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Business
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RESOLUTION RDC NO. 751, OF SEPTEMBER 15, 2022

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

The Collegial Board of Governors of the Brazilian Health Surveillance Agency, in exercising the powers vested thereupon in article 15, III and IV, combined with article 7, III and IV, Law no. 9782, of January 26, 1999, and with article 187, VI, paragraphs 1 and 3 of the Internal Regulations approved by Collegial Board of Governors' Resolution 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, CEO, determine the publication thereof.

CHAPTER I

PRELIMINARY PROVISIONS

Section I

Purpose

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

Section II

Scope

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

Paragraph 1. The risk classification procedures, and the specification described herein for notification and registration purposes apply to medical devices and accessories thereof.

Paragraph 2. This Resolution does not apply to used or refurbished medical devices, which are subject to the specific rules established in the Collegial Board of Governors' Resolution - RDC no. 579, of November 25, 2021, published in the Brazilian Federal Gazette (DOU) no. 225, of December 1, 2021.

Paragraph 3. This Resolution does not apply to customized medical devices, which are subject to the specific rules established in the Collegial Board of Governors'

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Resolution RDC no. 305, of September 24, 2019, published in the Brazilian Federal Gazette (DOU) no. 186, of September 25, 2019, Section 1, page 69.

Paragraph 4. This Resolution does not apply to medical devices for in vitro diagnostics, including the in vitro diagnostic instruments, which are subject to the specific rules established in the Collegial Board of Governors' Resolution RDC no. 36, of August 26, 2015, published in the Brazilian Federal Gazette (DOU) no. 164, of August 27, 2015, Section 1, page 43.

Paragraph 5. This Resolution does not apply to medicinal products, cells, tissues, organs or human blood or blood derivatives, cosmetics, sanitizers or foodstuffs treated 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 the cleaning, disinfection or sterilization of medical devices are considered medical devices.

Paragraph 8. Medical devices intended for clinical investigations are exempt from notification or registration, with the legal provisions of the competent health authority being met for carrying out this activity, with the marketing and use for other purposes being prohibited.

Paragraph 9. Presentations made up of two or more notified or registered medical devices and in their individual packaging of intact presentation shall be exempted from notification or registration; their label shall contain the information of the corresponding medical devices, including the notification or registration numbers.

Paragraph 10. Accessories produced by a manufacturer, exclusively to be part of the medical devices they manufacture which are already notified or registered and whose technical dossiers contain information about such accessories, are exempted from notification or registration.

Paragraph 11. The new accessories may be included in the notification or in the original registrations, detailing the fundamentals of operation, action and contents.

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

Sole Paragraph. The grouping of products, for notification or registration purposes, shall take place in accordance with the rules provided for in a specific regulation.

Section III

Definitions

Article 4. For the purposes of this Resolution the terms below, which may have a different meaning in other contexts, shall have the following meanings:

I - accessory (of a medical device): a product intended by its manufacturer to be used in conjunction with one or several specific medical devices, to specifically and directly enable or assist the medical device(s) to be used as per the intended purpose;

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

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

V - amendment of required approval: an amendment of major health relevance, which deals with a change to be introduced in the registration process, being authorized in the national territory only after technical documentary analysis and favorable opinion of Anvisa;

VI - amendment for immediate implementation: an amendment of intermediate health relevance, which deals with a change to be introduced in the notification or registration process, its implementation being authorized in the national territory after filing a petition with Anvisa;

VII - non-reportable amendment: any other amendment of minor health relevance, resulting from a change that is not classified as required approval or immediate implementation, and that does not depend on protocols at Anvisa for implementation purposes;

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

IX- surgically invasive device: an invasive device that penetrates the body through its surface, including through the mucous membranes of the body orifices, in the context of a surgical intervention; and a device that penetrates the body through a way other than a body orifice;

X - medical device (health care 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 jointly, in human beings, for any of the following specific medical purposes, and whose main intended action is not achieved by pharmacological, immunological or metabolic means in the human body, but that can be assisted in its 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 disability;

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

d) life support or maintenance;

e) conceiving control or support; or

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f) provision of information by means of in vitro testing of samples from the human body, including donations of organs and tissues.

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

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

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

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

XV - invasive medical device: any device that partially or completely penetrates into the body, either through one of its orifices or by crossing its surface;

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

XVIII - 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 framework of treatment or mitigation of a disease, injury or disability;

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

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

XX - family: grouping of medical devices, for notification or registration purposes, provided for in a specific regulation, wherein each product has similar technical characteristics of:

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a) Indication, purpose of use;

b) Operation and action;

c) Technology;

d) Contents or composition, where applicable; and

e) Precautions, restrictions, warnings and special care.

