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RESOLUTION OF THE COLLEGIATE BOARD - RDC No. 751, OF SEPTEMBER 15, 2022

(Published in DOU [Brazilian Official Gazette] No. 180, of September 21, 2022)

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

The **Collegiate Board of Directors of the National Health Surveillance Agency**, in the use of the attributions conferred on it by art. 15, III and IV, allied to 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 Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021, resolves to adopt the following Resolution, as resolved at a meeting held on September 14, 2022, and I, Director- President, I order its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Purpose

Art. 1 This Resolution defines the rules for classifying the risk 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

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 subject to the specific rules established in the Collegiate Board Resolution - RDC No. 579, of November 25, 2021, published in DOU No. 225, of November 1, December 2021.

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§ 3 This Resolution does not apply to personalized medical devices, which are subject to the specific rules established in the Resolution of the Collegiate Board of Directors - RDC No. 305, of September 24, 2019, published in DOU No. 186, of September 25, 2019, Section 1, pg. 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 established in the Resolution of the Collegiate Board of Directors - RDC No. 36, of August 26, 2015, published in the 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, sanitizing products 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 cleaning, disinfecting or sterilizing medical devices are considered medical devices.

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

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

§ 10. Accessories produced by a manufacturer exclusively to integrate the medical devices of its manufacture already notified or registered and whose technical dossiers contain information about these accessories are exempt 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 for families, systems and sets (or kits) of medical devices.

Sole paragraph. The grouping of products, for the purpose of notification or registration, will take place according to the rules provided for in a specific regulation.

Section III

Definitions

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

I - accessory (of a medical device): product intended by its 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 medical device(s) are used in accordance with the intended purpose;

II - agglomerate: for the purposes of defining a nanomaterial, a set of loosely 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 purposes of the definition of nanomaterial, a particle that comprises strongly bonded or fused particles, in which the resulting external surface area can be significantly less than the sum of the calculated surface areas of the individual components;

IV - alteration: 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 sanitary relevance, which deals with a change to be introduced in the registration process, being authorized in the national territory only after technical document analysis and favorable opinion from 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, with its implementation authorized in the national territory after the filing of a petition with Anvisa;

VII - non-reportable change: any other change of lesser sanitary relevance, resulting from a change that is not classified as required approval or immediate implementation, and which does not depend on a protocol at Anvisa for implementation;

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

IX - surgically invasive device: invasive device that penetrates the body through its surface, including through the mucous membranes of body orifices, within the scope of a surgical intervention; and device that enters the body by a route other than a bodily orifice;

X - medical device (medical product); any instrument, apparatus, equipment, implant, in vitro diagnostic medical device, software, material or other article, intended by the manufacturer to be used, alone or in combination, in human beings, for any of the following specific medical purposes, and whose main action intended is not achieved by pharmacological, immunological or metabolic means in the human body, but which may be aided in its intended action by such means:

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- a) diagnosis, prevention, monitoring, treatment (or alleviation) of a disease;
- b) diagnosis, monitoring, treatment or repair of an injury or disability;
- c) investigation, replacement, alteration of the anatomy or of a physiological or pathological process or state;
- d) life support or maintenance;
- e) design control or support; or
- f) provision 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 a source of energy not generated by the human body for this purpose, or by gravity, and which acts by altering the density or by converting this energy, with the exception of 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 with a view to the detection, diagnosis, monitoring, observation or treatment of physiological states, health conditions, diseases or congenital malformations;

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

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

XV - invasive medical device: any device that partially or totally penetrates the body, either through one of its orifices 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, with intended use by the manufacturer for the in vitro analysis of samples derived from the human body, solely or primarily, to provide information for diagnostic purposes, diagnostic aid, monitoring, compatibility, screening, predisposition, prognosis, prediction or determination of physiological status;

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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 within the scope of a treatment or attenuation of a disease, injury or disability;

XVIII - technical dossier: document that describes 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, with responsibility 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 in its name.

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) Functioning and action;
- c) Technology;
- d) Content or composition, when applicable; and
- e) Precautions, restrictions, warnings and special precautions.

