COLLEGIATE BOARD RESOLUTION – RDC NO. 830 OF 6 DECEMBER 2023

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Provides for risk classification, notification and marketing authorization regimens, and instructions for use of *in vitro* diagnostic medical devices, including its instruments.

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, and Article 7, items III and IV of Law no. 9,782 of 26 January 1999, and item VI, paragraph 1 of Article 187 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 6 December 2023, and I, Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Objective

Article 1. This Resolution provides for risk classification, notification and marketing authorization regimens, labeling requirements, instructions for use, and the procedures for notification, marketing authorization, alteration, revalidation, and cancellation of notification or marketing authorization of *in vitro* diagnostic medical devices, including its instruments.

Section II

Scope

Article 2. This Resolution applies to *in vitro* diagnostic medical devices defined in item XI of Article 4, subject to notification or marketing authorization according to their risk classification.

Paragraph 1. The following are exempt from notification or marketing authorization:

I – *in vitro* diagnostic medical devices intended for clinical investigation, if the legal provisions regarding such activities are complied with, and their commercialization and use for other purposes are prohibited;
II – presentations comprised of two or more notified or approved medical devices, in their intact individual packaging, and the label must contain the information of corresponding medical devices, including notification or marketing authorization numbers.

Paragraph 2. Used or reconditioned *in vitro* diagnostic medical devices (instruments) are addressed by Collegiate Board Resolution – RDC no. 579 of 25 November 2021.

Paragraph 3. Software as medical device (SaMD) with *in vitro* diagnostic application is addressed by Collegiate Board Resolution – RDC no. 657 of 24 March 2022.

Paragraph 4. This Resolution does not apply to the following:

I – reagents and reference materials specifically intended for quality assessment in proficiency testing or interlaboratory comparison;

II – inputs for the manufacture of *in vitro* diagnostic medical devices;

III – reagents or reagent sets used in in-house methodology, validated and used at the laboratory itself;

IV – materials of general laboratory use;

V – products intended for exclusive use in legal medicine or evidential purposes due to regulations or laws with no *in vitro* diagnostic purposes;

VI – products exclusively intended for doping control testing in sports, the results of which are not used for treatment or health purposes;

VII – freeze-dried culture media and supplements that depend on processing and controls carried out by the user before its utilization;

VIII – culture media and instruments intended for environmental, industrial, food, or water control analyses;

IX – products of research use only, including imported ones and products labeled as Research Use Only – RUO; and

X – products exclusively intended for use in technical assistance or maintenance procedures.

Article 3. Anvisa shall also grant notification or marketing authorization to families of *in vitro* diagnostic medical devices.

Sole paragraph. Grouping of products, with the purposes of notification or marketing authorization, shall be carried out in accordance with the rulings provided for in Normative Instruction – IN no. 3 of 26 August 2015.

Section III

Definitions

Article 4. For the purposes of this Resolution, the following definitions are applicable:

I – accessory (of an *in vitro* diagnostic medical device): product that is not an *in vitro* diagnostic medical device on its own, intended by its manufacturer to be used jointly with one or several *in vitro* diagnostic medical devices, to allow or help – in a specific and direct manner – device(s) to be used according to the intended purpose;

II – change: alteration in the information presented to Anvisa in the notification or marketing authorization process of the in vitro diagnostic medical device and in its respective secondary petitions;

III – change of required approval: change of greater health relevance, which refers to an alteration to be introduced in the marketing authorization process, and is approved in Brazilian territory only after technical documental analysis and favorable manifestation by Anvisa;

IV – change of immediate implementation: change of medium health relevance, which refers to an alteration to be introduced in the notification or marketing authorization process, and its implementation is approved in Brazilian territory after petition to Anvisa;

V – non-reportable change: any other change of minor health relevance, resulting from an alteration not classified as of required approval or immediate implementation, and that does not depend on a protocol with Anvisa to be implemented;

VI – previous analysis: laboratory analysis conducted to verify characteristics of the product with a view to evidencing its performance for the purpose of marketing authorization, alteration (when applicable), or revalidation;

VII – calibration: set of operations that establishes the correspondence between the values indicated by a measurement instrument and a reference material as accurately as possible and under specified conditions, with the purpose of adjustment or standardization of laboratory instruments and/ or procedures;

VIII – Companion Diagnostics Medical Device: *in vitro* diagnostic medical device critical for the safe and effective use of a corresponding medicinal product:

a) to identify patients most likely to benefit from the corresponding medicinal product, before and/ or during the treatment; or

b) to identify patients with increased risk of serious adverse reactions from the treatment with the corresponding medicinal product, before and/ or during the treatment.

IX – (notification or marketing authorization) holder: public or private legal person, either manufacturer or importer, responsible for the *in vitro* diagnostic medical device in the Brazilian territory, who holds the *in vitro* diagnostic medical device marketing authorization issued by Anvisa;

X – self-testing device: *in vitro* diagnostic medical device intended to be used by a lay user, exclusively based on the instructions provided by the manufacturer, without the purpose of conclusive diagnosis;

XI – *in vitro* diagnostic medical device: reagents, calibrators, standards, controls, sample collectors, software, instruments, or other products used individually or in combination, with intended use determined by the manufacturer, for *in vitro* analysis of samples from the human body, exclusively or mainly, to provide information for the purpose of diagnosis, diagnosis

assistance, monitoring, compatibility, triage, predisposition, prognosis, prediction, or determination of physiological status;

XII – technical dossier: document that describes the elements of the product, indicating characteristics, purpose, mode of use, content, special precautions, potential risks, manufacturing process, and additional information;

XIII – high-dose hook effect (or prozone phenomenon): result of an antigen-antibody reaction, in which the excess of antigen or antibody results in an incomplete reaction or blocks it;

XIV – package: wrap, recipient, or any packaging form, either removable or not, intended to cover, pack, protect, or maintain the product;

XV – primary packaging: package in direct contact with the product or its components;

XVI – clinical or diagnostic specificity: percentage of truly negative results, obtained when the trial is conducted with individuals certainly not suffering from the disease in study;

XVII – analytical specificity: capability of a measurement method to determine the intended measurement only;

XVIII – stability: capability of a product to maintain its characteristics and/ or performance unaltered during a certain period, according to the conditions established previously;

XIX – performance studies: performance assessment of an *in vitro* diagnostic medical device based on available data and laboratory or clinical investigations to determine characteristics such as sensitivity, specificity, repeatability, and reproducibility;

XX – legal manufacturer: public or private legal person responsible for the project, manufacture, packaging, and labeling of a product, with the purpose of making it available for use under its name, those operations being carried out by the company itself or by third parties on its behalf;

