COLLEGIATE BOARD RESOLUTION – RDC No. 751 OF 15 SEPTEMBER 2022

Provides for risk classification, notification and marketing authorization systems, as well as labeling requirements and use instructions regarding medical devices.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 15, items III and IV, combined with Article 7, items III and IV, of Law no. 9782 of 26 January 1999, and Article 187, item VI, paragraph 1 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 14 September 2022, and I, the Director-President, determine its publication:

CHAPTER I

INITIAL PROVISIONS

Section I

Objective

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

Section II

Scope

Article 2. This Resolution applies to the medical devices defined herein, and their notification or marketing authorization is mandatory, according to risk classification.

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

Paragraph 2. This Resolution does not apply to used or reconditioned medical devices, which are submitted to the specific rules set forth in Collegiate Board Resolution – RDC no. 579 of 25 November 2021, published in the Federal Official Gazette no. 225 of 1 December 2021.

Paragraph 3. This Resolution does not apply to personalized medical devices, which are subject to the specific rules established in Collegiate Board Resolution – RDC no. 305 of 24 September

2019, published in the Federal Official Gazette no. 186 of 25 September 2019, Section 1, page 69.

Paragraph 4. This Resolution does not apply to medical devices for *in vitro* diagnosis, including the instruments for *in vitro* diagnosis, which are submitted to the specific rules established in Collegiate Board Resolution – RDC no. 36 of 26 August 2015 published in the Federal Official Gazette no. 164 of 27 August 2015, Section 1, page 43.

Paragraph 5. This Resolution does not apply to medicinal products, cells, tissues, organs, or blood of human origin or derivatives, cosmetics, sanitizers, or foodstuffs provided for by other regulations.

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

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

Paragraph 8. The medical devices intended for clinical investigations are exempt from notification or marketing authorization, as long as they comply with the legal provisions of the competent health authority to perform such activity, and their commercialization and use for other purposes are prohibited.

Paragraph 9. The presentations consisting of two or more medical devices notified or granted marketing authorization and in their full packaging of individual presentation are exempt from notification or marketing authorization, and they must contain in the label the information of the corresponding medical devices, including notification or marketing authorization numbers.

Paragraph 10. The accessories produced by a manufacturer exclusively to integrate their own medical devices already notified or granted marketing authorization, and whose technical dossiers contain information about these accessories, are exempt from notification or marketing authorization.

Paragraph 11. The new accessories may be included in the original notifications or marketing authorization processes, describing in detail the foundations of operation, action, and content.

Article 3. Anvisa shall also grant notification or marketing authorization to families, systems, and sets (or kits) of medical devices.

Sole paragraph. Product grouping, with the purpose of notification or marketing authorization, shall occur according to the rules provided for in specific regulation.

Section III

Definitions

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

I – accessory (of a medical device): product intended by its manufacturer to be used jointly with one or several specific medical devices, to allow or help in a specific and direct way that the medical device(s) is (are) used according to the intended purpose;

II – agglomerate: for the purposes of the definition of nanomaterial, a set of weakly linked particles where the resulting external surface area is equal to the sum of the surface areas of the individual components;

III – aggregate: for the purposes of the definition of nanomaterial, a particle that comprises strongly linked or cast particles, where the resulting external surface area may be significantly smaller than the sum of the surface areas calculated from individual components;

IV – alteration: modification of information presented to Anvisa in the process of notification or marketing authorization of the medical device and in their respective secondary applications;

V – alteration of approval required: alteration of greater health relevance, which is an alteration to be introduced in the marketing authorization process, and it shall be authorized in Brazilian territory only after documentary technical analysis and favorable manifestation by Anvisa;

VI – alteration of immediate implementation: alteration of medium health relevance, which is an alteration to be introduced in the notification or marketing authorization process, and its implementation shall be authorized in Brazilian territory after the application is submitted to Anvisa;

VII – non-reportable alteration: any other alteration of lower health relevance, resulting from an alteration that is not classified as required approval or immediate implementation, which does not depend on submission to Anvisa for implementation;

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

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

X – medical device (medical product): any instrument, apparatus, equipment, implant, medical device for *in vitro* diagnosis, software, material, or other article, intended by the manufacturer to be used, either isolated or jointly, in humans, 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 can be assisted in their intended action by such means:

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

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

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

d) support or maintenance of life;

e) control of or support for conception; or

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

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

XII – active medical device for diagnosis and monitoring: any active device used in isolation or in combination with other devices to provide information with a view to detect, diagnose, monitor, observe, or treat physiological states, health states, diseases, or congenital malformations;

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

XIV – implantable medical device: any device, including those that are partially or fully absorbed, intended to be fully introduced into the human body; or to replace an epithelial surface or the eye surface, through clinical intervention, which is intended to remain in this place after 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 partially or fully penetrates in 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 intention of use determined by the manufacturer for *in vitro* analysis of samples from the human body, exclusively or mainly to provide information for the purposes of diagnosis, aid to diagnosis, monitoring, compatibility, screening, predisposition, prognosis, prediction, or determination of physiological state;

XVII – active therapeutic medical device: any active device used in isolation or in combination with other devices to maintain, modify, replace, or restore biological functions or structures within a treatment or attenuation of a disease, injury, or deficiency;

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

XIX – legal manufacturer: legal, public, or private entity, with responsibility for the project, manufacturing, packaging, and labeling of a product, with the intention of making it available for use under its name, and such operations are performed by the company itself or by third parties in its name;

XX – family: grouping of medical devices, for the purpose of notification or marketing authorization, provided for in specific regulation, where each product has similar technical characteristics of:

a) indication, purpose of use;

b) operation and action;

c) technology;

d) content or composition, when applicable; and

e) precautions, restrictions, warnings and special care.