XXI - intended purpose (purpose of use): the use for which a device is intended, according to the information declared 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 possible precautions to be taken;

XXIV - reusable surgical instrument: an instrument intended for cutting, drilling, scarifying, sawing, scraping, removing, stapling, removing, trimming or performing similar procedures, within the scope of clinical and surgical interventions, whether or not it may be connected to an active device, and intended by the manufacturer to be reused after proper procedures have been carried out, such as cleaning, disinfection and sterilization;

XXV - clinical investigation: any investigation or systematic study in one or more human beings, carried out to evaluate 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";

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XXVI - kit (set, assembly or tray): set of medical devices that, regardless of being individually registered or notified, are grouped into a sales unit for a specific purpose of 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 a relationship of interdependence to obtain the functionality and performance for which it is intended.

XXVII - lot or batch: quantity of a medical device produced in a manufacturing or sterilization cycle, whose essential characteristic is homogeneity;

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

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

b) manufactured materials with dimensions that go beyond the upper limit of the nanoscale (established between 1 and 100 nm), up to the 1000 nm mark, and that exhibit size-dependent properties or phenomena different from those presented by the same material on the macroscale, may be classified 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 a medical device, intended to prove the right to manufacture and import a medical device exempt from registration in the form of §1 of art. 25 of Law No. 6,360, of September 23, 1976, and classified in risk classes I or II, indicating the name, manufacturer, purpose and other elements that characterize it;

XXXI - body orifice: any natural opening of the body, as well as the eye socket, 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;

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XXXIII - injured skin or mucous membrane: a skin surface or mucous membrane that presents a pathological alteration 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 purposes of auditing the processes;

XXXV - registration: private act of Anvisa intended to prove the right to manufacture and import a product subject to the regime of Law No. 6.360, of September 23, 1976, and classified in risk classes III or IV, indicating the name, manufacturer, 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 guardian: individual designated in statute, articles of association or minutes, responsible for representing, actively and passively, in judicial and extrajudicial acts, the requesting legal entity (manufacturer or importer);

XXXVIII - technical officer: a professional with a higher level, 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 marketed product;

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

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

XLI - central circulatory system: system that includes the following blood vessels: pulmonary arteries, ascending aorta, aortic arch, descending aorta to the aortic bifurcation, coronary arteries, common carotid artery, external carotid artery, internal carotid artery, cerebral arteries, trunk brachycephalic, 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 (SaMD): 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, with the following characteristics:

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

b) the “computer platform” includes hardware and software resources (operating system, processing hardware, storage, database, display devices, input devices, programming language, etc.);

c) “not part of” means that the program does not need the hardware of a medical device to achieve its intended use;

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

e) a SaMD may 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 another SaMD, as well as general-purpose software; and

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

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

XLV - manufacturing unit: place where one or more manufacturing steps take place, which may be the legal manufacturer itself, contracted manufacturer or original product manufacturer;

XLVI - short-term use: use normally carried out on a continuous basis for a period comprised between sixty (60) minutes and thirty (30) days;

XLVII - long-term use: use normally carried out on a continuous basis for a period exceeding thirty (30) days;

XLVIII - transitory use: use normally carried out on a continuous basis for less than sixty (60) minutes; and

XLIX - user: health professional or layperson, which 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 Regimes

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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 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.

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§ 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 a continuous basis” the following must be considered:

a) the entire duration of use of the same device, without taking into account temporary interruptions of use during a procedure or temporary excitement for the purpose of cleaning or disinfecting the device, must be determined whether the interruption of use, or removal, is temporary depending on the duration of use before and after the period in which use is interrupted or the device is removed; and

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

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

Section III

Classification Rules

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

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

§ 2 The evaluation of the documentation will be carried out within the legal terms and conditions provided for in the Brazilian sanitary 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 documents and additional information.

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§ 4 The petition with the absence of documents, forms and statements, provided for in the list of procedural instruction documents, incompletely filled out or with missing or illegible, or obsolete information, without a certificate of compliance when applicable, shall not be subject to a 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 will be no technical analysis of the notification and change notification petitions for the products to be considered regularized, without prejudice to the performance, at any time, of documentary or tax assessments on the notification processes and their changes, and, if necessary, requesting additional information or clarification.

§ 6 The processing of the medical device notification will occur routinely within thirty (30) 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 safety and performance requirements and specific regulations, when they exist.

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

§ 9 Application forms, instructions for use or user/operator manuals and labeling templates must be submitted in Portuguese.

§ 10. The other documents, not mentioned in the previous paragraph, that make up the medical device petitions can be presented in Portuguese, Spanish or English, according to the rules defined in a specific regulation.

Art. 11. The registration of medical devices will be valid for ten (10) years, counting from the day of its publication in the Brazilian Official Gazette, and may be successively revalidated for an equal period, under the terms established in section V of this Resolution.