XXI – family: grouping of *in vitro* diagnostic medical devices of the same legal manufacturer, for the purposes of notification or marketing authorization, with similar characteristics of technology, methodology, and indication, framed in the same group established in specific regulations;

XXII – intended purpose (intended use): the use a medical device is intended to, according to the manufacturer's definition;

XXIII – importer: public or private legal person responsible for import activities so foreign medical devices may enter the Brazilian territory;

XXIV – inaccuracy: numeric difference between the average of measurements and the true value;

XXV – instructions for use: document including information provided by the manufacturer to explain the user about the intended purpose of a device, its correct use, and eventual precautions to be taken;

XXVI – instrument: equipment or device developed with the purpose of being used as an *in vitro* diagnostic medical device;

XXVII – clinical investigation: any investigation or systematic study in one or more human subjects, carried out to assess the safety, clinical performance, and/ or effectiveness of a medical device. For the purposes of this Resolution, "clinical investigation" is synonymous with "clinical trial" or "clinical research";

XXVIII – batch: quantity of an *in vitro* diagnostic medical device elaborated in a manufacturing cycle, the essential characteristic of which is homogeneity;

XXIX – reference method: method that, after extensive investigation, presented insignificant inaccuracy and imprecision. The term "reference method' is often used in general to determine a method to which another method in test is compared;

XXX – technical standard: document established by consensus and approved by a recognized organization, which provides for rules, guidelines, or characteristics of activities or their results, for common and repetitive use, with a view to obtaining an optimum level of order in a particular scenario;

XXXI – notification: communication to Anvisa about the intention to commercialize an *in vitro* diagnostic medical device, intended to prove the right to manufacture, import, and commercialize a medical device exempted from marketing authorization, in accordance with Paragraph 1 of Article 25 of Law no. 6,360 of 23 September 1976, and classified as risk class I or II, including the name, manufacturer, purpose, and other elements characterizing such medical device;

XXXII – batch number: any combination of numbers and/ or letters through which it is possible to trace the full manufacturing history of a particular batch of product;

XXXIII – process reassessment: procedure carried out by Anvisa technical area in notifications and marketing authorizations of *in vitro* diagnostic medical devices for the purposes of auditing processes;

XXXIV – marketing authorization: Anvisa exclusive act intended to prove the right to manufacture, import, and commercialize a product subject to the provisions of Law no. 6,360 of 23 September 1976, and classified as risk class III or IV, including the name, manufacturer, purpose, and other elements characterizing such product;

XXXV – repeatability (intra-study reproducibility): degree of consistency among the results from successive measurements of the same substance, carried out under the same conditions, and such measurements may be expressed quantitatively due to the characteristics of dispersion of results;

XXXVI – medical device document repository: digital tool for the storage and availability of documents relating to medical devices notified and granted marketing authorization, available on Anvisa website;

XXXVII – (inter-study) reproducibility: degree of consistency among the results from measurements of the same substance, carried out under varied measurement conditions, and such measurements may be expressed quantitatively due to the characteristics of dispersion of results;

XXXVIII – legally responsible officer: natural person designated in a statute, social contract, or minutes, who is responsible for representing, both active and passively, the petitioning legal person (either manufacturer or importer) in judicial and extrajudicial acts;

XXXIX – technically responsible officer: legally qualified professional of higher education capacitated in the technologies composing the product, responsible for the technical information presented by the petitioner (either manufacturer or importer) and the quality, safety, and performance of the product commercialized;

XL – label: written, printed, or graphic information included in the product itself, the package of each unit, or the package of several devices;

XLI – clinical or diagnostic sensitivity: percentage of truly positive results obtained from a trial conducted in samples from individuals with the disease being studied;

XLII – analytical sensitivity: capability of a method to obtain positive results compared to the positive results obtained from the reference method. The lowest quantity, different from zero, that the method is capable of measuring;

XLIII – Software as a Medical Device (SaMD): product or application intended for one or more purposes indicated in the definition of *in vitro* diagnostic medical device, which performs its functions without being part of the hardware of an *in vitro* diagnostic medical device, with the following characteristics:

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

b) “computer platform” includes hardware and software resources (operational system, processing hardware, storage, database, visualization devices, entry devices, programming language, etc.);

c) “without being part of” means that the program does not need the hardware of a medical device to reach its intended use;

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

e) SaMD may be used in combination (for example, as a module) with other products, including other medical devices;

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

g) mobile apps that comply with the definition are considered SaMD.

XLIV – petitioner: public or private legal person who forwards petitions for notification or marketing authorization of medical devices to the competent health authority;

XLV – manufacturing unit: location where one or more manufacturing stages occur, and it may be the legal manufacturer itself, a subcontracted manufacturer, or original manufacturer of a product;

XLVI – user: health professional or lay person, maybe the patient him/herself, who uses an *in vitro* diagnostic medical device, following the instructions of use;

XLVII – lay user: individual without formal technical or scientific training in the use of an *in vitro* diagnostic medical device; and

XLVIII – reference value: category of values for a particular analyte obtained in a population selected according to ethnical, epidemiological, demographic, and statistic criteria.

CHAPTER II

RISK CLASSIFICATION OF *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

Section I

Classification and Control Regimens

Article 5. The *in vitro* diagnostic medical devices, object of this Resolution are classified in accordance with the intrinsic risk they represent to user, patient, or public health, as Classes I, II, III, or IV:

I – Class I: low risk to the individual and low risk to public health;

II – Class II: medium risk to the individual and/ or low risk to public health;

III – Class III: high risk to the individual and/ or medium risk to public health; and

IV – Class IV: high risk to the individual and/ or high risk to public health.

Paragraph 1. The *in vitro* diagnostic medical device shall be classified into one of these classes in accordance with the rules established in this Resolution.

Paragraph 2. In case of doubt related to the classification resulting from the application of the rules established in this Resolution, Anvisa competent organization unit shall be responsible for the classification of the *in vitro* diagnostic medical device.

Paragraph 3. The classification rules established in this Resolution may be updated considering technological progress, epidemiological scenario, and post-market information obtained from the use or application of *in vitro* diagnostic medical devices.

Article 6. The *in vitro* diagnostic medical devices classified into Risk Classes I and II are subject to notification.

Article 7. the *in vitro* diagnostic medical devices classified into Risk Classes III and IV are subject to marketing authorization.

Section II

Classification Rules

Article 8. The *in vitro* diagnostic medical devices are classified according to risk level, in accordance with the rules established in Annex I of this Resolution.

Section III

Application of the Classification Rules

Article 9. The application of the classification rules is defined by the intended purpose of *in vitro* diagnostic medical devices.

Paragraph 1. If the device is intended to be used in combination with another device, the classification rules are applicable separately to each one of them.

Paragraph 2. The petitioner must consider all rules to establish the correct classification of the product.