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

XXII – importer: legal, public, or private entity, responsible for the import activity for the entry of medical devices from abroad into Brazilian territory;

XXIII – use instructions: document containing information provided by the manufacturer to clarify the user about the intended purpose of a device, its correct use, and eventual precautions to be taken;

XXIV – reusable surgical instrument: an instrument that is intended to cut, drill, scarify, saw, shave, remove, staple, retract, trim, or perform similar procedures, within the scope of clinical and surgical interventions, which may or may not be connected to an active device, and is intended by the manufacturer to be reused after the appropriate procedures such as cleaning, disinfection, and sterilization have been performed;

XXV – clinical investigation: any systematic investigation or study in one or more humans, 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 or tray): set of medical devices that, regardless of whether they are granted marketing authorization or notified individually, are grouped into a unit of sale for a specific use or procedure:

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

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

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

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

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

b) materials manufactured with dimensions that extrapolate the upper limit of nanoscale (established between 1 and 100 nm), to the landmark of 1000 nm, and which present size-dependent properties or phenomena that are different from those presented by the same material in macroscale, may be included in the definition of nanomaterial;

XXIX – technical standard: document established by consensus and approved by a recognized organism, which provides for rules, guidelines, or characteristics for activities or their results,

for common and repetitive use, with a view to obtain an optimum degree of ordering in a given context;

XXX – notification: act of communicating to Anvisa the intention to commercialize the medical device, intended to prove the right of manufacture and import of medical device exempted from marketing authorization pursuant to Paragraph 1 of Article 25 of Law no. 6,360 of 23 September 1976, and classified in risk classes I or II, with the indication of the name, the manufacturer, the purpose, and the other elements that characterize it;

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

XXXII – particle: for the purposes of the definition of nanomaterial, a tiny portion of matter with defined physical boundaries;

XXXIII – injured skin or mucous membrane: a skin surface or a mucous membrane that presents a pathological alteration or an alteration caused by disease or injury;

XXXIV – process reassessment: procedure performed by Anvisa's technical area for medical devices notifications and marketing authorizations for the purposes of audits in processes;

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

XXXVI – Documentary Repository of Medical Devices: digital tool for storage and availability of documents related to medical devices notified and granted marketing authorization, available on Anvisa's website;

XXXVII – legally responsible person: Individual designated in a statute, social contract, or minutes, responsible for representing the requesting legal entity (manufacturer or importer), both actively and passively, in judicial and extrajudicial acts;

XXXVIII – technically responsible person: legally qualified graduate level professional, trained in the technologies that compose the product, responsible for the technical information presented by the applicant (manufacturer or importer), as well as for the quality, safety, and performance of the commercialized product;

XXXIX – label: written, printed or graphic information present 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 in order to achieve a purpose intended by the manufacturer;

XLI – central circulatory system: it includes the following blood vessels: pulmonary arteries, ascending aorta, aortic arch, descending aorta to aortic bifurcation, coronary arteries, ordinary carotid artery, external carotid artery, internal carotid artery, brain arteries, brachiocephalic trunk, coronary veins, pulmonary veins, superior vena cava, and inferior vena cava;

XLII – central nervous system: it 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 medical device and performing its functions without being part of the hardware of a medical device, with the following characteristics:

a) the SaMD may be executed on a general-purpose computational platform (non-medical purpose);

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

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

d) a software is not considered a SaMD if its objective 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 of other medical devices and another SaMD, as well as general use software; and

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

XLIV – applicant: legal, public or private entity, who submits applications for notification or marketing authorization for medical devices to the health authority;

XLV – manufacturing unit: site where one or more manufacturing steps occur, and it may be the legal manufacturer itself, contracted manufacturer, or original product manufacturer;

XLVI – short-term use: utilization normally carried out continuously for a period between 60 (sixty) minutes and 30 (thirty) days;

XLVII – long-term use: utilization normally carried out continuously for a period exceeding 30 (thirty) days;

XLVIII – transitional use: utilization normally carried out continuously for less than 60 (sixty) minutes; and

XLIX – user: health professional or layman, and it may be the patient himself, who uses a medical device, according to the instructions of use.

CHAPTER II

RISK CLASSIFICATION OF MEDICAL DEVICES

Section I

Control Classification and Systems

Article 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.

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

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

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

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

Section II

Application Rules

Article 8. The application of classification rules is governed by the intended purpose of medical devices, except for *in vitro* diagnostic devices, which are governed by specific classification rules.

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

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

Paragraph 3. The software that controls a device or influences its use is classified in the same class as that device.

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

Paragraph 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.