Art. 12. Medical devices subject to certification of conformity within the scope of the Brazilian Conformity Assessment System (SBAC) may only be imported and marketed if manufactured during the effective term of the Certificate of Conformity.

Section II

Medical Device Notification

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

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

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II - for imported medical devices: declaration issued by the legal manufacturer, consularized or apostilled, written in Portuguese, English or Spanish or accompanied by a sworn translation, 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 within the scope of the Brazilian Conformity Assessment System (SBAC), applicable only to medical devices with compulsory certification, listed by Anvisa in specific regulations; and

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

Sole paragraph. The declaration 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 statement about the knowledge and service to the requirements of Good Manufacturing Practices for Health Products established in the Resolution of the Collegiate Board of Directors - RDC No. 665, of March 30, 2022, or regulation that may replace it.

Section III

Medical Device Registration

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

I - form for medical device registration, duly completed, available on Anvisa's electronic portal;

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

III - for imported medical devices: declaration issued by the legal manufacturer, consularized or apostilled, written in Portuguese, English or Spanish or accompanied by a sworn translation, 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, which must be consularized or apostilled, and accompanied by a sworn translation when not written in Portuguese, English or Spanish;

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V - Certificate of Good Manufacturing Practices issued by Anvisa or proof of protocol for requesting a Certificate of Good Manufacturing Practices;

VI - copy of the Certificate of Conformity issued within the scope of the Brazilian Conformity Assessment System (SBAC), applicable only to medical devices with compulsory certification, listed 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 declaration referred to in item III 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 statement about knowledge and compliance with the requirements of Good Manufacturing Practices for Health Products established in the Resolution of the Collegiate Board of Directors - RDC No. 665, of March 30, 2022, or regulation that replaces it.

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

§ 3 The approval of applications for granting registration is conditioned to the publication of a valid Good Manufacturing Practices Certificate issued by Anvisa and to the fulfillment of the other requirements for registration of medical devices.

Section IV

Change of Notification or Registration of Medical Devices

Art. 15. To apply for the change of the notification or medical device registration, the applicant must proceed with the payment of the corresponding fee, if applicable, and present the declaration listing the requested changes and other required documents, according to the applied subject.

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

I - change of approval required;

II - immediate implementation change; and

III - non-reportable alteration.

§ 1 The petition for the changes contained in items I and II of this article must 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, page 111, which details the applicable petition matters.

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§ 2 Any minor changes not classified as required approval or immediate implementation are classified as non-reportable changes, as well as: changes to information that do not change the design of the medical device; software bug fixes; non-technical changes such as images, formatting, layouts, symbols and text adaptations of documents without adding risk; business authorization information updates; contact changes (e.g., telephone or postal address), technical assistance and website.

§ 3 The changes listed in § 2 must be controlled by the regularization holder's quality system and be incorporated in subsequent petitions.

§ 4 The change petition for risk classes I and II medical devices will be executed by the immediate implementation regime, except in the case of a non-reportable change.

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

Art. 18. The request to change information must be accompanied by supporting documentation of the change to be implemented, in compliance with current health legislation.

Art. 19. The change of immediate implementation that has interdependence with the change of approval required must be petitioned together with it, 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 analysis prioritized.

Sole paragraph. To request the prioritization of analysis mentioned in the caput, the company must file 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 Brazilian Official Gazette and, when applicable, updated data will be published on Anvisa's electronic portal.

Art. 22. The changes for immediate implementation will be published in the Brazilian Official Gazette and, when applicable, the updated data will be published on Anvisa's electronic portal, within a term of up to thirty (30) days, counted from the completion of the protocol of the respective petition, regardless of document analysis by Anvisa.

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Art. 23. The petition for immediate implementation may be subject to documentary or tax assessment at any time by Anvisa and, if necessary, additional information or clarifications may be requested.

Sole paragraph. Anvisa may suspend the commercialization, importation and/or use of the product until its regularization, in the event of inconsistency in the request for an immediate implementation change that justifies such a sanitary measure.

Art. 24. The granting of petitions for alteration/inclusion of a manufacturing unit or for a change in the address of a manufacturing unit or inclusion of products or models in a family/system/set of products classified in risk classes III and IV, is subject to the publication of the Certificate of Good Manufacturing Practices issued by Anvisa and compliance with the other requirements corresponding to each type of petition.

