GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
Chapter I			
Section I - Objective	Establish risk classification, registration and registration control regimes, and labeling requirements and instructions for use	Provides risk classification, notification and registration regimes, labeling requirements and instructions for use and procedures for notification, registration, amendment, revalidation and cancellation of notification or registration	Highlights : Inclusion, in the scope: notification, registration, amendment, revalidation and cancellation regimes.
Section II - Scope	Applicability: in vitro diagnostic products manufactured in the national territory and those manufactured in other countries that may be imported into Brazil	Brings the applicability of the new RDC: reagents, calibrators, standards, controls, sample collectors, **software** , instruments or other articles, used individually or in combination, with intended use determined by the manufacturer, for the in vitro analysis of samples derived from the body human, exclusively or primarily, to provide information for the purposes of diagnosis, aid in diagnosis, monitoring, compatibility, screening, predisposition, prognosis, prediction or determination of physiological status.	Highlights : Specifies the scope and applicability of the RDC. Includes software, although I consider that SaMDs are versed in their own RDC. Controls without assigned values are now considered IVD and must be regularized.
	<u>Non-applicability</u> : I - reagents and reference materials specifically intended for quality assessment in proficiency or interlaboratory comparison tests ; II - isolated reagents sold as inputs for the manufacture of in vitro diagnostic products; III - reagents or sets of reagents assembled in clinical analysis laboratories to be used exclusively in the same institution, following defined work protocols, with their sale or donation being prohibited; IV - laboratory reagents intended for diagnosis in any type of non-human sample;	<u>Non-applicability</u> : I - reagents and reference materials specifically intended for quality assessment in proficiency or interlaboratory comparison tests ; II - inputs for the manufacture of medical devices for in vitro diagnosis; III - reagents or sets of reagents used in in- house methodology , validated and used in the laboratory itself; IV - materials for general laboratory use;	Highlights : Item III – modification of the nomenclature only. The item dealing with the non-applicability of the RDC to reagents intended for diagnosis in any type of non-human sample was removed from the section.

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	V - materials for general laboratory use; VI - products intended for exclusive use in legal medicine; VII - products intended exclusively for sports doping control tests, the results of which are not used for treatment or health purposes; VIII - products for exclusive use in research, including those imported and labeled as RUO - Research Use Only; IX - culture media and freeze-dried supplements that depend on processing and controls carried out by the user before their use; X - culture media and instruments intended for environmental, industrial, food or water control analyses ; It is XI - software for in vitro diagnostics not embedded in the equipment, which is dealt with in specific regulations.	V - products intended for exclusive use in legal medicine or for evidentiary purposes pursuant to standards or laws that do not have the purpose of in vitro diagnosis; VI - products intended exclusively for sports doping control tests, the results of which are not used for treatment or health purposes; VII - culture media and freeze-dried supplements that depend on processing and controls carried out by the user before their use; VIII - culture media and instruments intended for environmental, industrial, food or water control analyses; IX - products for exclusive use in research, including those imported and labeled as Research Use Only - RUO; X - products intended exclusively for use in technical assistance or maintenance procedures.	Item V – inclusion of the purpose of in vitro diagnosis for products intended for legal medicine Included is the non-applicability of the RDC to products intended exclusively for use in technical assistance or maintenance procedures The non-applicability of the RDC to IVD software that is not embedded in the equipment has been removed.
		The following are exempt from notification or registration : I- medical devices for in vitro diagnosis intended for clinical investigations, in compliance with the legal provisions for carrying out these activities, with commercialization and use for other purposes being prohibited.	Highlights : Inclusion of items exempt from notification/registration in the scope of the standard