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

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

a) the entire duration of use of the same device without regard to temporary interruptions of use during a procedure or temporary removal for the purposes of cleaning or disinfection of the device, and the company shall determine whether the interruption of use, or removal, is temporary due to the duration of previous use and after the period when the use is interrupted or that the device is removed; and

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

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

Section III

Classification Rules

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

CHAPTER III

APPLICATION FOR NOTIFICATION OR MARKETING AUTHORIZATION AND ITS MAINTENANCE

Section I

Procedures for Notification of or Marketing Authorization for Medical Devices

Article 10. The applicant must submit to Anvisa the documents for notification, marketing authorization, alteration, revalidation, or cancellation of notification of or marketing authorization for the medical device, as listed in this Resolution.

Paragraph 1. Anvisa shall assess the documentation presented for marketing authorization, alteration, or revalidation of the marketing authorization, and shall issue its opinion through official means.

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

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

Paragraph 4. The application with no documents, forms, and statements, provided for in the list of procedural instruction documents, filled incompletely or with missing or unreadable information, or obsolete documents, forms, and statements, without certificate of compliance when applicable, or without clinical evidence for products with innovative technology or indication, shall not be subject to a technical requirement, leading to disapproval or rejection of the application.

Paragraph 5. There shall be no technical analysis of applications for notification and notification alteration so that the products are considered regularized, without prejudice to the performance of documentary or tax assessments on notification processes and their alterations at any time and, if necessary, to the request of additional information or clarifications.

Paragraph 6. The processing of the medical device notification shall occur routinely in up to 30 (thirty) days after submission by the applicant.

Paragraph 7. The maintenance of notification and marketing authorization is bound to compliance with the requirements of Good Manufacturing Practices, essential safety and performance requirements, and specific regulations, as appropriate.

Paragraph 8. The granting of the marketing authorization is subject to the publication of the Good Manufacturing Practices Certificate issued by Anvisa.

Paragraph 9. The application forms, instructions of use or user/ operator manuals, and labeling models must be presented in Portuguese.

Paragraph 10. The other documents, not referred to in the previous paragraph, which compose medical device applications may be presented in Portuguese, Spanish, or English, according to rules defined in specific regulation.

Article 11. The marketing authorization for medical devices shall be valid for 10 (ten) years, counting from the date of its publication in the Federal Official Gazette, and may be revalidated successively for an equal period, pursuant to section V of this Resolution.

Article 12. Medical devices subject to certification of compliance within the Brazilian Conformity Assessment System (SBAC, in Portuguese) may only be imported and commercialized if manufactured during the validity of the Compliance Certificate.

Section II

Notification of Medical Devices

Article 13. In order to submit the application for medical device notification, the applicant must pay the corresponding fee and submit the following documents to Anvisa:

I – medical device notification form duly completed, available on Anvisa's website;

II – for imported medical devices: consular or certified statement issued by the legal manufacturer, written in Portuguese, English, or Spanish, or accompanied by sworn translation signed for a maximum period of two years when there is no express validity indicated in the document, authorizing the requesting company to represent and commercialize its product(s) in Brazil;

III – copy of the Certificate of Compliance issued within the Brazilian Conformity Assessment System (SBAC, in Portuguese), applicable only to the medical provisions with compulsory certification, listed by Anvisa in specific regulations; and

IV – proof of compliance with the legal provisions determined in technical regulations, pursuant to legislation regulating specific medical devices.

Sole paragraph. The statement referred to in item II must include the corporate name and full address of the legal manufacturer and the requesting company, the express authorization for the requesting company to represent and commercialize its products in Brazil, and the affirmation about knowledge and compliance with the requirements of Good Health Product Manufacturing Practices established in Collegiate Board Resolution – RDC no. 665 of 30 March 2022, or a regulation replacing it.

Section III

Marketing Authorization for Medical Devices

Article 14. In order to submit the application for medical device marketing authorization, the applicant must pay the corresponding fee and submit the following documents to Anvisa:

I – medical device marketing authorization form duly completed, available on Anvisa's website;

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

III – for imported medical devices: consular or certified statement issued by the legal manufacturer, written in Portuguese, English, or Spanish, or accompanied by sworn translation signed for a maximum period of two years when there is no express validity indicated in the document, authorizing the requesting company to represent and commercialize its product(s) in Brazil;

IV – for imported medical devices: proof of marketing authorization or certificate of free trade or equivalent document, granted by the competent authority of the country where the medical device is manufactured and commercialized or only commercialized, issued for a maximum period of two years when there is no express validity indicated in the document, and such document must be consular or certified, and accompanied by sworn translation when not written in Portuguese, English, or Spanish;

V – Good Manufacturing Practices Certificate issued by Anvisa or proof of submission of application for the Good Manufacturing Practices Certificate;

VI – copy of the Certificate of Compliance issued within the Brazilian Conformity Assessment System (SBAC, in Portuguese), applicable only to the 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.

Paragraph 1. The declaration referred to in item III must include the corporate name and full address of the legal manufacturer and the requesting company, the express authorization for the requesting company to represent and commercialize its products in Brazil; and the affirmation of knowledge and compliance with the requirements of Good Health Product Manufacturing Practices established in Collegiate Board Resolution – RDC no. 665 of 30 March 2022, or a regulation replacing it.

