructions for use uploaded over time will be kept in a database for control and audit by Anvisa.

Art. 35. The instructions for use uploaded or the absence of them under this Resolution may be subject to documentary or fiscal evaluation at any time by Anvisa and, if necessary, the Agency may:

I - to request information, further clarification or loading of the appropriate instructions for use; and/or

II - withdraw instructions for use or restore a previous version, where there is justification for such measures.

Art. 36. The companies that enter information in the Documentary Repository of Medical Devices that do not comply with the current legislation and consistency with the regularized product are subject to the penalties provided for in Law No. 6,437 of August 20, 1977.

Single 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 instructions for use appropriate to the terms of this Resolution, in accordance with the provisions of article 15 of Law no. 6,437, of august 20, 1977.

Section IX.

Procedure for Reevaluation Procedure

Art. 37. Medical device notification and registration processes are subject to procedural assessment and reassessment, audit, market monitoring and inspection by the competent health authority.

Art. 38. In cases where inconsistencies or the need to supplement information are evident, the holders will be urged to adapt their processes.

§ 1 The adjustments to which the caput is processed must be answered by the holder of the notification or registration within thirty (30) days from the date of confirmation of its receipt.

§ 2º The situations that cause correction of the previously presented information should be treated by means of specific petitioning.

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

CHAPTER IV

ADMINISTRATIVE SANCTIONS

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

I - The validity of any of the documents referred to in Articles 13 and 14 of this Resolution is suspended for reasons of duly justified security;

II - It is proven that no compliance with any requirement of Chapter III, Section VII of this Resolution is complied with; or

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

Art. 40. The suspension of the manufacture, import, marketing and use of medical device will be published in the Official Gazette and will be maintained until the solution of the problem that caused the sanction and its annulment is communicated.

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

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

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

IV - an error in the health environment is identified in the notification procedures; or

V - When there is no compliance with the demands of procedural revaluation presented by Anvisa.

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

Art. 43. Anvisa may at its discretion and at any time request information or clarifications prior to the decision to cancel irregular notification of medical device.

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

CHAPTER V

REQUESTER INFORMATION FORMS AND THEIR MEDICAL DEVICES

Art. 45. The applicable forms on information of the applicant and the product subject to notification or registration process must be completed electronically on the Anvisa electronic portal.

Single paragraph. Where applicable, the forms must be submitted with the signatures of legal and technical officials.

CHAPTER VI.

LABELS AND INSTRUCTIONS FOR USE OF MEDICAL DEVICES

Section I

Information requirements on labels and instructions for use

Art. 46. The label information and instructions for use of medical devices must meet the following general requirements:

I - the information on the labels and instructions for use must be written in the portuguese language;

II - all medical devices must include instructions for use in their packaging or refer to the way in which they are accessed;

III - Exceptionally, these instructions may not be included in the packaging of medical devices falling within Classes I and II, provided that the safety of use of these products can be guaranteed without such instructions;

IV - the information necessary for the safe use of the medical device shall be included, where possible, on the medical device itself or on the label of its individual packaging, or, where this is not possible, on the label of its commercial packaging;

V - if it is not possible to individually pack each unit, this information shall be included in the instructions for use accompanying one or more medical devices;

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

VII - if there is no regulation, the symbols and colors must be described in the documentation accompanying the medical device; and

VIII - if additional information is required in a specific technical regulation of a medical device due to the specific nature of the product, it shall be incorporated into the label or instructions for use, as applicable;

Art. 47. The label template must contain the following information:

I - the corporate reason and address of the legal manufacturer, preceded by the term "manufacturer" or equivalent symbology;

II - social reason and address of the holder of the notification or registration;

III - the information necessary for the user to identify the medical device and the contents of its packaging;

IV - Where applicable, the word "Sterile" and the method of sterilization;

V - The lot code, preceded by the word "Lot", or the serial number, as the case may be;

VI - as applicable, date of manufacture and expiry date or date before which the medical device is to be used;

VII - where applicable, the indication that the medical device is of use unique;

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

IX - The special instructions for operation and/or use of the medical device; X - all warnings and precautions to be taken;

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

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

Art. 48. The Model Instructions for Use must contain the following information, as applicable:

I - The information referred to in article 47 of this Resolution, except those contained in sections "V", "VI" and "XI";

II - the purpose of use assigned by the manufacturer as well as any possible undesirable side effects;

III - if a medical device is to be installed or connected to other medical devices to function according to the intended purpose, sufficient detailed information on its characteristics must be provided to identify the medical devices that can be used with the product, in order to obtain a safe combination;