Paragraph 3. If the manufacturer states that a device has multiple intended purposes, which makes it fit more than one class, the device shall be classified into the highest risk class.

Paragraph 4. In case several classification rules apply to the same device, the rule leading to the highest risk class shall be applied.

Article 10. The products with the following purposes are not classifiable as self-tests and therefore may not be supplied to lay users:

I – testing samples to verify the presence of or exposure to pathogenic organisms or communicable agents, including agents that cause infectious diseases subject to compulsory notification;

II – defining blood type;

III – conducting genetic tests to determine the presence of or predict susceptibility to disease or physiological condition;

IV – helping diagnosis or indicating the presence of disease, heart or tumor markers, or conditions with serious health implications; and

V – indicating the presence of drugs or their metabolites.

Paragraph 1. The prohibition to supply products to lay users referred to in the caption of this article may be nulled by a Collegiate Board Resolution, due to a demand received from the Ministry of Health.

Paragraph 2. The prohibition referred to in the caption of this article does not apply to devices intended to detect the presence of or exposure to an agent causing genital infection, as long as it is not classified as disease subject to compulsory notification.

CHAPTER III

PETITION FOR NOTIFICATION OR MARKETING AUTHORIZATION AND ITS MAINTENANCE

Section I

In vitro Diagnostic Medical Device Notification or Marketing Authorization Procedures

Article 11. The petitioner must present to Anvisa the documentation for notification, marketing authorization, alteration, revalidation, or cancellation of notification or marketing authorization of the *in vitro* diagnostic medical device, as defined in this Resolution.

Paragraph 1. Anvisa shall analyze the documentation presented for the marketing authorization, alteration or revalidation of marketing authorization and manifest its decision officially.

Paragraph 2. Documentation analysis shall be carried out in legal periods and conditions provided for in the Brazilian health legislation.

Paragraph 3. Anvisa may require additional documents and information due to technical reasons to confirm the safety and performance of the product, on account of potential risk to public health.

Paragraph 4. The petition lacking documents, forms, and declarations provided for in the list of process procedures, either obsolete, filled up incompletely, with unreadable information, or lacking information, without conformity certification when applicable, or without clinical evidence for products of innovative technology or indication, shall not be subject to technical requirements, and the petition shall be immediately rejected.

Paragraph 5. There shall be no technical analysis of petitions for notification and alteration of notification, so the products are considered regularized, without prejudice to the conduction, at any time, of documental or fiscal assessments of notification processes and their alterations, and, if necessary, requirement for additional information or clarification.

Paragraph 6. The processing of *in vitro* diagnostic medical device notification shall be carried out in up to 30 (thirty) days after protocol by the petitioner.

Paragraph 7. Maintenance of notification and marketing authorization is subject to compliance with the Good Manufacturing Practices requirements, critical safety and performance requirements, and specific regulations, when applicable.

Paragraph 8. When required, the petitioner must present a report of previous analysis considered satisfactory, carried out by a unit pertaining to the Brazilian Public Health Laboratories Network, as provided for in item IV, article 16 of Law no. 6,360 of 23 September 1976.

Article 12. The marketing authorization for *in vitro* diagnostic medical devices shall by valid for 10 (ten) years, counting from the day it is published in the Federal Official Gazette, and it may be revalidated successively for equal periods.

Section II

Notification of *In Vitro* Diagnostic Medical Devices

Article 13. With a view to petitioning the notification of *in vitro* diagnostic medical devices, the petitioner must pay the corresponding fee and present the following documentation to Anvisa:

I – *in vitro* diagnostic medical device notification form duly filled up, available on Anvisa website;

II – images of the product, its parts, and accessories;

III – images of the set of primary and secondary labels expected to be applied to the products, in accordance with the requirements set forth in articles 46 and 49 of this Resolution;

IV – instructions of use, in accordance with the requirements set forth in articles 46 and 50 of this Resolution;

V – for the products in risk class II, technical dossier including the information required from that risk class;

VI – indication of the family corresponding to the grouping of products, in accordance with the alternatives described in Normative Instruction – IN no. 3 of 26 August 2015, when applicable;

VII – for imported *in vitro* diagnostic medical devices, a certified declaration, or declaration authenticated by a consulate, issued by the legal manufacturer, written in Portuguese, English, or Spanish, accompanied of a certified translation, issued two years prior at the most when there is no expiration date expressly indicated on the document, authorizing the petitioning company to represent and commercialize its product(s) in Brazil; and

VIII – proof of compliance with the legal provisions determined in technical regulations, in the form of legislation regulating specific *in vitro* diagnostic medical devices.

Sole paragraph. The declaration referred to in item VII of this article must include the corporate name and full address of the legal manufacturer and the petitioning company, the express

authorization for the petitioning company to represent and commercialize its products in Brazil, and a statement declaring knowledge of and compliance with the requirements established by the Good Manufacturing Practices for Health Products set forth in Collegiate Board Resolution – RDC no. 665 of 30 March 2022, or a regulation superseding it.

Section III

Marketing Authorization for *In Vitro* Diagnostic Medical Devices

Article 14. To petition for the marketing authorization for an *in vitro* diagnostic medical device, the petitioner must pay the corresponding fee and present the following documentation to Anvisa:

I – *in vitro* diagnostic medical device marketing authorization form duly filled up, available on Anvisa website;

II – images of the set of primary and secondary labels expected to be applied to the products, in accordance with the requirements set forth in articles 46 and 49 of this Resolution;

III – instructions of use, in accordance with the requirements set forth in articles 46 and 50 of this Resolution;

IV – technical dossier in accordance with the provisions in Chapter VII of this Resolution;

V – indication of the family corresponding to the grouping of products, in accordance with the alternatives described in Normative Instruction – IN no. 3 of 26 August 2015, when applicable;

VI – for imported *in vitro* diagnostic medical devices, a certified declaration, or declaration authenticated by a consulate, issued by the legal manufacturer, written in Portuguese, English, or Spanish, accompanied of a certified translation, issued two years prior at the most when there is no expiration date expressly indicated on the document, authorizing the petitioning company to represent and commercialize its product(s) in Brazil;

VII – proof of compliance with the legal provisions determined in technical regulations applied to specific *in vitro* diagnostic medical devices; and

VIII – Good Manufacturing Practices Certificate issued by Anvisa or proof of protocol to petition a Good Manufacturing Practices Certificate.

Paragraph 1. The protocol to petition a Good Manufacturing Practices Certificate shall be accepted for the purpose of petitioning, as well as of starting the analysis of marketing authorization petition documents.

Paragraph 2. The approval of marketing authorization petitions is conditional 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 *in vitro* diagnostic medical devices.