Paragraph 2. The protocol of the application for the Good Manufacturing Practices Certification shall be accepted for the purposes of application for marketing authorization, and to start the analysis of applications for the grant of marketing authorization.

Paragraph 3. The approval of marketing authorization grant applications is subject to the publication of a valid Good Manufacturing Practices Certificate issued by Anvisa and the compliance with the other requirements for the marketing authorization for medical devices.

Section IV

Alteration of Notification of or Marketing Authorization for Medical Devices

Article 15. In order to submit the application for altering the notification of or marketing authorization for medical devices, the applicant must pay the corresponding fee, if applicable, and submit the declaration listing the pleaded alterations and other required documents, according to the subject of the application.

Article 16. Alterations in the information presented in the medical device notification or marketing authorization process are classified as:

I – alteration of required approval;

II – alteration of immediate implementation; and

III – non-reportable alteration.

Paragraph 1. The application for the alterations referred to in items I and II of this article shall comply with the provisions of Normative Instruction – IN no. 74 of 16 September 2020, published in the Federal Official Gazette no. 180 of 18 September 2022, Section 1, Page 111, which details the applicable subjects of application.

Paragraph 2. Any alterations of less relevance not classified as required approval or immediate implementation are classified as non-reportable alterations, in addition to alterations in information that does not modify the medical device project; bug corrections in software; non-technical alterations such as images, formatting, layouts, symbols, and text adjustments in documents without increased risk; Company Operating Authorization information updates; contact alterations (e.g., phones or postal address), technical assistance, and website.

Paragraph 3. The alterations referred to in paragraph 2 shall be controlled by the regularization holder quality system and be incorporated into subsequent applications.

Paragraph 4. The application for alteration in medical devices of risk classes I and II shall be carried out through the immediate implementation regime, except when it refers to a non-reportable alteration.

Article 17. The subjects related to applications for alterations in medical device notification or marketing authorization are provided for in Normative Instruction – IN no. 74 of 16 September 2020, which identifies the alterations that are considered of required approval or immediate implementation.

Article 18. The application for information alteration shall be accompanied by the supporting documentation of the alteration to be implemented, and the health legislation in force must be complied with.

Article 19. The alteration of immediate implementation that has interdependence with alteration of required approval shall be applied for together with it, incorporating its contents to it.

Article 20. The alterations arising from field action notified to Anvisa with a view to ensure the safety and performance of the device in relation to users and patients shall be analyzed with priority.

Sole paragraph. In order to request the prioritization of analysis referred to in the caption of this article, the company must submit the application, presenting evidence of sending the field action notification to Anvisa.

Article 21. The alteration of required approval shall only take effect after the final decision is published in the Federal Official Gazette and, when applicable, updated data shall be made available on Anvisa's website.

Article 22. Alterations of immediate implementation shall be published in the Federal Official Gazette and, when applicable, updated data shall be made available on Anvisa's website, observing the period of up to 30 (thirty) days, counting from the completion of the submission of the respective application, regardless of documentary analysis by Anvisa.

Article 23. The application for immediate implementation may be the subject to documentary or tax assessment at any time by Anvisa and, if necessary, additional information or clarification may be requested.

Sole paragraph. Anvisa may suspend the commercialization, import and/ or use of the product until its regularization, if there is inconsistency in the application for alteration of immediate implementation that justifies such a health measure.

Article 24. The approval of applications for alteration/ inclusion of manufacturing unit or alteration in manufacturing unit address, or inclusion of products or models in family/ system/ set of products framed in risk classes III and IV, is conditioned to the publication of the Good Manufacturing Practices Certificate issued by Anvisa and the compliance with the other requirements corresponding to each type of application.

Sole paragraph. The submission of the request for Good Manufacturing Practices Certification shall be accepted for the purposes of application, and to start the analysis of the applications.

Article 25. If there is a need for inventory depletion of finished products due to an alteration, the import and simultaneous commercialization of the versions involved is allowed until the end of the validity period or useful life of the product.

Sole paragraph. Alterations made to solve problems of product safety and performance do not fit the permission referred to in the caption of this article.

Article 26. The inventory depletion of packaging, labels, and use instructions is allowed for a period of 120 (one hundred and twenty) days counting from the date the alteration was published.

Sole paragraph. Alterations made to solve problems of product safety and performance do not fit the permission referred to in the caption of this article.

Section V

Medical Device Marketing Authorization Revalidation

Article 27. In order to submit the application for medical device marketing authorization revalidation, the applicant must pay the corresponding fee and submit the following documents to Anvisa:

I – for imported medical devices: consular or certified statement issued by the legal manufacturer, written in Portuguese, English, or Spanish, or accompanied by sworn translation signed for a maximum period of two years when there is no express validity indicated in the document, authorizing the requesting company to represent and commercialize its product(s) in Brazil;

II – valid Good Manufacturing Practices Certificate issued by Anvisa.