Sole paragraph. The protocol of the application for Certification of Good Manufacturing Practices 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 to run out of stock of finished products as a result of a change, the simultaneous import and sale of the versions involved is allowed until the end of the expiration date or useful life of the product.

Sole paragraph. Changes made to address product safety and performance issues do not fall under the caput permission.

Art. 26. It is allowed to run out of stock of packaging, labels and instructions for use for a term of one hundred and twenty (120) days as of the publication of the alteration.

Sole paragraph. Changes made to address product safety and performance issues do not fall under the caput permission.

Section V

Medical Device Registration Revalidation

Art. 27. To petition for 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, consularized or apostilled, 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.

II - Valid Good Manufacturing Practices Certificate issued by Anvisa.

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§ 1 The declaration referred to in item I 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 statement about knowledge and compliance with the requirements of Good Manufacturing Practices for Health Products established in the Resolution of the Collegiate Board of Directors - RDC No. 665, of March 30, 2022, published in DOU No. 62, of March 31, 2022, Section 1, page 334, or regulation that may replace it.

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

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

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 a notification or registration of a medical device that intends to no longer sell it on the Brazilian market must request its cancellation.

Section VII

Information Compliance

Art. 30. Changes made by the manufacturer to the information related to the medical device contained in the notification or registration must 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 aforementioned change in the Brazilian Official Gazette and Anvisa's electronic portal.

Art. 32. Any communication or advertising of a medical device on the market must be in strict accordance with the information submitted by the holder of the notification or registration to Anvisa.

Section VIII

Documentary Repository of Medical Devices

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Art. 33. The loading of instructions for use in the Medical Devices 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 (such as a specific document), the labeling model must be loaded in the field of instructions for use, also including the information provided for in Chapter VI.

§ 2 The loading of instructions for use must occur through the applicable petition subjects, identified as “Providing Instructions for Use on the Anvisa Portal”.

§ 3 The uploading of instructions for use is the responsibility of the holder of the notification or registration and must be controlled by the latter for eventual audits.

§ 4 Loading instructions for use is mandatory and must be carried out by the company responsible for notifying or registering the product, which certifies that its content is in accordance with current legislation and consistency with the regularized product.

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

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

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

§ 1 The update is carried out by means of a new insertion of instructions for use.

§ 2 If there is a new upload of instructions for use in the notification or registration process, only the recently uploaded ones will be kept public.

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

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

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

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II - remove the instructions for use or restore a previous version, when there is justification for such measures.

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

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 appropriate instructions for use have been loaded in accordance with 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. The notification and registration processes for medical devices are subject to procedural evaluation and re-evaluation, audit, market monitoring and inspection by the competent health authority.

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

§ 1 The adjustments mentioned in the caput must be answered by the holder of the notification or registration within thirty (30) days as of the date of confirmation of its receipt.

§ 2 The situations that give rise to correction of the information previously presented must be dealt with by means of a specific petition.

§ 3 The lack of response to the notification of adequacy referred to in the caput within a term of up to thirty (30) days, counted from its issuance, will give rise to the cancellation of the notification, registration or alteration.

CHAPTER IV

ADMINISTRATIVE SANCTIONS

Art. 39. Anvisa may suspend the manufacture, import, sale 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;

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

III - the product is under investigation by the competent health authority, as to 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 the manufacture, importation, commercialization and use of a medical device will be published in the Brazilian Official Gazette and will be maintained until the solution of 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 false information provided in any of the documents requested in this Resolution is proven, or any of these documents is 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 - absence of information or documents is identified in the processes of products subject to notification;

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

V - when the demands for procedural reassessment presented by Anvisa are not met.

Art. 42. Anvisa may determine the cancellation of changes that lead to incorrect information or medical device irregularity.

Art. 43. Anvisa may, at its discretion and at any time, request information or clarification before the decision to cancel the irregular medical device notification.

Art. 44. Cancellation of notification or medical device registration will be published in the Brazilian Official Gazette.