IV - all information that can prove whether a medical device is well installed and can function properly and safely, as well as information regarding the nature and frequency of the maintenance and calibration operations to be carried out in order to ensure the permanent functioning and safety of the medical device;

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

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

VII - the necessary instructions in the event of damage to the protective sterility packaging and, where applicable, the indication of the appropriate methods of re-sterilization;

VIII - where the medical device is reusable, information on appropriate procedures for re-use, including cleaning, disinfection, packaging and, as appropriate, the sterilization method, if the product is to be re-sterilized, and any restrictions on the possible number of re-uses;

IX - Where the medical device is to be sterilized before use, the instructions for cleaning and sterilization shall be formulated in such a way that, if properly performed, the product meets the requirements laid down by the manufacturer as to the essential requirements of Safety and Performance (or Effectiveness);

X - information on additional treatment or procedure to be performed before using the medical device;

XI - where a medical device emits radiations for medical purposes, information concerning the nature, type, intensity and distribution of such radiations shall be described;

XII - instructions for use shall include information enabling the health professional to inform the patient of contraindications and precautions to be taken;

XIII - the precautions to be taken in the event of a change in the functioning of the medical device;

XIV - precautions to be taken concerning exposure, under reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or pressure variations, acceleration and thermal ignition sources, among others;

XV - appropriate information on the medicinal product(s) which the medical device is intended to administer, including any restrictions on the choice of such substances;

XVI - the precautions to be taken if the medical device presents a specific unpredictable risk associated with its elimination;

XVII - mention of medicinal products incorporated into the medical device as an integral part of the medical device; and

XVIII - the level of accuracy assigned to medical measuring devices.

Art. 49. The notified or registered health surveillance equipment must have affixed an indelible label indicating:

I - trade name of the product, with indication of the model, where

applicable; II - name of the legal manufacturer or brand;

III - Notification number or registration with Anvisa; and

IV - serial number or other identifier allowing traceability of the equipment.

§ 1 For small size and/or implantable equipment, where such a label cannot be fixed, identification of the manufacturer or brand and traceability elements shall be required.

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

§ 3 Excludes non-implantable single-use equipment from the caput.

Section II.

Instructions for use in unprinted format

Art. 50. Instructions for use in non-printed form may be provided on physical media or made available on the Internet or in another format that meets all the requirements of this Resolution.

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

I - to inform on the external label how to obtain the correlation between the product provided and the version of the corresponding instruction of use;

II - Indicate on the label a Consumer Care Service where the printed format of the instructions for use can be requested at no additional cost (including shipping);

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

IV - specify the necessary resources for reading user instructions for use.

§ 1 Where the dimensions of external labeling do not permit, 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 specified service life for the product, counted from the last unit marketed of the product.

Art. 52. Instructions for use provided in non-printed format should contain
:

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

II - identification of the version of the instructions for 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 made available by the manufacturer; and

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

Art. 53. In order to provide the instructions for use over the internet, in addition to the provisions set out in articles 51 and 52, the following requirements must also be met:

I - provide with the product clear guidance on how to find the corresponding and up-to-date instructions for use at the e-mail address available on the internet;

II - ensure the basic security requirements of the e-mail address;

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

IV - provide in the electronic address free access to the necessary tool for reading the instructions for use; and

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

Art. 54. It is forbidden to provide the instructions for use in non-printed format for the following products:

I - Equipment for health use that have indication of:

a) Household use in general, including those used in home care service - SAD; E

b) operation by laypersons , regardless of the place of use. II -

Health use materials used by lay public.

CHAPTER VII.

TECHNICAL DOSSIER

Art. 55. The legal and technical officers 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 up to date, containing all the documents and information indicated in this Resolution, for the purpose of surveillance by the National Health Surveillance System.

§ 1 This Technical Dossier must not be filed with Anvisa as part of the product notification request, and must remain in the possession of the company that owns the notification.

§ 2º 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 make up other files or records of the company's quality system, Which should be available for supervision of the National Health Surveillance System.

§ 3 In specific cases, when investigations and investigations are necessary, the Technical Dossier may be requested to send to Anvisa.

Art. 57. The Technical Dossier must include the following information, which must be structured as described in Annex II to this Resolution:

I - a detailed description of the medical device, including the grounds for its operation and its action, its content or composition, where applicable, and the list of accessories intended to integrate the product;

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

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

IV - forms of presentation of the medical device;

V - label templates and instructions for use, according to art. 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 stages;

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

§ 1 The proof of the safety and performance of the medical device must meet the requirements set out in applicable technical standards.