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

XXII - importer: a legal public or private entity responsible for the import activity for the entry of medical devices from abroad into the national territory;

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

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

XXV - clinical investigation: any systematic investigation or study in one or more human beings, carried out to assess the safety, clinical performance and/or efficacy of a medical device. For the purposes of this regulation, this term is a synonymous with "clinical trial" or "clinical research";

XXVI - kit (assembly, set or tray): a set of medical devices that, regardless of being individually registered or notified, are grouped into a sales unit for a specific End of use or procedure:

a) for compliance purposes, the set shall be of the same manufacturer or manufacturing group; and

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

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

XXVIII - nanomaterial: natural, incidental or manufactured material containing particles in an unbound state or in the form of aggregate or agglomerate, wherein 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 below 1 nm are also considered nanomaterials.

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b) materials manufactured with dimensions that extrapolate the upper limit of the nanoscale (established between 1 and 100 nm), up to the mark of 1000 nm, and that exhibit different size-dependent properties or phenomena when compared to those showed by the same material in macroscale, may be included in the definition of nanomaterial;

XXIX - technical standard: a document defined by consensus and approved by a recognized body, which provides for common and repetitive use of rules, guidelines or characteristics for activities or their results, aiming to obtain an optimal degree of ordering in a given context;

XXX - notification: the action of communicating to Anvisa the intention to commercialize medical devices, intended to prove the right to manufacture and import the medical devices exempted from registration as per paragraph 1 of Article 25 of Law no. 6,360, of September 23, 1976, and classified in risk classes I or II, showing the name, manufacturer, purpose and other elements characterizing 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 purpose of defining nanomaterial, a tiny portion of matter with defined physical boundaries;

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

XXXIV - process reassessment: a procedure carried out by Anvisa's technical area in NOTIFICATION and registrations of medical devices for processes audit purposes;

XXXV - registration: a private action of Anvisa intended to prove the right to manufacture and import products subject to the scheme of Law 6,360 of September 23, 1976 and classified in risk classes III or IV, showing the name, manufacturer, purpose and other elements that characterizing it;

XXXVI - Medical Devices Documentary Repository: a digital tool for storing and making available documents related to notified and registered medical devices, available on Anvisa's web portal;

XXXVII - legal person in charge: a natural person designated by statute, articles of incorporation or minutes, responsible for actively and passively representing the applicant legal entity (manufacturer or importer) in judicial and extrajudicial actions;

XXXVIII - technical person in charge: a higher-level professional legally qualified, and qualified in the technologies that make up the product, being responsible for the technical information submitted by the applicant (manufacturer or importer) and for the quality, safety and performance of the marketed product;

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

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

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XLI - central circulatory system: a 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, brachiocephalic trunk, coronary veins, pulmonary veins, superior vena cava and inferior vena cava;

XLII - central nervous system: a system that includes the brain, meninges and spinal cord;

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

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

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

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

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

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

f) a SaMD may interact with other medical devices, including hardware of other medical devices and other SaMD, as well as a general-purpose software; and

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

XLIV - applicant: a legal public or private entity that files medical devices notification or registration petitions with the health authority;

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

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

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

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

XLIX - user: a health professional or layperson who may be the patient himself, and who uses a medical device according to the instructions for use.

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CHAPTER II

RISK CLASSIFICATION FOR MEDICAL DEVICES

Section I

Classification and Control Schemes

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

I- Class I: low risk;

II - Class II: intermediate risk;

III - Class III: high risk; and

IV - Class IV: maximum risk.

Paragraph 1. For classifying the medical device in one of these classes, the classification rules set out in this Resolution shall be applied.

Paragraph 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 medical device classification.

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

Article 7. Medical devices falling within risk classes III and IV are subject to registration.

Section II

Application Rules

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

Paragraph 1. If the device concerned is intended to be used in combination with another device, the classification rules shall apply separately to each device.

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

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

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

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

Paragraph 6. If multiple rules apply to a same device or, within the same rule, several subrules based on their intended purpose, the stricter rule and subrule leading to a higher classification shall apply.