Paragraph 1. The declaration referred to in item I must include the corporate name and full address of the legal manufacturer and the requesting company, the express authorization for the requesting company to represent and commercialize its products in Brazil; and the affirmation of knowledge and compliance with the requirements of Good Health Product Manufacturing Practices established in Collegiate Board Resolution – RDC no. 665 of 30 March 2022, published in the Federal Official Gazette no. 62 of 31 March 2022, Section 1, Page 334, or a regulation replacing it.

Paragraph 2. The application for revalidation must be submitted within the period provided for in Collegiate Board Resolution – RDC no. 250 of 20 October 2004.

Paragraph 3. The protocol of the application for the Good Manufacturing Practices Certification shall be accepted for the purposes of application for marketing authorization revalidation, and to start the analysis of the respective applications.

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

Section VI

Cancellation of Notification of or Marketing Authorization for Medical Devices

Article 29. The medical device notification or marketing authorization holder who intends to no longer commercialize it in the Brazilian market must apply for its cancellation.

Section VII

Conformity of Information

Article 30. The alterations made by the manufacturer in the information related to the medical device contained in the notification or marketing authorization shall be communicated by the holder to Anvisa, in accordance with the requirements provided for in Section IV of this Resolution.

Article 31. The alterations related to a medical device that require prior approval by Anvisa may only be disclosed to the market after publication of such alteration in the Federal Official Gazette and Anvisa's website.

Article 32. All medical device communication or advertisement conveyed on the market must keep strict agreement with the information presented by the notification or marketing authorization holder to Anvisa.

Section VIII

Documentary Repository of Medical Devices

Article 33. Loading use instructions in the Documentary Repository of Medical Devices corresponds to inserting and updating such documents linked to medical device notification or marketing authorization processes.

Paragraph 1. If a medical device has no use instructions (as a specific document), the labeling model must be loaded in the field of use instructions, also including the information provided for in Chapter VI.

Paragraph 2. The loading of use instructions shall occur through the applicable petition subjects, identified as "Availability of Use Instructions on Anvisa's Website".

Paragraph 3. The notification or marketing authorization holder is responsible for loading use instructions and such activity must be controlled by the holder for eventual audits.

Paragraph 4. The loading of use instructions is mandatory and must be executed by the company responsible for the notification of or marketing authorization for the product, which attests that its content complies with the legislation is force and is consistent with the regularized product.

Paragraph 5. For the new products notified or granted marketing authorization and for the alterations of those products previously notified or granted marketing authorization, the application and the respective loading of use instructions must be carried out in up to 30 (thirty) days after publication in the Federal Official Gazette.

Paragraph 6. For non-reportable alterations of those products previously notified or granted marketing authorization, the application and the respective loading of use instructions must be carried out in up to 180 (one hundred and eighty) days after the implementation of the alteration that implies change in use instructions.

Article 34. The availability of use instructions shall be performed exclusively on Anvisa's website, immediately after the completion of the protocol of the respective application, regardless of documentary analysis by the Agency.

Paragraph 1. The update is carried out through a new insertion of use instructions.

Paragraph 2. If there is a new loading of use instructions in the process of notification or marketing authorization, only those recently loaded shall be kept public.

Paragraph 3. The use instructions loaded over time shall be kept in a database for control and audit by Anvisa.

Article 35. The use instructions loaded or their absence under the terms of this Resolution may be object of documentary or tax assessment at any time by Anvisa and, if necessary, the Agency may:

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

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

Article 36. The companies that insert information in the documentary repository of medical devices that do not comply with the legislation in force and are not consistent with the regularized product are subject to the penalties provided for in Law no. 6,437 of 20 August 1977.

Sole paragraph. In case of non-compliance with the legislation in force or inconsistency that justifies a health measure, Anvisa may suspend the commercialization, import and/ or use of the product until the loading of use instructions adequate to the terms of this Resolution, and the provisions of Article 15 of Law no. 6,437 of 20 August 1977 must be complied with.

Section IX

Process reassessment procedure

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

Article 38. In cases where there is evidence of inconsistencies or the need to complement information, holders shall be urged to make their processes adequate.

Paragraph 1. The adjustments referred to in the caption of this article shall be carried out by the notification or marketing authorization holder in up to 30 (thirty) days from the date of confirmation of their receipt.

Paragraph 2. The situations that lead to correction of previously presented information must be addressed through specific applications.

Paragraph 3. The absence of response to the notification of adequacy referred to in the caption of this article within 30 (thirty) days counting from its issuance, shall result in cancellation of the notification, marketing authorization, or alteration.

CHAPTER IV

ADMINISTRATIVE SANCTIONS

Article 39. Anvisa may suspend the manufacture, import, commercialization, and use of the medical device in the following cases:

I – the validity of any of the documents referred to in Articles 13 and 14 of this Resolution is suspended, due to safety reasons, duly justified;

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

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

Article 40. The suspension of manufacture, import, commercialization, and use of medical device shall be published in the Federal Official Gazette and shall be maintained until the problem that caused the sanction is solved and its cancellation is communicated.