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

Art. 58. The information of the Technical Dossier shall be organized according to the health risk class of the product, as set out in Annex II to this Resolution.

CHAPTER VIII FINAL

PROVISIONS AND TRANSITÓRIAS

Art. 59. The notification regime applies the same types of health violations and the associated actions in force for the registration regime
of medical devices.

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

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

§ 2 Products manufactured 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 the Resolution of the Collegiate Board of Directors - RDC No. 185, of October 22, 2001, protocolized until February 28, 2023.

Single paragraph. For records granted during the term of RDC No. 185, of October 22, 2001, the maintenance of the structuring of technical report will be allowed until possible request for change of approval registration required, which should include the new structure of Technical Dossier.

Art. 62. The period of 365 (three hundred sixty-five) days, counted from the entry into force of this Resolution, is hereby established. in order for the holders of medical device notifications to protocol sanitary reframing petitions of products that had their regime modified from notification to registration according to the updating of classification rules.

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

§ 2º The protocol of the Application for Certification of Good Manufacturing Practices will be accepted for the purpose of petitioning, as well as the beginning of the analysis in the petitions for sanitary reframing.

§ 3º The approval of requests for sanitary reframing is conditional on the publication of a certificate of good manufacturing practice issued by Anvisa and on compliance with the other requirements for registration of medical devices.

§ 4º The failure to comply with the provisions of the caput will result in the cancellation of the product notification.

Art. 63. The registration processes whose products have had their regularization regime modified from registration to notification due to the updating of the classification rules will be treated by means of Anvisa rectification office.

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, becomes effective with the following amendment:

"Article 5 Notification of medical devices, their changes and other acts will be published in the Official Gazette and will remain available for consultation on the electronic portal of Anvisa."

Art. 65. The Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020, published in DOU No. 48, of March 11, 2020, Section 1, p. 56, becomes effective with the following amendment:

"Article 9 The immediate implementation changes will be published in the Official Gazette and, where applicable, the updated data will be published in the electronic portal of Anvisa, observing the period of up to thirty (30) days, counted from the completion of the protocol of the respective petition, Regardless of document analysis by Anvisa."

Art. 66. They shall be repealed from the date of entry into force of the latter Resolution

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

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

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

IV - Article 2(I) and (ii) and Article 5(ii) of the Instruction Normative - IN No. 4, of June 15, 2012;

V - Resolution of the Collegiate Board of Directors - RDC No. 15, of March 28, 2014; VI - Resolution of the Collegiate Board of Directors - RDC No. 40, of August 26, 2015. Art. 67. This Resolution comes into force on March 1, 2023.

ANTONIO BAR TOWERS
Director-President

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

ANNEX I

Rules of Risk Classification of Medical Devices Non-invasive devices

Rule 1

All non-invasive devices are classified in Class I unless one of the following rules applies.

Rule 2

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

a) If they can be connected to an active class II, III or IV device;

or

b) if they are intended to be used for driving or storage
Blood or other body fluids or for the storage of organs, parts of organs or cells and body tissues, with the exception of blood bags and hemocomponents, which are classified in Class III.

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

Rule 3

All non-invasive devices intended to alter the composition
Biological or chemical of tissues or cells of human origin, blood, other bodily fluids, or other liquids for implantation or administration in the body are classified in Class III, unless the treatment in which the device is used consists of filtration, centrifugation or exchange of gases or heat, Case in which they are classified in class II.

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 in the body, They are classified in class IV.

Rule 4

All non-invasive devices that come into contact with injured skin or mucous membrane are classified:

a) In Class I, where 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 rupture of the dermis or mucous membranes and which can only heal by second intention;

c) In class II, the case is mainly intended to control the microenvironment of the injured skin or mucous membrane; and

d) In class II in all other cases.

This rule also applies to invasive devices that come into contact with a damaged mucous 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 are intended to be connected to an active class I device, are classified:

a) In Class I, where they are intended for transitional use;

b) In class II, if they are intended for short-term use, except if used in the oral cavity to the pharynx, in the ear canal to the tympanum or in the nasal cavity, in which case they are classified in class I; and

c) In class III, if they are intended for long-term use, except if used in the oral cavity to the pharynx, in the ear canal to the tympanum 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 Class II, III or IV medical device, are classified in Class II.