Paragraph 7. When calculating the duration of use "continuously", one should consider:

a) the entire duration of use of the same device without considering temporary interruptions of use during a procedure or temporary removal for the purposes of cleaning or disinfecting the device; it should be determined whether the interruption of use, or removal, is temporary regarding the duration of use prior to and after the period in which the use is interrupted or the device is removed; and

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

Paragraph 8. It is considered that a device allows a direct diagnosis when it provides, by itself, the diagnosis of the disease or condition concerned, or when it provides decisive information for the diagnosis.

Section III

Classification Rules

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

CHAPTER III

REQUEST FOR NOTIFICATION OR REGISTRATION AND ITS MAINTENANCE

Section I

Procedures for the Notification or Registration of Medical Devices

Article 10. The applicant shall submit to Anvisa the documents for notification, registration, amendment, revalidation or cancellation of the medical device notification or registration, listed in this Resolution.

Paragraph 1. Anvisa will assess the documentation submitted for registration, amendment or revalidation of the registration and will reply to it by official means.

Paragraph 2. The documentation will be assessed within the deadlines and legal conditions provided for in the Brazilian health legislation.

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Paragraph 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 submission of additional documents and information.

Paragraph 4. It shall not be subject to the technical requirement the petition that misses documents, forms and declarations as provided for in the list of process instruction documents, not fully completed or with missing or illegible information, or obsolete documents, missing the certificate of conformity where applicable, or without clinical evidences for products with innovative technology or indication, giving rise to the non-approval or expedited rejection of the petition.

Paragraph 5. There will be no technical analysis of notification petitions neither notification amendments so that the products are considered compliant, without prejudice to the conduction, at any time, of documentary or fiscal assessments on the notification processes and their amendments, and, if necessary, of the request for additional information or clarifications.

Paragraph 6. The medical device notification will be processed routinely within thirty (30) days as of the filing by the applicant.

Paragraph 7. Maintaining the NOTIFICATION and the registration is bound to meeting the requirements of the Good Manufacturing Practices, essential safety and performance requirements and specific regulations, if any.

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

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

Paragraph 10. The other documents not mentioned in the previous paragraph, which make up the petitions for medical devices, may be submitted in the Portuguese, Spanish or English, as per the rules defined in specific regulations.

Article 11. The registration of medical devices shall remain valid for ten (10) years as of the date of its publication in the Brazilian Federal Gazette, and may be revalidated successively for the same period, under the terms set out in section V of this Resolution.

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

Section II

Medical devices Notification

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

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

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II - for imported medical devices: a declaration issued by the legal manufacturer, with consular authentication or apostille, written in Portuguese, English or Spanish, or accompanied by the certified translation for at most two years when no express validity is indicated in the document, authorizing the applicant company to represent and market its product(s) in Brazil;

III - a copy of the Certificate of Conformity issued under 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, as per the legislation regulating specific medical devices.

Sole Paragraph. The declaration dealt with in item II shall contain the corporate name and full address of the legal manufacturer and the applicant company, the express authorization for the applicant company to represent and market its products in Brazil, and the statement of knowledge and compliance with the requirements of the Good Manufacturing Practices for Health Products established in the Collegial Board of Governors' Resolution - RDC no. 665, of March 30, 2022, or a regulation that replaces it.

Section III

Registration of Medical Devices

Article 14. In order to request the medical device registration, the applicant must pay the corresponding fee and submit Anvisa the following documents:

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

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

III - for imported medical devices: a declaration issued by the legal manufacturer, with consular authentication or apostille, written in Portuguese, English or Spanish, or accompanied by the certified translation for at most two years when no express validity is indicated in the document, authorizing the applicant company to represent and market its product(s) in Brazil;

IV - for imported medical devices: proof of registration or certificate of free sale or equivalent document, granted by the competent authority of the country where the medical device is manufactured and marketed, or only marketed, having been issued for at most two years when no express validity is indicated in the document, and it must contain the consular authentication or apostille, and accompanied by the certified translation when not written in Portuguese, English or Spanish;

V - Certificate of Good Manufacturing Practices issued by Anvisa or the Certificate of Good Manufacturing Practices application docket confirmation;

VI - a copy of the Certificate of Conformity issued under the Brazilian Conformity Assessment System (*SBAC*), applicable only to medical devices with compulsory certification, listed by Anvisa in specific regulations; and

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

Paragraph 1. The declaration dealt with in item III shall contain the corporate name and full address of the legal manufacturer and the applicant company, the express authorization for the applicant company to represent and market its products in Brazil; and the statement of knowledge and compliance with the requirements of the Good Manufacturing Practices for Health Products established in the Collegial Board of Governors' Resolution - RDC no. 665, of March 30, 2022, or regulation that will replace it.