CHAPTER V

APPLICANT INFORMATION FORMS AND THEIR MEDICAL DEVICES

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

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

CHAPTER VI

LABELS AND INSTRUCTIONS FOR USE OF MEDICAL DEVICES

Section I

Information Requirements on Labels and Instructions for Use

Art. 46. Information on medical device labels and instructions for use must meet the following general requirements:

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

II - all medical devices must include instructions for use on their packaging or make reference to the form of access to these documents;

III - exceptionally, these instructions may not be included in the packaging of medical devices classified in 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 use of the medical device with complete safety must appear, whenever possible, on the medical device itself or on the label of its individual packaging, or, if this is not possible, on the label of its commercial packaging;

V - if it is not possible to pack each unit individually, this information must be included in the instructions for use that accompany 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 regulations 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 additional information due to the specificity of the product, these will be incorporated into the label or instructions for use, as applicable;

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

I - corporate name and address of the legal manufacturer, preceded by the term “manufacturer” or equivalent symbology;

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

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

IV - when applicable, the word “Sterile” and the sterilization method;

V - the batch code, preceded by the word “Batch”, or the serial number, as the case may be;

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 single use;

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

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

X - all warnings and precautions to be adopted;

XI - name of the technically responsible person legally qualified for the function;

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

Art. 48. The Instructions for Use template 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 assigned by the manufacturer as well as any possible undesirable side effects;

III - in case a medical device is to be installed or connected to other medical devices to operate in accordance with the intended purpose, sufficiently detailed information on their characteristics must be provided to identify medical devices that can be used with the product, in order to obtain a safe combination;

IV - all information that makes it possible to prove whether a medical device is properly installed and can function correctly and in complete safety, as well as information on the nature and frequency of maintenance and calibration operations to be carried out in order to guarantee permanent good operation and safety of the medical device;

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

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

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

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

IX - in case the medical device must be sterilized before its use, the instructions regarding cleaning and sterilization must be formulated in such a way that, if correctly executed, the product satisfies the requirements established by the manufacturer regarding the Essential Safety and Performance Requirements (or Efficacy);

X - information about treatment or additional procedure that must be performed before using the medical device;

XI - in case a medical device emits radiation for medical purposes, the information regarding the nature, type, intensity and distribution of said radiation must be described;

XII - instructions for use must include information that allow the health professional to inform the patient about the 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 - the precautions to be taken regarding exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharges, pressure or pressure variations, acceleration and thermal ignition sources, among others;

XV - adequate information on the drug(s) that the medical device is intended to administer, including any restrictions on the choice of these substances;

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

XVII - mention of the drugs incorporated in the medical device as an integral part thereof; and

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

Art. 49. The notified or registered equipment under the sanitary surveillance regime must have an indelible label affixed, indicating:

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

II - name of the legal manufacturer or brand;

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III - notification or registration number with Anvisa; and

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

§ 1 For equipment of reduced size and/or implantable, in which it is not possible to affix such a label, registration of the manufacturer's identification or brand and traceability elements will 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 Non-implantable single-use equipment is excluded from the provisions of the caput.

Section II

Instructions for Use in Unprinted Format

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

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

I - inform on the external label the way to obtain the correlation between the supplied product and the version of the corresponding instructions for use;

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

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

IV - specify the resources necessary for the user to read the instructions for use.

§ 1 When the dimensions of the external labeling do not allow it, 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 must consider the period indicated in item III as the specified useful life time for the product, counted from the last unit sold of the product.

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

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

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

III - an alert to the user so that the correlation of the version of the instructions for use indicated with the purchased product is observed, as made available by the manufacturer; and

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

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

I - provide the product with clear guidance on how to find the corresponding and updated instructions for use at the electronic address available on the internet;

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

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

IV - make available at the electronic address free access to the tool necessary for reading the instructions for use; and

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

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

I - equipment for health use that has indication of:

a) domestic use in general, including those used in home care services - SAD; and

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

II - materials for health use used by the lay public.

CHAPTER VII

TECHNICAL DOSSIER

Art. 55. The legal and technical managers of the requesting company are responsible for the information and documents presented.

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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 inspection purposes 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 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 consist of references to documents and information that make up other files or records of the company's Quality System, which must be available for inspection. of the National Health Surveillance System.

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

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 a 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 clarification on the use of the medical device, as well as its storage and transport;

IV - forms of presentation of the medical device;

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

VI - flow diagram containing the steps of the medical device manufacturing process with a description of each step of the process, until obtaining the finished product, with an 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 safety and performance requirements of medical devices.

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

§ 2 If necessary, the health authority may request additional information or clarifications, as well as the presentation of complementary documentation, including a

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clinical study report specifically designed and conducted to investigate the medical device of interest.

Art. 58. The information in the Technical Dossier must be organized according to the product's health risk class, as provided in Annex II of this Resolution.

CHAPTER VIII

FINAL AND TEMPORARY PROVISIONS

Art. 59. The same typification of sanitary infractions and the associated penalties in force for the medical device registration system apply to the notification regime.