Rule 6

All surgically invasive devices intended for transitory 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 reusable surgical instruments, in which case they are classified
In class I;

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

d) Are intended to provide 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) They are intended for the administration of medicines by means of a delivery system, when carried out in a potentially dangerous manner, 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) They 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 provide 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) They are intended to undergo a chemical transformation in the body, in which case they belong to Class III, unless they are placed on the teeth; or

f) they are intended to administer medicines, in which case they are classified

In class III.

Rule 8

All implantable devices and devices surgically
Invasive drugs intended for long-term use are classified in Class III, unless:

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

Class II;

b) they are intended to be used in direct contact with the heart, the system Central circulatory system or 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, except if they are placed on the teeth;

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

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

g) Breast implants or surgical screens, 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) They 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
Provide energy to the human body or exchange energy with it in a potentially dangerous way, taking into account the nature, density and place of application of energy, in which case they are classified in Class III.

All active medical devices intended to control or monitor the performance of active Class III therapeutic devices, or to directly influence the performance of these 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 such devices or that directly influence their performance, are classified in Class III.

All active medical devices intended to directly control, monitor, or 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, except for devices intended to illuminate the patient's body in the visible spectrum, in which case they are classified in Class I;

b) they are intended to visualize in vivo the dissemination of radiopharmaceutical products; or

c) Are intended to allow direct diagnosis or monitoring of vital physiological processes, unless specifically intended for monitoring or observing vital physiological parameters and that the nature of the variations in these parameters may result in immediate danger to the patient, as is the case of das

Variations in the heart rate, breathing and activity of the central nervous system, or are intended for diagnosis in clinical situations where 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 such 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 may 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 in the health status of a person or a surgical intervention, in which case it is classified in Class III.

The 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 the variations of these parameters may result in 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 administer in the body
Human or to remove from it medicinal products, body fluids or other substances 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, Case in which they are classified in class III.

Rule 13

All other active medical devices, not framed in the rules Previous ones are classified in class I.

Special Rules

Rule 14

All devices containing, as an integral part, a substance which, if used separately, can be considered a medicinal product, including a medicinal product derived from human blood or plasma, and which has a complementary action 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 in the case of 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, if 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 the final stage of processing, Case in which they are classified in class III.

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

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

Rule 17

The devices specifically intended Recording X-ray generated diagnostic images are classified in class II.

Rule 18

All devices manufactured by the use of cells, tissues, or their non-viable derivatives (without metabolism or multiplication capacity) or made non-viable, are classified in Class IV, unless they are devices intended to come into contact solely with intact skin.

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

Rule 19

All devices incorporating nanomaterials or consisting of nanomaterials are classified:

a) In class IV, if they have a high or medium internal exposure potential;

b) In class III, if they have a low potential for internal exposure; and

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

Rule 20

All invasive devices applicable to body holes except
Surgically invasive devices intended for the administration of inhalation medications are classified in Class II unless their mode of action has a significant impact on the efficacy and safety of the medicinal product administered or is intended to treat life-threatening conditions, Case in which they are classified in class III.

Rule 21

Medical devices consisting of substances or combinations of substances intended to be introduced into the human body by means of a body hole or applied to the skin and which are absorbed or disseminated by the human body or locally dispersed therein shall be classified:

a) In Class IV if devices or their metabolism products are absorbed or disseminated systematically by the human body to achieve the intended purpose;

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

c) In Class II if applied to the skin or if applied to the nasal or oral cavities to the pharynx, and if the intended purpose in those cavities is achieved; and

d) In class III in all other cases.

Rule 22

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

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

ANNEX II.

Technical Dossier Structure of Medical Devices subject to notification and registration with Anvisa

Technical Device dossier Médico[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 Medical Device and Fundamentals of Operation and Action	X	X	X	X
Description of the Packaging and presentation ways of the device	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 Marketing History	-	X	X	X
Chapter 3				
Risk management	X	X	X	X
List of essential Safety and Performance requirements	-	X	X	X
List of technical standards	X	X	X	X
Physical and Mechanical Characterization	X	X	X	X
Characterization of Material/Chemistry	X	X	X	X
Electrical Systems: Safety, Mechanical and Environmental Protection, and Electromagnetic Compatibility	X	X	X	X
Description of Software / Firmware	X	X	X	X
Biocompatibility assessment	X	X	X	X
Review of Pirogenicity	X	X	X	X

Safety of Biological Materials	X	X	X	X
Validation of sterilization	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 (factory addresses)	X	X	X	X
Manufacturing Process (Flowchart)	X	X	X	X
Project and Development Information	X	X	X	X

Notes:

1) The Medical Device 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 can be updated considering future editions.

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