Paragraph 2. The Certificate of Good Manufacturing Practices application docket will be accepted for petitioning purposes, as well as to begin the analysis of the registration granting petitions.

Paragraph 3. The approval of applications for granting registration is dependent on the publication of a valid Certificate of Good Manufacturing Practices issued by Anvisa and on the compliance with the other requirements for medical devices registration.

Section IV

Amendment of the Notification or Registration of Medical Devices

Article 15. In order to request the medical device notification or registration amendment, the applicant must pay the corresponding fee, if applicable, and submit the declaration with the requested changes and other required documents, as per the subject requested.

Article 16. Amendments to the information submitted in the medical device notification or registration process are classified as:

I - amendment of a required approval;

II - amendment for immediate implementation: and

III - non-reportable amendment:

Paragraph 1. The request for amendments contained in items I and II of this Article shall comply with the provisions of the Normative Instruction - IN no. 74, of September 16, 2020, published in the Brazilian Federal Gazette no. 180, of September 18, 2022, Section 1, page 111, which details the applicable petitioning subjects.

Paragraph 2. Any minor changes not classified as required approval or immediate implementation are classified as non-reportable changes, and also: amendments in information that do not modify the medical device design; bug fixes in software; non-technical changes such as images, formatting, layouts, symbols and document text adaptations without any risk added; updates of the Company Operating Authorization information; changes in contact (e.g. telephone numbers or postal addresses), technical assistance and website.

Paragraph 3. The changes listed in § 2 shall be controlled by the quality system of the compliance holder and incorporated into subsequent petitions.

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Paragraph 4. Amendment for medical devices in risk Classes I and II will be requested as per the immediate implementation scheme, except when it is a non-reportable amendment.

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

Article 18. The petition to amend information must be accompanied with documentation evidencing the modification to be implemented, in accordance with the health legislation in force.

Article 19. The immediate implementation amendment that is interdependent with the required approval amendment should be requested in conjunction with this amendment, by incorporating its contents.

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

Sole Paragraph. In order to request the analysis priority mentioned in the heading paragraph, the company shall file the request by submitting evidences that the field action NOTIFICATION was forwarded to Anvisa.

Article 21. The required approval amendment will only take effect after the final decision is published in the Brazilian Federal Gazette and, where applicable, the updated data will be published on Anvisa's web portal.

Article 22. Changes in immediate implementation will be published in the Brazilian Federal Gazette and, where applicable, the updated data will be published on Anvisa's web portal, observing the period of up to thirty (30) days as of the completion of said petition docket, regardless of document analysis by Anvisa.

Article 23. The request for immediate implementation may be subject to documentary or fiscal 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 it is compliant, in case of inconsistency of the immediate implementation amendment petition that justifies such health action.

Article 24. The approval of petitions for the amendment/inclusion of a manufacturing plant or change of the factory address or inclusion of products or models in the family/system/set of products included in risk Classes III and IV, is dependent on the publication of the Certificate of Good Manufacturing Practices issued by Anvisa and on the fulfillment of the other requirements corresponding to each type of petition.

Sole Paragraph. The Certificate of Good Manufacturing Practices application docket will be accepted for petitioning purposes, as well as to begin the petitions analysis.

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Article 25. If a stock of finished products has to be cleared as a result of a change, the simultaneous import and commercialization of the versions involved is allowed until the end of the product shelf-life or lifespan.

Sole Paragraph. Amendments made to troubleshoot product safety and performance issues do not fall under the permission mentioned in the heading paragraph.

Article 26. Clearing the stock of packaging, labels and instructions for use is allowed for a period of one hundred and twenty (120) days as of the amendment publication.

Sole Paragraph. Amendments made to troubleshoot product safety and performance issues do not fall under the permission mentioned in the heading paragraph.

Section V

Medical Device Registration Revalidation

Article 27. In order to request the medical device registration revalidation, the applicant must pay the corresponding fee and submit the following documents:

I - for imported medical devices: a declaration issued by the legal manufacturer, with consular authentication or apostille, written in Portuguese, English or Spanish, or accompanied by the certified translation for at most two years when no express validity is indicated in the document, authorizing the applicant company to represent and market its product(s) in Brazil.

II - Valid Certificate of Good Manufacturing Practices issued by Anvisa.