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		II- presentations consisting of two or more notified or registered medical devices and in their intact individual presentation packaging, must contain information on the corresponding medical devices on the label, including notification or registration numbers.	Includes notification/registration for product family in scope
Section III - Definitions		<u>Important inclusions</u> : III - change of approval required: change of greater health relevance, which deals with a change to be introduced in the registration process, being authorized in national territory only after technical documentary analysis and favorable statement from Anvisa; IV - change of immediate implementation: change of medium health relevance, which deals with a change to be introduced in the notification or registration process, with its implementation authorized in the national territory after filing a petition with Anvisa; V - non- reportable change : any other change of less health relevance, resulting from a change that is not classified as requiring approval or immediate implementation, and that does not depend on an Anvisa protocol for implementation; VIII - Companion Diagnostics Medical Device: in vitro diagnostic medical device that is essential for the safe and effective use of a corresponding medicine:	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		a) to identify, before and/or during treatment, patients most likely to benefit from the corresponding medicine; or b) to identify, before and/or during treatment, patients at increased risk of serious adverse reactions as a result of treatment with the corresponding medication. IX - holder (of notification or registration): legal entity, public or private, manufacturer or importer, responsible for the medical device for in vitro diagnosis in the national territory, which holds the marketing authorization for the medical device for in vitro diagnosis, issued by Anvisa; XXI - family: grouping medical devices for in vitro diagnosis from the same legal manufacturer, for notification or registration purposes, with similar characteristics of technology, methodology and indication, within the same group established in specific regulation; XXIX - reference method: method that, after intense investigation, was shown to present inaccuracy and inaccuracy of little significance. The term "reference method" is often used generically to determine a method with which another method under examination is compared; XXXIII - procedural reassessment: procedure carried out by Anvisa's technical area in notifications and registrations of medical devices for in vitro diagnosis for process audit purposes;	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		XLIII - Software as a Medical Device (SaMD): Product or application intended for one or more purposes indicated in the definition of medical device for in vitro diagnosis that performs its functions without being part of the hardware of a medical device to in vitro diagnostics, with the following characteristics: a) SaMD can be run on a general purpose computing platform (non-medical purpose); b) "computing platform" includes hardware and software resources (operating system, processing hardware, storage, database, display devices, input devices, programming language , etc.); c) "without being part of" means that the program does not need the hardware of a medical device to achieve its intended use; d) software is not considered SaMD if its purpose is to control the hardware of a medical device. e) a SaMD can be used in combination (e.g. as a module) with other products, including other medical devices; f) a SaMD may interact with other medical devices, including hardware from other medical devices and other SaMD , as well as general purpose software; It is	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		g) mobile applications (apps) that meet the definition are considered SaMD .	
Chapter II		***ANNEX I***	
Section I – Risk Classes		Relevant inclusions: Article 5 §2 In case of doubt regarding the classification resulting from the application of the rules established in this Resolution, the responsible organizational unit of Anvisa will be responsible for classifying the medical device for in vitro diagnosis. §3 The classification rules established in this Resolution may be updated considering technological progress, the epidemiological context and post-market information obtained with the use or application of medical devices for in vitro diagnosis. Art. 6 Medical devices for in vitro diagnosis falling into risk classes I and II are subject to notification. Art. 7 Medical devices for in vitro diagnosis classified in risk classes III and IV are subject to registration.	Highlights : There was no change in risk classes. The difference is the inclusion of paragraphs 2 and 3 in Article 5 , which: - Opens the sector the possibility of consulting GEVIT for doubts regarding the framework - Guarantees ANVISA the flexibility of classification rules due to changes in the epidemiological scenario (included here due to the Covid-19 pandemic) Articles 6 and 7 state that IVDs classes I and II are objects of notification, while classes III and IV are objects of registration, as already mentioned for Medical Devices (materials and equipment) PoCT (Point of Care Testing) are no longer class III and are now classified according to the risk class of the analyte/measurand.

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	Art. 5 The risk classification of in vitro diagnostic products is based on the following criteria: I - indication of use specified by the manufacturer; II - technical, scientific or medical knowledge of the user; III - importance of the information provided for the diagnosis; IV - relevance and impact of the result for the individual and for public health; It is V - epidemiological relevance .	Art. 9 The application of the classification rules is governed by the intended purpose of the medical devices for in vitro diagnosis. §1 If the device is intended to be used in combination with another, the classification rules apply separately to each of them. §2 The applicant must take into account all the rules in order to establish the correct classification of the product. §3 If the manufacturer declares that a device has multiple intended purposes and is therefore covered by more than one class, the device is classified in the higher risk class. §4 If several classification rules apply to the same device, the rule that leads to the highest classification applies.	Highlights : In the previous version, risk classification was based on 4 items. In the new version, it is classified only by the intended purpose, in addition to applying rules for isolated cases.
	Art. 15. Products that have the following purposes cannot be classified as self-testing and, therefore, cannot be provided to lay users:	Art. 10. Products that have the following purposes cannot be classified as self-testing and, therefore, cannot be provided to lay users: (...) §2 The prohibition provided for in the caput of this article does not apply to devices intended for detecting the presence of or exposure to an agent causing genital infection, as long as it is not classified as a notifiable disease.	Highlights : In this article, the restrictions remained the same. However, paragraph 2 was included, allowing the provision of devices intended for detecting infectious agents of the genital tract to lay users, as long as they are not detectors of compulsorily notifiable diseases (e.g.