Paragraph 3. The declaration referred to in item VI of this article must include the corporate name and full address of the legal manufacturer and the petitioning company, the express authorization for the petitioning company to represent and commercialize its products in Brazil, and a statement declaring knowledge of and compliance with the requirements established by the Good Manufacturing Practices for Health Products set forth in Collegiate Board Resolution – RDC no. 665 of 30 March 2022, or a regulation superseding it.

Section IV

Alteration in Notification of or Marketing Authorization for *In Vitro* Diagnostic Medical Devices

Article 15. To petition for the alteration in notification of or marketing authorization for an *in vitro* diagnostic medical device, the petitioner must pay the corresponding fee, if applicable, and present a declaration listing the alterations requested and other required documentation, according to the subject at issue.

Article 16. The alteration of information presented in the process of notification of or marketing authorization for medical devices are classified as follows:

I – alteration of required approval;

II – alteration of immediate implementation; and

III – non-reportable alteration.

Paragraph 1. The petition for 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, which provides for the applicable petition subjects.

Paragraph 2. Alterations considered as non-reportable are any alterations of lower relevance not classified as of required approval or immediate implementation, in addition to alterations in information that do not change the medical device project; software bug corrections; non-technical alterations such as images, format, layout, symbols, and adequation of document texts without the addition of risk; updates of information on Company Operation Authorization; contact (for example, telephones or postal addresses), technical assistance, and website alterations.

Paragraph 3. The alterations referred to in Paragraph 2 of this article must be controlled by the regularization holder quality system and included in posterior petitions.

Paragraph 4. The alteration petition for *in vitro* diagnostic medical devices of risk classes I and II shall be carried out in the immediate implementation regimen, except when it is a non-reportable alteration.

Article 17. The subjects of petitions for alteration in notification of or marketing authorization for *in vitro* diagnostic medical devices are provided for in Normative Instruction – IN no. 74 of 16

September 2020, which identifies the alterations considered as of required approval or immediate implementation.

Article 18. The petition to alter information must be accompanied by documentation confirming the alteration to be implemented, in compliance with the health legislation in force.

Article 19. The alteration of immediate implementation that has an interdependence with an alteration of required approval must be petitioned together with the latter, its contents being incorporated into the process.

Article 20. Alterations resulting from a field action notified to Anvisa with the purpose of ensuring the safety and performance of the device regarding users and patients shall have their analyses prioritized.

Sole paragraph. To request the analysis prioritization referred to in the caption of this article, the company must protocol the request, presenting evidence that the field action notification was sent to Anvisa.

Article 21. The alteration of required approval shall only be effective after the final decision is published in the Federal Official Gazette and, when applicable, the updated data are published on Anvisa website.

Article 22. Alterations of immediate implementation shall be published in the Federal Official Gazette and, when applicable, the updated data shall be published on Anvisa website.

Article 23. The petition for immediate implementation may be object of documental or fiscal assessment at any time by Anvisa and, if necessary, additional information or clarification shall be requested.

Article 24. The approval of petitions for alteration in/ inclusion of manufacturing unit, or for alteration in the manufacturing unit address or inclusion of products in a family classified as risk classes III and IV, is conditional to the publication of the Good Manufacturing Practices Certificate issued by Anvisa and compliance with the other requirements corresponding to each type of petition.

Sole paragraph. The request protocol for the Good Manufacturing Practices Certification shall be accepted as petition and the start of petition analysis.

Article 25. In case there is a need for ending the stock of finished products due to an alteration, simultaneous import and commercialization of the versions involved is allowed until the product expiration shelf-life date.

Sole paragraph. Alterations made to solve product safety and performance issues are not included in the permission referred to in the caption of this article.

Article 26. Ending of stock of packages, labels, and instructions of use is allowed for 120 (one hundred and twenty) days counting from the date the alteration was published.

Sole paragraph. Alterations made to solve product safety and performance issues are not included in the permission referred to in the caption of this article.

Section V

Revalidation of Marketing Authorization for *In Vitro* Diagnostic Medical Devices

Article 27. To petition for the revalidation of marketing authorization for an *in vitro* diagnostic medical device, the petitioner must pay the corresponding fee and present the following documents:

I – for imported *in vitro* diagnostic medical devices, a certified declaration, or declaration authenticated by a consulate, issued by the legal manufacturer, written in Portuguese, English, or Spanish, accompanied of a certified translation, issued two years prior at the most when there is no expiration date expressly indicated on the document, authorizing the petitioning company to represent and commercialize its product(s) in Brazil; and

II – valid Good Manufacturing Practices Certificate issued by Anvisa.

Paragraph 1. The declaration referred to in item I of this article must include the corporate name and full address of the legal manufacturer and the petitioning company, the express authorization for the petitioning company to represent and commercialize its products in Brazil, and a statement declaring knowledge of and compliance with the requirements established by the Good Manufacturing Practices for Health Products set forth in Collegiate Board Resolution – RDC no. 665 of 30 March 2022, or a regulation superseding it.

Paragraph 2. The petition for revalidation must be presented within the period provided for in Collegiate Board Resolution – RDC no. 250 of 20 October 2004, or a regulation superseding it.

Paragraph 3. The request protocol for the Good Manufacturing Practices Certification shall be accepted as petition and marketing authorization revalidation petition analysis.

Article 28. Products submitted to notification regimen are exempt from revalidation.

Section VI

Cancellation of Notification of or Marketing Authorization for *In Vitro* Diagnostic Medical Devices

Article 29. The holder of a notification of or marketing authorization for an *in vitro* diagnostic medical device that intends to no longer commercialize it in the Brazilian market must petition for its cancellation.

Section VII

Conformity of Information

Article 30. The alterations made by the manufacturer in the *in vitro* diagnostic medical device information included in the notification or marketing authorization must be communicated by the holder to Anvisa, in accordance with the requirements provided for in Section IV of Chapter III of this Resolution.

Article 31. The alterations relating to an *in vitro* diagnostic medical device that require previous approval by Anvisa may only be divulged to the consumer market after such alterations are published in the Federal Official Gazette and Anvisa website.

Article 32. All communication or publicity related to *in vitro* diagnostic medical devices disseminated in the consumer market must be strictly correspondent to the information presented to Anvisa by the notification or marketing authorization holder.

Section VIII

Medical Devices Documental Repository

Article 33. Use instructions upload to the Medical Devices Documental Repository corresponds to insertion and update of such documents related to *in vitro* diagnostic medical device notification or marketing authorization processes.

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

Paragraph 2. Upload of use instructions must occur through the applicable petitioning subjects, identified as “Provision of Use Instructions on Anvisa Website”.

Paragraph 3. The notification or marketing authorization holder is responsible for the use instructions upload, which must be controlled by the holder for eventual audits.

Paragraph 4. Upload of use instructions is compulsory and must be made by the company responsible for the notification of or marketing authorization for the product, which attests that its contents correspond to the legislation in force and are consistent with the regularized product.