Paragraph 1. The declaration dealt with in item I shall contain the corporate name and full address of the legal manufacturer and the applicant company, the express authorization for the applicant company to represent and market its products in Brazil, and the statement of knowledge and compliance with the requirements of the Good Manufacturing Practices for Health Products established in the Collegial Board of Governors' Resolution - RDC no. 665, of March 30, 2022, published in the Brazilian Federal Gazette no. 62, of March 31, 2022, Section 1, page 334, or regulation that will replace it.

Paragraph 2. The request for revalidation shall be submitted within the deadline set out in the Collegial Board of Governors' Resolution - RDC no. 250, of October 20, 2004.

Paragraph 3. The Certificate of Good Manufacturing Practices application docket will be accepted for petitioning purposes and analysis of the registration revalidation petitions.

Article 28. Products subject to the notification scheme are exempted from revalidation.

Section VI

Cancellation of Medical Devices Notification or Registration

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

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Section VII

Information Compliance

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

Article 31. Amendments related to a medical device that require prior approval by Anvisa may only be disclosed to the market after the publication of the said change in the Brazilian Federal Gazette and on Anvisa's web portal.

Article 32. All communication or advertising of a medical device on the market must keep strict compliance with the information submitted to Anvisa by the notification or registration holder.

Section VII

Medical Devices Documentary Repository:

Article 33. The uploading of instructions for use in the Medical Device Documentary Repository corresponds to the insertion and updating of these documents bound to the medical devices' notification or registration processes.

Paragraph 1. In the case of a medical device not having instructions for use (as a specific document), the labeling model must be uploaded into the instructions for use field, also including the information provided for in Chapter VI.

Paragraph 2. Instructions for use should be uploaded through the applicable petition subjects, identified as "Provision of Instructions for Use on Anvisa's Portal".

Paragraph 3. The notification or registration holder is responsible for uploading the instructions for use and uploading should be controlled by the holder for any audits.

Paragraph 4. Uploading the instructions for use is mandatory and must be carried out by the company responsible for the product notification or registration, which attests that its contents comply with the legislation in force and is consistent with the compliant product.

Paragraph 5. For new notified or registered products and for changes to those previously notified or registered, the request and the respective uploading of instructions for use shall be carried out within thirty (30) days as of the publication in the Brazilian Federal Gazette.

Paragraph 6. For non-reportable amendments to those previously notified or registered products, the request and the respective uploading of instructions for use shall be carried out within one hundred and eighty (180) days as of the implementation of the change that implies a change in the instructions for use.

Article 34. The instructions for use will be provided exclusively on Anvisa's web portal, immediately after the docket completion for the respective petition, regardless of document analysis by the Agency.

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

Paragraph 2. In case of a new uploading of instructions for use in the notification or registration process, only those recently uploaded will be kept public.

Paragraph 3. Instructions for use uploaded over time will be kept in a database for control and auditing by Anvisa.

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

I - request the company to submit information, further clarification or upload the appropriate instructions for use; and/or

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

Article 36. Companies entering information in the Medical Devices Documentary Repository that do not comply with the legislation in force and are consistent with the compliant 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 the legislation in force or inconsistencies that justify a health action, Anvisa may suspend the marketing, import and/or use of the product until the instructions for use are uploaded meeting the terms of this Resolution, in accordance with the provisions of Article 15 of Law no. 6,437, of August 20, 1977.

Section IX

Process Reassessment Procedure

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

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

Paragraph 1. Adjustments mentioned in the heading paragraph shall be carried out by the notification or registration holder within thirty (30) days as of the date of receipt confirmation.

Paragraph 2. Situations leading to the correction of the previously submitted information should be treated by means of specific petition.

Paragraph 3. The absence of a reply to the notification of adequacy referred to in the heading paragraph within thirty (30) days as of its issuance will lead to the cancellation of the notification, registration or amendment.

CHAPTER IV

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ADMINISTRATIVE SANCTIONS

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

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

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

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

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

Article 41. Anvisa may cancel the medical device NOTIFICATION or registration in cases that:

I - the information provided in any of the documents requested in this Resolution is provenly false, or if any of these documents are canceled by the competent health authority;

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

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

IV - an error in health classification is Identify in the notification procedures; or

V - the requirements for process reassessment submitted by Anvisa.

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

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

Article 44. The medical device notification registration cancellation will be published in the Brazilian Federal Gazette.