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
			syphilis), these being intended for professional users. .
Classification Rules	**Class IV** : I - detect the presence of, or exposure to, an agent transmissible by blood, its components and derivatives, cells, tissues or organs, in order to assess their suitability for transfusion or transplantation; II- monitor or detect the presence of, or exposure to, a transmissible agent that causes a risk of death or illness, generally incurable, with a high risk of spread. **Class III:** Reagents and devices intended for blood or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissues or organs intended for transfusion or transplantation. Single paragraph. Products for ABO system, Rhesus system, Kell system , Kidd system and Duffy system determinations are classified as Class IV. Reagents and devices intended for the diagnosis of notifiable diseases provided for in Ordinance No. 1,271, of June 6, 2014 and Ordinance No. 1,984, of	**Class IV:** Rule 1: a) detection of the presence or exposure to a transmissible agent in blood and its components, cells, tissues or organs, or any of their derivatives, in order to determine their suitability for transfusion, transplantation or administration of cells; It is b) detection of the presence or exposure to a transmissible agent that causes a potentially lethal disease and with a high or presumably high risk of propagation. **Class III:** Rule 2: Devices for determining blood groups or tissue groups in order to ensure the immunological compatibility of blood, blood components, cells, tissues or organs intended for transfusion, transplantation, or administration of cells, with the exception of products for determinations of the ABO system, the Rhesus, the Kell system , the Kidd system and the Duffy system, which are classified in class IV. Rule 3:	Highlights : In Class III, which refers to the risk to the individual or fetus, the scope of the Class was expanded to embryos and offspring, and neonatal screening Inclusion of item F to Class III (Companion Medical Devices, i.e. complementary diagnostics, i.e. an in vitro medical device that provides the facts necessary for the safe and effective use of a corresponding medicine or biological product) Inclusion of a classification rule for IVD instruments that do not use reagents, which must be classified according to the analyte or clinical condition identified. Removed the text “VI - monitor viral load of patients suffering from a generally incurable infectious disease” Classification foreseen for detection of transmissible agent in blood, for the purpose of cell administration (in

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	September 12, 2014, of the Ministry of Health, are classified as Class III. Art. 9. Reagents and devices intended for: I - detect the presence of, or exposure to, a sexually transmitted agent; II - detect the presence of an infectious agent in cerebrospinal fluid or blood, with limited risk of propagation; III - detect the presence of an infectious agent when there is a significant risk that an erroneous result could cause death or serious disability for the individual or fetus; IV - prenatal screening of women in order to determine their immunological status against transmissible agents; V - determination of the status of infectious disease or immunological status when there is a risk that an erroneous result will lead to a decision to manage the patient, resulting in a situation of imminent risk to the patient's life; VI - monitor viral load of patients suffering from a generally incurable infectious disease; VII - cancer screening, staging or diagnosis;	Devices intended for use in class III are classified as: a) the detection of the presence of or exposure to a sexually transmitted agent; b) detection of the presence in cerebrospinal fluid or blood of an infectious agent with limited risk of propagation; c) detection of the presence of an infectious agent, if there is a significant risk that an erroneous result will cause death or serious disability to the individual, fetus, embryo or their offspring; d) prenatal screening of women in order to determine their immunological status against transmissible agents; e) determining the immunological status or infectious disease, where there is a risk that an erroneous result will lead to a decision to treat the patient, generating a situation of imminent risk to life or serious disability for the patient or their descendants; f) to be used as diagnostic tests for therapeutic selection or to provide essential information for the safe and effective use of a medicine or biological product (used as a companion diagnostic medical devices); g) to be used in screening, diagnosis, or staging of cancer;	addition to transfusion and transplantation, as was already recommended in RDC 36/2015) There was no significant difference in the other classification items; What ANVISA did was provide the separation of risk classes in rules and in a separate Annex, as in RDC 751/2022, unlike RDC 36/2015, in which risk classes were part of separate articles.