Article 41. Anvisa may cancel the notification of or the marketing authorization for the medical device in the following cases:

I – there is proof that false information was provided in any of the documents requested in this Resolution, or there is cancellation of any of these documents by the competent health authority;

II – there is proof that the product or manufacturing process may pose risk to the health of the user, patient, operator, or third parties involved;

III – there is absence of information or documents in the processes of products subject to notification;

IV – there is error regarding health classification in the notification processes; or

V – the procedural reassessment requirements presented by Anvisa were not complied with.

Article 42. Anvisa may determine the cancellation of alterations that lead to incorrect information or irregularity of a medical device.

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

Article 44. The cancellation of the notification of or the marketing authorization for a medical device shall be published in the Federal Official Gazette.

CHAPTER V

INFORMATION FORMS OF APPLICANTS AND THEIR MEDICAL DEVICES

Article 45. The applicable forms on information about the applicant and the product object of notification or marketing authorization process must be completed electronically on Anvisa's website.

Sole paragraph. When applicable, the forms must be presented with the signatures of the legally and technically responsible people.

CHAPTER VI

LABELS AND USE INSTRUCTIONS OF MEDICAL DEVICES

Section I

Information requirements for labels and use instructions

Article 46. Information on labels and use instructions of medical devices must meet the following general requirements:

I – the information contained on labels and use instructions must be written in Portuguese;

II – all medical devices must include use instructions in their packaging or refer to the way to access such documents;

III – exceptionally, these instructions may not be included in the packaging of medical devices of classes I and II, provided that the use safety of such products may be ensured without the instructions;

IV – the information necessary for the completely safe use of the medical device should be, whenever possible, on the medical device itself or on the label of its individual packaging or, if this is impossible, 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 use instructions 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 regulation or technical standards;

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

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

Article 47. The label model must contain the following information:

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

II – company name and address of the notification or marketing authorization holder;

III – the necessary information for the user to identify the medical device and the content of its packaging;

IV – when applicable, the word "Sterile" and the sterilization method;

V – batch code, preceded by the word "Batch", or the serial number, as appropriate;

VI – as applicable, date of manufacture and shelf life 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 – special instructions for operation and/ or use of the medical device;

X – all warnings and precautions to be adopted;

XI – name of the technical responsible person legally qualified for the function;

XII – notification or marketing authorization number of the medical device, preceded by Anvisa identification acronym.

Article 48. The model of use instructions must contain the following information, as applicable:

I – the information indicated in Article 47 of this Resolution, except those contained in items "V", "VI", and "XI";

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

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

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

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

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

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

VIII – if the medical device is reusable, information on the appropriate procedures for reuse, including cleaning, disinfection, packaging and, as appropriate, sterilization method, if the product must be sterilized again, as well as any restrictions on the possible number of reuses;

IX – if the medical device must be sterilized before its use, the instructions on cleaning and sterilization must be formulated so that, if correctly performed, the product meets the requirements provided for by the manufacturer as to the Essential Safety and Performance (or Effectiveness) Requirements;

X – information on additional treatment or procedure that must be carried out before the medical device is used;

XI – if a medical device emits radiation for medical purposes, information regarding nature, type, intensity, and distribution of such radiation must be described;

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

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

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

XV – adequate information about the medicinal product(s) that the medical device is intended to administer, including any restrictions regarding the choice of such substances;

XVI – the precautions to be adopted if the medical device poses an unexpected specific risk associated to its disposal;

XVII – reference to medicinal products incorporated to the medical device as an integral part of it; and

XVIII – the level of accuracy attributed to measurement medical devices.

Article 49. Equipment submitted to health surveillance notified or granted marketing authorization must have an indelible label attached, indicating the following information:

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

II – name of the legal manufacturer or brand;

III – number of notification or marketing authorization granted by Anvisa; and

IV – serial number or other identifier that allows equipment traceability.

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

Paragraph 2. In cases of systems, all their components must be identified as integrating the system to which they are associated.

Paragraph 3. The provisions in the caption of this article do not apply to non-implantable single-use equipment.

Section II

Use Instructions in Non-Printed Format

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

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

I – inform on the external label the way to obtain the correlation between the product supplied and the version of the corresponding use instruction;

II – indicate on the label a Consumer Service where the printed format of use instructions may be requested at no additional cost (including shipping);

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

IV – specify the resources required to read the use instructions.

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

Paragraph 2. The equipment manufacturer or notification or marketing authorization holder must consider the period indicated in item III as the shelf life specified for the product, counting from the last marketed unit of the product.

Article 52. Use instructions provided in non-printed format must contain:

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

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

III – a warning to the user to observe the correlation of the indicated version of the use instructions 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 product use instructions in printed format.

Article 53. For the supply of use instructions on the Internet, in addition to the provisions in articles 51 and 52, the following requirements must also be complied with:

I – together with the product, provide clear guidance on how to find the corresponding and updated use instructions at the email address available on the Internet;

II – ensure the basic security requirements of the email address;

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

IV – ensure free access to the tool required to read the use instructions at the email address; and

V – ensure that the file made available and printed through such way is identical to that provided by the manufacturer or notification or marketing authorization holder, when requested, in printed format.

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

I – health use equipment with an indication of:

a) domestic use in general, including those of use in home care services; and

b) operation by lay people, regardless of the place of use.

II – health use materials used by lay people.