CHAPTER V

APPLICANT INFORMATION FORMS AND ITS MEDICAL DEVICES

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

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Sole Paragraph. Where applicable, the forms must be submitted with the signatures of legal and technical persons in charge.

CHAPTER VI

MEDICAL DEVICES LABELS AND INSTRUCTIONS FOR USE

Section I

Information requirements on labels and instructions for use

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

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

II - all medical devices must include the instructions for use on their packaging or mention how to access to these documents;

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

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

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

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

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

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

Article 47. The label template must include 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 notification or registration holder;

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

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

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

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VI - as applicable, the date of manufacture and validity term or date before which the medical device shall be used;

VII - where applicable, the indication that the medical device is for single use;

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

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

X - all warnings and precautions to be taken;

XI - name of the technical person in charge legally qualified for the position;

XII - medical device notification or registration number, preceded by Anvisa's identification acronym.

Article 48. The instructions for use template must contain the following information, as applicable:

I - the information provided in Article 47 of this Resolution, except as set out in items "V", "VI" and “XI”;

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

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

IV - all information able to prove whether a medical device is well installed and able to operate properly and fully safely, as well as the information regarding the nature and frequency of the maintenance and calibration operations to be carried out in order to ensure the permanent good operation and safety of the medical device;

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

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

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

VIII - if the medical device is reusable, information on appropriate reuse procedures, including cleaning, disinfection, packaging and as appropriate, the sterilization method, if the product is to be resterilized, and any restrictions on the possible number of reuses;

IX - where the medical device is to be sterilized before use, the cleaning and sterilization instructions shall be created in such a way that, if properly followed, the product

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meets the requirements provided for by the manufacturer as to the Essential Safety and Performance (or Efficacy);

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

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

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

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

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

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

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

XVII - mentioning the medicinal products incorporated into the medical device as an integral part Destination; and

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

Article 49. Notified or registered equipment under the health surveillance scheme shall have an indelible label affixed, stating:

I - product trade name, indicating the model, where applicable;

II - name of the legal manufacturer or brand;

III - notification or registration number with Anvisa; and

IV - serial number or other identifier allowing equipment traceability.

Paragraph 1. For small size and/or implantable equipment where such a label cannot be affixed, an identification of the manufacturer or brand, as well as traceability elements shall be required.

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

Paragraph 3. Non-implantable single-use equipment is excluded from the heading paragraph.

Section II

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Instructions for Use in Non-printed Format

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

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

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

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

III - ensure that the instructions for use are available for the whole period of time the product supplied is on the market; and

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

Paragraph 1. Where 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 registration holder shall consider the period of time indicated in item III as the specified lifespan of the product, as of the last product unit marketed.

Article 52. The instructions for use provided in non-printed format must contain:

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

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

III - an alert to the user to observe the correlation of the instructions for use indicated version and 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 instructions for use in printed format.

Article 53. For the provision of the instructions for use on the Internet, in addition to that established in Articles 51 and 52, the following requirements shall also be met:

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

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

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

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

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

Article 54. It is forbidden to exclusively provide the non-printed instructions for use for the following products:

I - health care equipment having an indication for:

a) household use in general, including those used in home care service - HCS; and

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

II - health care materials used by laypersons.

CHAPTER VII

TECHNICAL DOSSIER

Article 55. The legal and technical persons in charge of the applicant company are responsible for the information and documents submitted.

Article 56. The medical device notification holder is responsible for keeping the technical dossier up to date, containing all the documents and information indicated in this Resolution, for the purpose of surveillance by the National Health Surveillance System.

Paragraph 1. This Technical Dossier shall not be filed with Anvisa as part of the product notification request and shall remain in the possession of the notification holder company.

Paragraph 2. The Technical Dossier is not required to correspond to a physical or electronic file containing all the information described below and may be made of references to documents and information that make up other files or records of the company's quality system, which should be available for supervision purposes by the National Health Surveillance System.

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

Article 57. The Technical Dossier shall include the following information, which shall be structured as described in Attachment II to this Resolution:

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

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

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

IV - medical device forms of presentation;

V - label and instructions for use templates, as per Articles 46 to 49 of this Resolution;

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

VII - a description of the medical device safety and performance, as per the regulation in force regarding the essential safety and performance requirements for medical devices.

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

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

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

CHAPTER VIII

FINAL AND TRANSITIONAL PROVISIONS

Article 59. The same types of health violations and their associated injunctions in force for the medical device registration scheme apply to the notification scheme.