Paragraph 5. For new products, either notified or granted marketing authorization, and for alterations in products previously notified or granted marketing authorization, the upload 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 products previously notified or granted marketing authorization, the upload of use instructions must be carried out in up to 180 (one hundred and eighty) days after implementation of the alteration leading to changes in use instructions.

Article 34. The provision of use instructions shall be carried out exclusively on Anvisa website, at the moment the respective petition protocol is finalized, regardless of documentation analysis by the Agency.

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

Paragraph 2. In case of a new upload of use instructions to a notification or marketing authorization process, only recently uploaded use instructions shall be kept publicly accessible.

Paragraph 3. Use instructions uploaded over time shall be kept in a database for the purposes of control and audit by Anvisa.

Article 35. Uploaded use instructions or their absence in the terms of this Resolution may be object of documental or fiscal assessment at any time by Anvisa and, if necessary, the Agency may:

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

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

Article 36. Companies that insert information not in compliance with the legislation in force and not corresponding to the regularized product are subject to the penalties provided for in Law no. 6,437 of 1977.

Section IX

Process Reassessment Procedure

Article 37. *In vitro* diagnostic medical device notification or marketing authorization processes are subject to procedural reassessment, audit, market monitoring, and inspection by the competent health authority.

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

Paragraph 1. Adequacies must be met by the notification or marketing authorization holder in up to 30 (thirty) days counting from the date their receipt is confirmed.

Paragraph 2. Situations requiring the correction of previously provided information must be solved through a specific petition.

Paragraph 3. The lack of response to the adequacy notification referred to in the caption of this article in up to 30 (thirty) days, counting from the date it was issued, shall lead to cancellation of notification, marketing authorization, or alteration.

CHAPTER IV

ADMINISTRATIVE SANCTIONS

Article 39. Anvisa may suspend the manufacture, import, distribution, commercialization, and use of the medical device in case of health risk originating from product irregularities, irregularities in its manufacturing process, lack of compulsory conformity certification, or conditions different from the ones approved by Anvisa.

Article 40. Anvisa may apply the penalties provided for in Law no. 6,437 of 20 August 1977, in cases where the companies or the medical devices do not comply with the legislation in force and the regularization process.

Article 41. Anvisa may cancel the *in vitro* diagnostic medical device notification or marketing authorization in the following cases:

I – there is evidence of false information provided in any of the documents required in this Resolution, or if any of such documents is cancelled by the competent health authority;

II – there is evidence that the product or manufacturing process may pose health risk to users, patients, operators, or third parties involved;

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

IV – there is evidence of health classification error in notification processes; or

V – where the procedural reassessment requirements presented by Anvisa are not met.

Article 42. Anvisa may determine the cancellation of alterations leading to incorrect information or irregularities in *in vitro* diagnostic medical devices.

Article 43. Anvisa may, at its discretion and at any time, request information or clarification before deciding upon the cancellation of the irregular notification or marketing authorization of an *in vitro* diagnostic medical device.

Article 44. The cancellation of notification or marketing authorization of *in vitro* diagnostic medical devices shall be published in the Federal Official Gazette.

CHAPTER V

FORMS OF INFORMATION ON THE PETITIONER AND ITS *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

Article 45. The applicable forms of information on the petitioner and the product related to notification or marketing authorization process must be filled out electronically on Anvisa website.

CHAPTER VI

LABELS AND USE INSTRUCTIONS OF *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

Section I

Information Requirements for Labels and Instructions of Use

Article 46. The information on labels and use instructions of *in vitro* diagnostic medical devices must meet the following general requirements:

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

II – all *in vitro* diagnostic medical devices must include instructions of use in their packages or refer to the way to access such documentation;

III – labels and instructions of use must be able to identify the product and its legal manufacturer, as well as to point out information related to safety and performance of the product to users, whether professionals or lay people;

IV – the inclusion of information on national companies on the labels, aside from the legal manufacturer and/ or the notification or marketing authorization holder, is prohibited;

V – the language used in labels and instructions of use must be compatible with the technical knowledge, experience, education, or training of intended user(s);

VI – the use of international symbols standardized for health product labels and use instructions is allowed, in accordance with standard ABNT NBR ISO 15223 – "Health products – Symbols to be used in labels, packaging, and information to be provided for health products";

VII – the symbols used in products intended for lay people must be accompanied by a key;

VIII – the use of other symbols not provided for in standard ABNT NBR ISO 15223 is allowed in products of professional use, as long as there are accompanied by a key;

IX – the use of graphs and diagrams in instructions of use is allowed, as long as they facilitate users' understanding; and

X – the use of instructions of use in non-printed formats must meet the requirements provided for in Section II of Chapter VI of this Resolution.

Article 47. Secondary (external) labeling of *in vitro* diagnostic medical devices must include the following information:

I – the product commercial name;

II – the details necessary for the user to identify the product and its use;

III – corporate name and address of the legal manufacturer, preceded by the term "manufacturer" or equivalent symbol;

IV – corporate name, address, and CNPJ of the notification or marketing authorization holder, preceded by the expression "regularized by";

V – name of the technical responsible officer, with the acronym and registration number of the professional council;

VI – number of notification or marketing authorization granted by Anvisa, preceded by the acronym "Anvisa";

VII – indication that the product is intended to be used as "*in vitro* diagnosis use" or "IVD";

VIII – when the product is intended for lay people, the expressions "Read carefully the use instructions before performing the test" and "Self-testing for (specify parameter or condition intended by the test), without diagnostic purposes";

IX – batch number, batch code, or serial number, preceded by the term identifying it, or by an equivalent symbol;

X – unequivocal indication of the product expiration date, except for instruments;

XI – indication of storage conditions; specific transportation and/ or handling conditions may also be mentioned;

XII – if the product is sterile, indication of its status and sterilization method;

XIII – warnings or precautions to be taken by the product user;

XIV – if the product is of single use and there is potential for inadvertent reuse, indication of such fact; and

XV – list of components comprising the product set, informing the respective quantities/ volumes.

Article 48. The primary labeling of *in vitro* diagnostic medical devices, except for instruments, must include the following information:

I – name of product and indication of component;

II – batch number or code preceded by the term identifying it, or by an equivalent symbol;

III – unequivocal indication of shelf life; and

IV – indication of adequate storage conditions for the product.

Article 49. The primary labeling of instruments must be indelible and include the following information:

I – commercial name of the product and commercial model;

II – serial number preceded by the term identifying it or by an equivalent symbol;

III – identification of the legal manufacturer; and

IV – number of notification or marketing authorization granted by Anvisa, preceded by the acronym “Anvisa”.