CHAPTER VII

TECHNICAL DOSSIER

Article 55. The legally and technically responsible people appointed by the requesting company are responsible for the information and documents presented.

Article 56. The medical device notification holder is responsible for keeping the technical dossier updated, containing all the documents and information indicated in this Resolution, for the purposes of supervision by the Brazilian Health Surveillance System.

Paragraph 1. This technical dossier should not be submitted to Anvisa as part of the product notification application, and it must be kept by the notification holding company.

Paragraph 2. The technical dossier does not need to correspond to a physical or electronic file containing all the information described below, and it may be composed of references to documents and information that compose other files or records of the company's Quality System, which must be available for inspection purposes by the Brazilian Health Surveillance System.

Paragraph 3. In specific cases, when investigations and checks are necessary, Anvisa may request the Technical Dossier.

Article 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 foundations of its operation and action, its content or composition, when applicable, as well as a list of the accessories intended to integrate the product;

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

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

IV – presentation forms of the medical device;

V – models of labels and use instructions, according to articles 46 to 49 of this Resolution;

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

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

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

Paragraph 2. If necessary, the health authority may request additional information or clarifications, as well as the submission of complementary documentation, including a report on a clinical study specifically designed and conducted to investigate the medical device of interest.

Article 58. The Technical Dossier information must be organized in accordance with the product's health risk class, as provided for in Annex II of this Resolution.

CHAPTER VIII

FINAL AND TRANSITIONAL PROVISIONS

Article 59. The same types of health infractions and the associated penalties in force for the medical device marketing authorization regime apply to the notification regime.

Article 60. Notifications of and marketing authorizations for medical devices, their alterations and other acts shall be published in the Federal Official Gazette and shall remain available for consultation on Anvisa's website.

Paragraph 1. Products subject to notification and marketing authorization may only be industrialized, imported, displayed for sale, or delivered for consumption after the publication of the notification or marketing authorization number referred to.

Paragraph 2. Products manufactured in Brazilian territory exclusively for export purposes do not require notification or marketing authorization by Anvisa.

Article 61. Protocols of medical device marketing authorization applications with the technical report structure provided for in Collegiate Board Resolution – RDC no. 185 of 22 October 2001, submitted until 28 February 2023, shall be accepted.

Sole paragraph. For marketing authorizations granted during the effectiveness of Collegiate Board Resolution – RDC no. 185 of 22 October 2001, the maintenance of the technical report structure shall be allowed until an eventual application for alteration in marketing authorization of required approval, which must include the new Technical Dossier structure.

Article 62. The period of 365 (three hundred and sixty-five) days, counting from the date this Resolution enters into force, is hereby established for the holders of medical device notifications to submit applications for the health reclassification of products that had their regime altered from notification to marketing authorization due to the update of classification rules.

Paragraph 1. The application must be submitted with the same documentation required for new marketing authorization for a product.

Paragraph 2. The submission of a request for Good Manufacturing Practices Certification shall be accepted for the purposes of application, as well as to start the analysis of health reclassification applications.

Paragraph 3. The approval of health reclassification applications is subject to the publication of a valid Good Manufacturing Practices Certificate issued by Anvisa and compliance with the other requirements for the marketing authorization for medical devices.

Paragraph 4. Failure to comply with the provisions set forth in the caption of this article shall lead to cancellation of product notification.

Article 63. The marketing authorization processes whose products had their regularization regime altered form marketing authorization to notification due to the update of classification rules shall be treated through Anvisa rectification document.

Article 64. Collegiate Board Resolution – RDC no. 270 of 28 February 2019, published in the Federal Official Gazette no. 43 of 1 March 2019, Section 1, page 68, enters into force with the following alteration:

“Article 5. Notifications of medical devices, their alterations and other acts shall be published in the Federal Official Gazette and shall remain available for consultation on Anvisa's website.”

Article 65. Collegiate Board Resolution – RDC no. 340 of 6 March 2020, published in the Federal Official Gazette no. 48 of 11 March 2020, Section 1, page 56, enters into force with the following alteration:

“Article 9. The alterations of immediate implementation shall be published in the Federal Official Gazette and, when applicable, the updated data shall be made public on Anvisa’s website, and the period of up to 30 (thirty) days, counting from the finalization of the submission of the respective application, must be complied with, regardless of documentary analysis by Anvisa.”

Article 66. The following are hereby revoked, on the date this Resolution enters into force:

I – Collegiate Board Resolution – RDC no. 185 of 22 October 2001;

II – Resolution – RE no. 1554 of 19 August 2002;

III – Collegiate Board Resolution – RDC no. 207 of 7 November 2006;

IV – items I and II of Article 2, and item II of Article 5 of Normative Instruction – IN no. 4 of 15 June 2012;

V – Collegiate Board Resolution – RDC no. 15 of 28 March 2014;

VI – Collegiate Board Resolution – RDC no. 40 of 26 August 2015.

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

ANTONIO BARRA TORRES

Director-President

ATTACHMENT I

Medical Device Risk Classification Rules

Non-invasive devices

Rule 1

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

Rule 2

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

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

b) if they are intended to be used for the conduction or storage of blood or other body fluids or for the storage of body organs, parts of organs, or cells and tissues, except for blood bags and blood components, which are classified in class III.