Article 60. Medical devices notifications and registrations, their changes and other acts will be published in the Brazilian Federal Gazette and will remain available for consultation on Anvisa's web portal.

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

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

Article 61. Petition dockets for the registration of medical devices will be accepted with the technical report structuring provided for in the Collegial Board of Governors' Resolution - RDC no. 185, of October 22, 2001, filed until February 28, 2023.

Sole Paragraph. For registrations granted during the term of RDC no. 185 dated October 22, 2001, the maintenance of the technical report structuring will be allowed until a possible request for change of approval registration is made, which should include the new structure of Technical Dossier.

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Article 62. The deadline of three hundred sixty-five (365) days as of this Resolution enters into force is set, so that medical device notification holders may file health reclassification petitions for products that had their scheme changed from notification to registration as a result of the classification rules update.

Paragraph 1. The petition shall be prepared with the same documentation required for the new registration of a product.

Paragraph 2. The Certificate of Good Manufacturing Practices application docket will be accepted for petitioning purposes, as well as to begin the health classification petitions analysis.

Paragraph 3. The approval of applications for granting registration is dependent on the publication of a valid Certificate of Good Manufacturing Practices issued by Anvisa and on the compliance with the other requirements for medical devices registration.

Paragraph 4. Failure to comply with the provisions set forth in the heading will result in notification of product.

Article 63. Registration processes whose products had their compliance scheme modified from registration to notification depending on the Classification rules update will be treated through Anvisa's Rectification file.

Article 64. The Collegial Board of Governors' Resolution - RDC no. 270, of February 28, 2019, published in the Brazilian Federal Gazette no. 43, of March 1, 2019, Section 1, page 68, shall become effective with the following amendment:

"Art. 5. Medical devices notifications, their changes and other acts will be published in the Brazilian Federal Gazette and will remain available for consultation on Anvisa's web portal."

Article 65. The Collegial Board of Governors' Resolution - RDC no. 340, of March 6, 2020, published in the Brazilian Federal Gazette no. 48, of March 11, 2020, Section 1, page 56, shall become effective with the following amendment:

"Art. 9. Changes in immediate implementation will be published in the Brazilian Federal Gazette and, where applicable, the updated data will be published on Anvisa's web portal, observing the period of up to thirty (30) days as of the completion of said petition docket, regardless of document analysis by Anvisa.

Article 66. As of the effective date of this Resolution, the following shall be revoked:

I - the Collegial Board of Governors' Resolution - RDC no. 185, of October 22, 2001;

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

III - Collegial Board of Governors' Resolution - RDC no. 207, of November 7, 2006;

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

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V - Collegial Board of Governors' Resolution - RDC no. 15, of March 28, 2014;

VI - the Collegial Board of Governors' Resolution - RDC no. 40, of August 26, 2015.

Article 67. This Resolution becomes effective on March 1, 2023.

ANTONIO BARRA TORRES
Chief Executive Officer

ATTACHMENT I

Risk Classification Rules for Medical Devices

Non-invasive Devices

Rule 1

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

Rule 2

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

a) in case they can be connected to an active device of Classes II, III, or IV; or

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

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

Rule 3

All non-invasive devices intended to alter the biological or chemical composition of tissues or cells of human origin, blood, other bodily fluids, or other liquids for implantation or administration into the body, are classified as Class III, except where the treatment in which the device is 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 for use in vitro in direct contact with human cells, tissues or organs taken from the human body or used in vitro with human embryos prior to their implantation or administration into the body, are classified in Class IV.

Rule 4

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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 absorption of exudates;

b) in Class III, if they are intended to be used mainly in skin lesions that have caused rupture of the dermis or mucous membranes and which can only heal by secondary intention;

c) in Class II, if they are mainly intended to control the microenvironment of the injured skin or mucous membrane; and

d) in Class II in all other cases.

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

Invasive Devices

Rule 5

All invasive medical devices applicable to body orifices, except for the surgically invasive devices, which are not intended to be connected to an active device or that are 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 up to the pharynx, in the ear canal up to the tympanum or in the nasal cavity, in which case they are classified in Class I; and

c) in Class III, if they are intended for long-term use, except if used in the oral cavity up to the pharynx, in the ear canal up to the tympanum or in the nasal cavity, and if they are not susceptible to absorption by the mucosa, in which case they are classified in Class II;

All invasive medical devices applicable to body orifices, except for the surgically invasive devices, which are intended to be connected to an active medical device of Classes II, III, or IV, are classified in Class II:

Rule 6

All surgically invasive devices intended for transitory use are classified in Class II, unless they:

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

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

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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 provide energy as ionizing radiation, in which case they are classified in Class III;

e) have a biological effect or are absorbed, completely or to a large extent, in which case they are classified in Class III; or

f) are intended for the administration of medicinal products by means of a delivery system, when carried out in a potentially dangerous manner, considering the mode of application, in which case they are classified in Class III.