Article 50. The use instructions of *in vitro* diagnostic medical devices must include the following information:

I – the product commercial name;

II – corporate name and address of the legal manufacturer;

III – telephone number or website where it is possible to obtain technical assistance (Customer Service);

IV – product purpose and mode of use, including indication that it is intended for “*in vitro* diagnosis use” or “IVD”;

V – intended user, where applicable;

VI – indications of applicable storage or handling conditions;

VII – operational principle or the test or instrument;

VIII – types of samples or matrices to be used, where applicable;

IX – conditions for sample collection, handling, preparation, and conservation;

X - description of the product, including accessories and any limitations to their use, such as use of dedicated instruments and, if applicable, software version;

XI – use stability of the product, except for instruments, including storage conditions after opening primary packaging, as well as storage conditions and stability of work solutions, where relevant;

XII – details of any treatment or handling of the products before they are ready to be used, such as installation, reconstitution, calibration, among others;

XIII – where applicable, recommendations of quality control procedures;

XIV – assay procedures, including calculations and interpretation of results;

XV – information on interfering substances or limitations that may affect assay performance;

XVI – applicable performance characteristics;

XVII – residual risks identified;

XVIII – reference intervals, where applicable;

XIX – requirements for special installations or special training or specific qualifications of product user, where applicable;

XX – if the product is sterile, instructions on how to proceed if the package is damaged before use;

XXI – information on other products, materials, or instruments necessary to carry out the assay or reaction;

XXII – warnings or precautions to be taken regarding disposal of the product, its accessories, and consumables used, including biological, environmental, and physical risks;

XXIII – for products intended to be used by lay people, the circumstances in which a health professional must be seen;

XXIV – indication of use instructions version control; and

XXV – indication of terms and conditions for the product quality guarantee.

Section II

Instructions of Use in Non-Printed Format

Article 51. The instructions of use in non-printed format may be provided in physical media or made available on the internet, or in another format in compliance with all requirements in this Resolution.

Article 52. The following are requirements to make use instructions available in non-printed format:

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

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

III – guarantee the availability of use instructions during the whole period the product is in the market; and

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

Paragraph 1. When the dimensions of the external label are not sufficiently large, the information required in this article may be included in a document attached to the product.

Paragraph 2. The manufacturer or holder of notification or marketing authorization of instruments must consider the period referred to in item III of this article as the shelf life specified for the product, counting from the latest commercialized unit of the product.

Article 53. The instructions of use provided in non-printed format must include the following:

I – all information required in this Chapter and, where applicable, in regulations relating to specific *in vitro* diagnostic medical devices;

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

III – warning for users to observe the correlation of the use instructions version indicated with the product supplied, as made available by the manufacturer; and

IV – how to obtain the printed format of use instructions at no additional cost (including shipping).

Article 54. To provide use instructions online, in addition to the rules established in articles 52 and 53 of this Resolution, the following requirements must also be complied with:

I – provide, with the product, a clear guidance on how to find the corresponding and updated use instructions on the website available;

II – ensure the website basic security requirements;

III – make the use instructions file available on the website in non-editable readable format;

IV – grant free access to the tool needed to read the use instructions on the website; and

V – ensure that the file available and printed through this path is identical to the one provided by the manufacturer or holder of notification or marketing authorization, when requested, in printed format.

Article 55. The provision of use instructions in exclusively non-printed format is prohibited for the following *in vitro* diagnostic medical devices:

I – instruments intended for general household use, including the ones used in house care services;

II – instruments intended to be operated by lay people, regardless of use location;

III – self-testing products; and

IV – Point of Care Testing (PoCT) products, that is, devices of professional use designed to be operated outside the clinical laboratory physical environment, usually near or beside the patient.

CHAPTER VIII

TECHNICAL DOSSIER

Article 56. The legal and technical responsible officers of the petitioning company are responsible for the information and documentation provided.

Article 57. The holder of the notification of an *in vitro* diagnostic medical device is responsible for keeping the technical dossier updated, including all documents and information provided for in this Resolution, for the purpose of inspection by the Brazilian Health Surveillance System.

Paragraph 1. The Technical Dossier of products of risk class I should not be sent to Anvisa as part of the notification petition for the risk class I product, however, the notification holder must keep the established information and documentation for the purpose of health control.

Paragraph 2. The Technical Dossier may be available in a physical file or a single electronic file, including all information described in this chapter, or it may be composed of references to documents and information comprising other files or records of the company Quality System, which must be available for inspection by the Brazilian Health Surveillance System.

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

Article 58. The Technical Dossier must include the following information, which must be presented as described in Annex II of this Resolution:

I – product description, including the data listed below:

a) indication of use or intended use:

1. analyte or measurand;

2. purpose (triage, monitoring, diagnosis, or aid to diagnosis);

3. specific situation, condition, or risk factors of interest intended to be detected, defined, or differentiated;

4. intended user (professionals or lay people);

5. use environment or location;

6. if it is of single or multiple use;

7. if it is automated, semi-automated, or non-automated;

8. if it is qualitative, quantitative, or semi-quantitative;

9. type(s) of sample(s) needed; and

10. when applicable, target population of the test.

b) detailed description of the testing method principle or instrument operation principles;

c) risk class and classification rule of the product;

d) description of the items comprising the product and their compositions;

e) description of commercial presentation and packaging (both primary and secondary);

f) for automated tests, description of the characteristics of the instrument necessary or dedicated instrument;

g) when applicable, indication of the software to be used with the *in vitro* diagnostic medical device;

h) when applicable, description or full list of configurations/ variations of the *in vitro* diagnostic medical device that will be available;

i) when applicable, description of accessories, other *in vitro* diagnostic medical devices, and any other products that must be used in combination with the target product; and

j) indication of the country(ies) where the product(s) is (are) authorized or approved for commercialization.

II – images of the products (photos of the product and the set of its parts);

III – risk management report of the product (identification, analysis, risk reduction measures, and acceptance criteria);

IV – when applicable, list of technical regulations adopted;

V – Conformity Certificate for the instruments of compulsory certification, listed by Anvisa in specific regulations;

VI – performance studies, including the following, when applicable:

a) biological samples:

1. characterization and validation of clinical samples used; and

2. storage conditions and stability of the samples;

b) determination of the metrological traceability of calibration and control values;

c) measurement accuracy;

d) measurement precision, including:

1. repeatability; and

2. reproducibility;

e) analytical sensitivity or detection limit;

f) analytical specificity;

g) high-dose hook effect;

h) measurement range (limits) or linearity;

i) definition of cut-off value;

j) testing procedure validation report;

k) cleaning and disinfection procedure validation report for instruments requiring direct contact with the patient or lay user; and

l) usability report for products intended for lay users.