In all other cases, such 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 to the body are classified in class III, unless the treatment in which the device is to be used consists in filtration, centrifugation, or exchanges of gases or heat, in which case they are classified in class II.

All non-invasive devices consisting of 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, before their implantation or administration to the body, are classified in class IV.

Rule 4

All non-invasive devices that come into contact with injured skin or mucosa 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;

b) in class III, if they are intended to be used mainly in skin lesions that have ruptured the dermis or mucous membranes and that can only heal through second intention;

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

d) in class II in all other cases.

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

Invasive devices

Rule 5

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

a) in class I, if 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 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 to the pharynx, in the ear canal to the eardrum, or in the nasal cavity, and if they are not susceptible to absorption by the mucosa, in which case they are classified in class II.

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

Rule 6

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

a) they are specifically intended to control, diagnose, monitor, or correct cardiac or central circulatory system dysfunctions through direct contact with those parts of the body, in which case they are classified in class IV;

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

c) 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;

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

e) they 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 pharmaceuticals 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) they are specifically intended to control, diagnose, monitor, or correct cardiac or central circulatory system dysfunctions through direct contact with those 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) they 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) they are intended to undergo a chemical alteration in the body, in which case they belong to class III, unless they are placed on teeth; or

f) they are intended for the administration of pharmaceuticals, 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) they are intended to be placed on teeth, in which case they are classified in class II;

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

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

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

e) they are intended for the administration of pharmaceuticals, in which case they are classified in class IV;

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

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

h) they are total or partial joint prostheses, in which case they are classified in class IV, except for 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, except for 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, due to their characteristics, they can supply energy to the human body or exchange energy with it in a potentially dangerous way, considering 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 such devices, or that directly influence their performance, are classified in class III.

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

Rule 10

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

a) they are intended to supply 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 radiopharmaceuticals; or

c) they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended to monitor or observe vital physiological parameters and the nature of variations in these parameters is likely to result in immediate danger for the patient, as it is the case of 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 diagnosis 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 lead to:

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

b) a serious deterioration of a person's health status 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 may result in immediate danger for 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 administrate pharmaceuticals, body fluids, or other substances into the human body, or remove them from it, are classified in class II, unless this is done in a potentially dangerous 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.

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, may be considered a medicinal product, including a medicinal product derived from human blood or plasma, and which has an action complementary to that of the devices, are classified in class IV.

Rule 15

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

Rule 16

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

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

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

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

Rule 17

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

Rule 18

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

This rule does not apply to advanced therapy products, which are addressed 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 for surgically invasive devices, intended for the administration of pharmaceuticals through inhalation are classified in class II, unless

their mode of action has a significant impact on the efficacy and safety of the pharmaceutical administered, or are intended to treat life-threatening conditions, in which case they are classified in class III.

Rule 21

Medical devices consisting of substances or combinations of substances that are intended to be introduced into the human body through a body orifice or applied to the skin and are absorbed or disseminated through the human body or locally dispersed on it are classified:

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

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

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

d) in class III in all other cases.

Rule 22

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

ATTACHMENT II

Technical Dossier Structure of Medical Devices Subject to Notification and Marketing Authorization by Anvisa

Medical Device Technical Dossier[1]	**Notification**		**Marketing Authorization**	
	Class I	**Class II**	**Class III**	**Class IV**
Chapter 1				
Administrative and Technical Information (forms available on Anvisa's website)	X	X	X	X
List of devices (Models / Components / Variants)	X	X	X	X
Chapter 2				
Detailed Description of the Medical Device and Foundation of Operation and Action	X	X	X	X
Description of Device Packaging and Presentation Forms	X	X	X	X
Intended Purpose; Purpose of Use; Intended User; Indication of Use	X	X	X	X
Environment / Context of Intended Use	X	X	X	X
Contraindications of Use	X	X	X	X
Global History of Commercialization	-	X	X	X
Chapter 3				
Risk Management	X	X	X	X
List of Essential Safety and Performance Requirements	-	X	X	X
List of Technical Standards	X	X	X	X
Physical and Mechanical Characterization	X	X	X	X
Material/ Chemical Characterization	X	X	X	X
Electrical Systems: Safety, Mechanical and Environmental Protection, and Electromagnetic Compatibility	X	X	X	X
Software / Firmware Description	X	X	X	X
Biocompatibility Assessment	X	X	X	X
Pyrogenicity Assessment	X	X	X	X
Safety of Materials of Biological Origin	X	X	X	X
Sterilization Validation	X	X	X	X
Residual Toxicity	X	X	X	X
Cleaning and Disinfection of Reusable Products	X	X	X	X
Usability / Human Factors	X	X	X	X
Product Shelf Life and Packaging Validation / Stability Study	X	X	X	X
Chapter 4				
General Summary of Clinical Evidence[2]	X	X	X	X
Relevant Clinical Literature	-	X	X	X
Chapter 5				
Product Labeling / Packaging	X	X	X	X
Use Instructions / 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 it 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 use indications. It must comply with the current health legislation for clinical trials conducted in Brazil, and the Specific Special Notice must be presented.