Rule 7

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

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 provide energy as ionizing radiation, in which case they are classified in Class III;

d) have a biological effect or are absorbed, completely or to a large extent, in which case they are classified in Class IV;

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

f) are intended to administer medicinal products, in which case they are classified in Class III.

Rule 8

All implantable devices and the surgically invasive devices intended for long-term use are classified in Class III, unless they:

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

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

c) have a biological effect or are absorbed, completely or to a large extent, in which case they are classified in Class IV;

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

e) are intended to administer medicinal products, 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 prosthesis, in which case they are classified in Class IV, except for the 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, except for components such as screws, wedges, plates, and instruments.

Active Devices

Rule 9

All active therapeutic devices intended to supply or exchange power are classified in Class II, unless that, according to their features, they may supply energy to the human body or exchange energy with it in a potentially dangerous way, considering the nature, density and 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 active therapeutic devices of Class III, 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 the diagnosis and monitoring are classified in Class II in cases wherein:

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 radiopharmaceutical products; or

c) they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless specifically intended to monitor or observe vital physiological

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parameters and unless that the nature of these parameters variations may result in immediate danger to the patient, such as in cases of variations in heart rate, breathing and central nervous system activity, or are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified in Class III.

The active devices intended to emit ionizing radiation for diagnostic and therapeutic radiology, including the interventional radiology devices e those that control or monitor such devices, or that directly influence their performance, are classified in Class III.

Rule 11

The software intended to provide information used in decision-making for therapeutic or diagnostic purposes is classified in Class II, unless such decisions have an impact that may cause:

a) the death or irreversible deterioration of a person's 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.

The software intended to monitor physiological processes is classified in Class II, except when it is intended to monitor vital physiological parameters, when the nature of these parameters variations may result in immediate danger to the patient, in which case it is classified in Class III.

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

Rule 12

All active medical devices intended to administer medicinal products, bodily fluids or other substances into the human body, or to remove them from it, are classified in Class II, unless this is carried out in a potentially dangerous manner, considering the nature of the substances or the body part involved, and the method of application, in which case they are classified in Class III.

Rule 13

All other active medical devices, not included in the previous rules, are classified in Class I.

Special Rules

Rule 14

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

Rule 15

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

Rule 16

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

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

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

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

Rule 17

Devices Specifically to record X-ray generated diagnostic images are classified in Class II.

Rule 18

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

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

Rule 19

All devices incorporating nanomaterials or consisting of nanomaterials are classified:

a) in Class IV, if they have a high or intermediate internal exposure potential;

b) in Class III, if they have a low internal exposure potential; and

c) in Class II, if they have a negligible internal exposure potential;

Rule 20

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

Rule 21

Medical devices consisting of substances or combinations of substances intended to be introduced into the human body by means of a body orifice or applied to the skin and that

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are absorbed or disseminated by the human body or locally dispersed therein, shall be classified:

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

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

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

d) in Class II in all other cases.

Rule 22

The active therapeutic devices with an integrated or built-in diagnostic function that significantly orientates patient management, such as closed-loop systems or automatic external defibrillators, are classified in Class IV.

ATTACHMENT II

Technical Dossier Structure for 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 Anvisa's portal)	X	X	X	X
List of devices (Models/Components/Variations)	X	X	X	X
Chapter 2				
Detailed Description of the Medical Device and Operation and Action Fundamentals	X	X	X	X
Packaging Description and Device Forms of Presentation	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 of Use	X	X	X	X
Global Marketing History	-	X	X	X
Chapter 3				

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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/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 Review	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				
Clinical Evidence General Summary[2]	X	X	X	X
Relevant Clinical Literature	-	X	X	X
Chapter 5				
Product Labeling/Packaging	X	X	X	X
Instructions for Use/User's Manual	X	X	X	X
Chapter 6				
General Manufacturing Information (Manufacturing Plants Addresses)	X	X	X	X
Manufacturing Process (Flowchart)	X	X	X	X
Project and Development Information	X	X	X	X

Notes:

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

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