VII – stability of the product (except instruments), including the following:

a) shelf life established from real time studies, or accelerated studies with data from the ongoing real study, with at least 3 (three) batches (protocol, acceptance criteria, results, conclusions, and recommended storage conditions);

b) stability during use – after opened or installed in an instrument (protocol, acceptance criteria, results, and conclusions); and

c) stability during transportation or shipment (protocol, acceptance criteria, conclusions, and recommended transportation conditions), when transportation or shipment are carried out in conditions different from storage conditions.

VIII – clinical performance, when applicable, including the following:

a) general summary of clinical evidence, including clinical sensitivity and clinical specificity;

b) expected values or reference values; and

c) clinical evidence assessment report (protocol, acceptance criteria, results, conclusions).

IX – labeling and instructions of use, including the following:

a) images of the set of primary and secondary labels intended to be applied to the products, in accordance with the requirements in articles 46 to 49 of this Resolution;

b) use instructions of the product, in accordance with the requirements in articles 46 and 50 of this Resolution; and

c) for instruments, operator manual.

X – name and addresses of manufacturing units, identifying the respective manufacturing stages, including subcontracted companies; and

XI - description of the manufacturing process, including in-process control stages, finished product tests, and production flowchart.

Article 59. The Technical Dossier information must be organized in accordance with the health risk class of the product, as provided for in Annex II of this Resolution.

CHAPTER VIII

FINAL AND TRANSITIONAL PROVISIONS

Article 60. The same classifications of health infractions and their related sanctions in force applied to the regimen of marketing authorization of *in vitro* diagnostic medical devices are applicable to the notification regimen.

Article 61. Notifications and marketing authorizations for *in vitro* diagnostic medical devices, their alterations, and other acts shall be published in the Federal Official Gazette and shall remain available for consultation on Anvisa website.

Paragraph 1. Devices subject to notification and marketing authorization may only be manufactured or imported for delivery to consumption and sale exposure after the notification or marketing authorization number is published.

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

Paragraph 3. The import of *in vitro* diagnostic medical devices, including its accessories, the manufacturing dates of which precede the dates of publication of notification or marketing

authorization is permitted, as long as the time gap do not exceed 5 (five) years, and as long as such products fully comply with the approval conditions established by Anvisa.

Paragraph 4. For the import of *in vitro* diagnostic medical devices in the terms of Paragraph 3, the import processes must include a statement by the holder of notification or marketing authorization, attesting compliance with both requirements.

Paragraph 5. The *in vitro* diagnostic medical device to be imported in the terms of Paragraph 3 must be within its validity period, as applicable, according to the legislation in force.

Article 62. The medical devices subject to conformity certification in the scope of the Brazilian Conformity Assessment System (SBAC, in Portuguese) may only be manufactured during the validity of the Conformity Certificate.

Sole paragraph. Import, distribution, and commercialization of the stock manufactured during the certification validity is permitted up to the end of the validity period or shelf life of the product, as long as certification cancellation or termination has not been due to issues of safety and performance of the medical device.

Article 63. The forms of petition, instructions of use, or user/ operator manuals and labeling models must be presented in Portuguese.

Sole paragraph. The other documents comprising petitions of *in vitro* diagnostic medical devices may be presented in Portuguese, Spanish, or English, in accordance with the rules defined in Collegiate Board Resolution – RDC no. 25 of 16 June 2011.

Article 64. At the first petition for validation of devices granted marketing authorization before 26 October 2015, a full and updated technical dossier must be presented.

Article 65. The period of 365 days is established, counting from the date this Resolution enters into force, for the holders of notifications of *in vitro* diagnostic medical devices to petition for health reclassification of products that had their regimen altered from notification to marketing authorization due to classification rules.

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

Paragraph 2. The Good Manufacturing Practices Certification request protocol shall be accepted for the purpose of petitioning and as the start of analysis in health reclassification petitions.

Paragraph 3. The approval of health reclassification requests is conditional to the publication of a valid Good Manufacturing Practices Certificate issued by Anvisa and to compliance with the other requirements for the marketing authorization of *in vitro* diagnostic medical devices.

Paragraph 4. Non-compliance with the provisions in the caption of this article shall give rise to the cancellation of product notification.

Article 66. The marketing authorization processes of products that had their regularization regimen altered to notification due to classification rules shall be treated through a rectification petition to Anvisa.

Article 67. Control devices without attributed quantitative or qualitative values are henceforth classified as *in vitro* diagnostic medical devices and must be duly regularized in up to 365 days counting from the date this Resolution enters into force.

Article 68. Products for the extraction of deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), auxiliaries to *in vitro* diagnosis procedures, must be duly regularized in up to 365 days counting from the date this Resolution enters into force.

Article 69. From the date this Resolution enters into force, the following regulations are revoked:

I – 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;

II – Collegiate Board Resolution – RDC no. 211 of 22 January 2018, published in the Federal Official Gazette no. 16 of 23 January 2018, Section 1, Page 20;

III – 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;

IV – 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;

V – Collegiate Board Resolution – RDC no. 403 of 21 July 2020, published in the Federal Official Gazette no. 144 of 29 July 2020, Section 1, Page 56;

VI – Collegiate Board Resolution – RDC no. 431 of 13 October 2020, published in the Federal Official Gazette no. 197 of 14 October 2020, Section 1, Page 124;

VII – Collegiate Board Resolution – RDC no. 27 of 2 May 2008, published in the Federal Official Gazette no. 84 of 5 May 2008, Section 1, Page 20;

VIII – Normative Instruction – IN no. 30 of 19 March 2019, published in the Federal Official Gazette no. 54 of 20 March 2019, Section 1, Page 66;

IX – Normative Instruction – IN no. 4 of 15 June 2012, published in the Federal Official Gazette no. 117 of 19 June 2012, Section 1, Page 48; and

X – Article 11 of Normative Instruction – IN no. 3 of 26 August 2015, published in the Federal Official Gazette no. 164 of 27 August 2015, Section 1, Page 49.

Article 70. Normative Instruction no. 3 of 26 August 2015 is henceforth valid with the following writings:

"(…)

Article 1. This Normative Instruction regulates the grouping of *in vitro* diagnostic medical devices in families, for the purposes of notification or marketing authorization. (New writing)

(…)

Article 12. The following products may also be grouped in families:

(…)

X – interdependent instruments for *in vitro* diagnosis grouped in a system and designed to be used in association, in which only one part of the system operates independently, and the other parts depend on such instrument to operate.

XI – flasks or materials for collection, storage, or transportation of biological samples.

Article 13. The transformation of a process from single device to family is not permitted after Anvisa grants the notification or marketing authorization. (New writing)"

Article 71. This Resolution enters into force on 1 June 2024.