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

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

§ 2 Products manufactured in the national territory exclusively for export purposes do not require notification or registration with Anvisa.

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

Sole paragraph. For registrations granted during the validity of RDC No. 185, of October 22, 2001, it will be allowed to maintain the structuring of the technical report until any petition for alteration of the required approval registration, which must include the new structure of the Technical Dossier.

Art. 62. A term of three hundred and sixty-five (365) days is established, counted from the entry into force and effect of this Resolution, for holders of notifications of medical devices to file petitions for sanitary reclassification of products that had their notification regime changed for registration due to the updating of classification rules.

§ 1 The petition must be accompanied by the same documentation required for a new product registration.

§ 2 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 of the petitions for sanitary reclassification.

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§ 3 The approval of requests for sanitary reclassification is conditioned to the publication of a valid Certificate of Good Manufacturing Practices issued by Anvisa and to the fulfillment of the other requirements for the registration of medical devices.

§ 4 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 had their regularization regime changed from registration to notification due to the updating of the classification rules will be dealt with through the Anvisa rectification file.

Art. 64. The Resolution of the Collegiate Board of Directors - RDC No. 270, of February 28, 2019, published in DOU No. 43, of March 1, 2019, Section 1, page 68, comes into force and effect with the following amendment:

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

Art. 65. The Resolution of the Collegiate Board of Directors - RDC No. 340, of Friday, March 6, 2020, published in DOU No. 48, of March 11, 2020, Section 1, page 56, comes into force and effect with the following amendment:

“Art. 9 The changes for immediate implementation will be published in the Brazilian Official Gazette and, when applicable, the updated data will be published on Anvisa’s electronic portal, within a term 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. As of the date of entry into force of this Resolution, the following are revoked:

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

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

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

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

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

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

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

ANTONIO BARRA TORRES
Director- President



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ANNEX I

Risk Classification Rules of Medical Devices

Non-Invasive Devices

Rule 1

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

Rule 2

All non-invasive devices intended for the conduction or storage of blood, fluids, cells or body 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 the conduction or storage of blood or other body fluids or for the storage of organs, parts of organs or body cells and tissues, with the exception of bags of blood and blood components, which are classified in the class III.

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

Rule 3

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

All non-invasive devices consisting of a substance or mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken from the human body or used in vitro with human embryos, prior to their implantation or administration into the body, are classified in class IV.

Rule 4

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

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

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b) in class III, if they are intended to be used mainly in cutaneous lesions that have produced a rupture of the dermis or mucous membranes and that can only heal by second intention;

c) in class II, if they are intended primarily to control the microenvironment of the damaged 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 an injured mucous membrane.

Invasive Devices

Rule 5

All invasive medical devices applicable to bodily orifices, except surgically invasive devices, that are not intended to be connected to an active device or that are intended to be connected to a Class I active device are classified:

a) in class I, if they are intended for transitory use;

b) in class II, if intended for short-term use, except if used in the oral cavity up to the pharynx, in the ear canal up to the eardrum 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 up to the pharynx, in the ear canal up 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 bodily 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;

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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) they 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;

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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

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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 the 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, such as

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 hazardous manner, taking into account the nature of the substances or the part of the body involved and the mode of application, in which case they are classified in class III.

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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 drug 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 preventing the transmission of sexually transmitted diseases are classified in class III, except when dealing with 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 cells, tissues, or their derivatives that are non-viable (without the capacity for metabolism or multiplication) or made non-viable are

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classified in class IV, unless they are devices intended to come into contact only with 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, which are 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 they are intended to treat life-threatening conditions, in which case they are classified as class III.

Rule 21

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

- a) in class IV if the devices, or their metabolism products, are systemically absorbed or disseminated by the human body to achieve their intended purpose;
- b) in class IV if they reach 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 they are applied to the skin or if they are applied in the nasal or oral cavities up to the pharynx, and if they achieve the intended purpose in these cavities; and
- d) in class III in all other cases.

Rule 22

Active therapeutic devices with an integrated or built-in diagnostic function that significantly direct patient management, such as closed-loop systems or automated external defibrillators, are classified in class IV.

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ANNEX II

Structure of Technical Dossier 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 Fundamentals of Operation and Action	X	X	X	X
Description of the Packaging and Forms of Presentation 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 / Intended Use Context	X	X	X	X
Contraindications for Use	X	X	X	X
Global Trade History	-	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/Chemistry 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

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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 submitted.

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