ANTONIO BARRA TORRES
Director-President

ANNEX I

RISK CLASSIFICATION RULES FOR *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

Rule 1

The devices intended to be used for the following purposes are classified as Class IV:

a) detection of or exposure to a transmissible agent in blood and its components, cells, tissues, or organs, or any of its derivatives, in order to determine suitability for transfusion, transplantation, or cell administration; and

b) detection of or exposure to a transmissible agent that causes a potentially lethal disease and with a high risk or presumably high risk of dissemination.

Rule 2

Devices are classified as Class III if they are intended to determine blood groups or tissue groups to ensure immunological compatibility of the blood, blood components, cells, tissues, or organs intended for transfusion, transplantation, or cell administration, except for products to determine ABO system, Rhesus system, Kell system, Kidd system, and Duffy system, which are classified as Class IV.

Rule 3

The following devices are classified as Class III, which are intended for:

a) detection of or exposure to a sexually transmissible agent;

b) detection, in cerebrospinal fluid or blood, of an infectious agent with limited risk of dissemination;

c) detection of an infectious agent, if there is significant risk that an erroneous result leads to death or serious disability of the individual, fetus, embryo, or his/ her progeny;

d) women pre-natal tracing to determine their immunological status against transmissible agents;

e) determination of immunological status or infectious disease, where there is risk that an erroneous result leads to a patient's treatment decision causing a situation of imminent risk to life or serious disability for the patient or his/ her progeny;

f) use as diagnostic testing for therapy selection or to provide essential information for the safe and effective use of a medicinal product or biological product (used as companion diagnostics medical devices);

g) use in cancer tracing, diagnosis, or staging;

h) genetic testing in humans;

i) monitoring of levels of medicinal products, substances, or biological components, when there is risk that an erroneous result leads to a patient's treatment decision causing a situation of imminent risk to his/ her life or progeny;

j) treatment management for patients suffering from a potentially fatal disease or condition;

k) tracing of congenital diseases in fetuses or embryos; and

l) tracing of congenital diseases in newborns, where failure in detecting and treating such diseases may lead to situations of risk to life or serious disabilities.

Rule 4

Devices intended for self-testing are classified as Class III, except for those the result of which does not determine a critical clinical status. In that case, they are classified as Class II.

Rule 5

The following devices are classified as Class I:

a) buffer solutions, dilutants, culture media ready to use, solutions for cleaning and coloring, and other solutions for laboratory analysis;

b) instrument to prepare and process samples for *in vitro* diagnosis;

c) material with the specific intended purpose of collecting, containing, and preserving biological samples; and

d) products for the extraction of deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), auxiliaries to *in vitro* diagnosis procedures.

Rule 6

The following are classified as Class II:

a) devices not covered by the previous classification rules; and

b) instruments used for *in vitro* diagnosis from human samples that generate results or analytical determinations, except for instruments that operate and generate results without the need for reagents or testing devices, which must be classified in accordance with the risk class corresponding to the analyte or identified clinical condition.

Rule 7

Control devices without attributed quantitative or qualitative values are classified as Class II.

In vitro diagnostic medical devices used as calibrators, standards, or controls for a specific analyte or for several analytes with pre-defined quantitative or qualitative values, including the ones established batch by batch, have the same classification as the main reagent.

Rule 8

Devices used for determinations relating to diseases of compulsory notification or listed in specific regulations issued by the national health authority are classified as Class III, unless they are classified as Class IV due to the previous rules.

ANNEX II

TECHNICAL DOSSIER STRUCTURE FOR *IN VITRO* DIAGNOSTIC MEDICAL DEVICES SUBJECT TO NOTIFICATION AND MARKETING AUTHORIZATION BY ANVISA

Technical Dossier Of *In Vitro* Diagnostic Medical Devices[1]	**Article 58**	**Notification**		**Marketing authorization**	
	Items and sub-items	**Class I**	**Class II**	**Class III**	**Class IV**
Chapter 1					
Administrative and technical information (forms available on Anvisa website)	-	X	X	X	X
List of devices (Commercial presentation/ Models/ Components/ Variants)	Item I, sub-items d, e, h, i	X	X	X	X
Risk class and classification rule	I, c	X	X	X	X
Chapter 2					
Detailed description of the device and its compositions and Basis of Operation and Action	I, a, b, d, f, g, i	X	X	X	X
Images of the Product	II	X	X	X	X
Description of device packaging	I, e	X	X	X	X
Intended purpose (intended use); purpose of use; intended user; use indication	I, a	X	X	X	X
Intended Environment/ Use Location	I, a	X	X	X	X
Global Commercialization History	I, j	-	X	X	X
Chapter 3					
Risk Management	III	X	X	X	X
List of Technical Standards Adopted	IV	X	X	X	X
Conformity Certificate	V	X	X	X	X
Performance Studies	VI	-	X	X	X
Biological Samples	VI, a	-	X	X	X
Metrological Traceability of Calibrators and Controls	VI, b	-	X	X	X
Measurement Accuracy	VI, c	-	X	X	X
Measurement Precision	VI, d	-	X	X	X
Analytical Sensitivity	VI, e	-	X	X	X
Analytical Specificity	VI, f	-	X	X	X
High-Dose Hook Effect	VI, g	-	X	X	X
Measurement Range	VI, h	-	X	X	X
Cut-off Value Definition	VI, i	-	X	X	X
Trial Procedure Validation	VI, j	-	X	X	X
Instrument Cleaning and Disinfection Validation	VI, k	-	X	X	X
Usability	VI, l	-	X	X	X
Product Stability	VII	X	X	X	X
Expiration Date	VII, a	X	X	X	X
Product Stability During Use	VII, b	X	X	X	X

Transportation or Shipping Stability	VII, c	X	X	X	X
Chapter 4					
Clinical Performance	VIII	-	-	X	X
General Summary of Clinical Evidence	VIII, a	-	-	X	X
Expected Values or Reference Values	VIII, b	-	-	X	X
Clinical Evidence Assessment Report	VIII, c	-	-	X	X
Relevant Clinical Literature	VIII, c	-	-	X	X
Clinical Studies Specific for the Product	VIII, c	-	-	X	X
Chapter 5					
Product Labeling	IX, a	X	X	X	X
Use Instructions/ User Manual	IX, b, c	X	X	X	X
Chapter 6					
General Manufacturing Information (Name and addresses of manufacturing units)	XI	X	X	X	X
Manufacturing Process (Flowchart)	XI	X	X	X	X
Design and Development Information	X, XI	X	X	X	X

Note:

1. The Medical Device Technical Dossier Structure is aligned with the document issued by the **International Medical Device Regulators Forum – IMDRF/RPS WG/N13 (Edition 3) FINAL:2019 – In Vitro Diagnostic Device Market Authorization Table of Contents (IVD MA ToC)** and may be updated considering eventual future editions.