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	VIII - human genetic test; IX - screening for congenital disorders in the fetus; X - Control the levels of drugs, substances or biological components, when there is a risk that a misleading result to a patient management decision, resulting in an immediate risk of death; It is XI - determinations of blood gases and glucose by point of care testing - PoCT . Products intended for self-testing are classified as Class III. Single paragraph. Products intended for self-testing where the result is not determining a clinically critical state, or is preliminary and requires follow-up with the appropriate laboratory test, belong to Class II.	h) genetic tests on humans; i) monitoring the levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a treatment decision for the patient, creating a situation of imminent risk to their life or that of their descendants; j) managing the treatment of patients suffering from a potentially fatal disease or condition; k) screening for congenital diseases in the fetus or embryo; It is l) screening for congenital diseases in newborns, where failure to detect and treat such diseases can lead to life-threatening situations or serious disabilities. Rule 4: Devices intended for self-testing are classified in class III, with the exception of those where the result is not determinant of a critical clinical state, in which case they are classified in class II. Rule 8 Devices used for determinations related to notifiable diseases or listed in specific regulations issued by the national health authority are classified in class III, unless, by application of the previous rules, they are classified in class IV.	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	Class I: I - reagents or other auxiliary articles for in vitro diagnostic procedures ; II - products intended for calibration, cleaning or maintenance of instruments in technical assistance or maintenance and cleaning procedures by a trained user as per the manufacturer's instructions specified in the instrument manual; III - culture media and devices intended for identifying microorganisms; IV - products for DNA and RNA extraction, auxiliary to in vitro diagnostic procedures; V - sample collectors or containers for collecting, storing and transporting biological samples for use in laboratory diagnostic tests; VI - instrument for preparing and processing samples for in vitro diagnosis. **Class II:** Art. 12. In vitro diagnostic products not covered by the classification rules provided for in articles 6 to 11 are classified in Class II. Art. 13.	**Class I** Rule 5: The following devices are classified in class I: a) buffer solutions, diluents, ready-to-use culture media, washing solutions and stains; and other solutions for laboratory analysis; b) instrument for preparing and processing samples for in vitro diagnosis; c) material with a specific intended purpose of collecting, containing and preserving biological samples; It is d) products for the extraction of deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), auxiliaries for in vitro diagnostic procedures. **Class II:** Rule 6 They are classified in class II: a) devices not covered by previous classification rules; It is b) instruments used for in vitro diagnosis from human samples that generate results or analytical determinations, except instruments that operate and generate results without the need for reagents or test devices, which must be classified according to the risk	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	Single paragraph. Calibrators, standards or controls used in cell counting instruments are always classified as Class II.	class corresponding to the identified analyte or clinical condition. Rule 7 Control devices without assigned quantitative or qualitative values are classified in class II. Medical devices for in vitro diagnostics used as calibrators, standards or controls for a specific analyte or for several analytes with pre-defined quantitative or qualitative values, including those established batch by batch, follow the same classification as the main reagent.	
Chapter I II - GENERAL AND DOCUMENTAL REQUIREMENTS		***Chapter III - REQUEST FOR NOTIFICATION OR REGISTRATION AND ITS MAINTENANCE***	
Section I	Product Registration or Registration Petitions :	Procedures for Notification or Registration of In vitro Diagnostic Medical Devices: Art. 11. The applicant must submit to Anvisa the documents for notification, registration, amendment, revalidation or cancellation of notification or registration of the medical device for in vitro diagnosis, listed in this Resolution. §1º Anvisa will evaluate the documentation presented for registration, alteration or revalidation of the registration and will express its opinion through official means.	Highlights : Included in the new RDC is Article 11, which determines ANVISA's administrative procedures for analyzing notification or registration documentation. The same article defines the time for analyzing notifications (30 days after the protocol). Determines that there will be no **technical analysis** for notifications and changes to notifications of regularized products. Determines which prior analysis by

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		§2 The evaluation of documentation will be carried out within the legal deadlines and conditions provided for in Brazilian health legislation. §3º For technical reasons, in order to prove the safety and performance of the product, due to potential risk to public health, Anvisa may determine the presentation of additional documents and information. §4º A petition with the absence of documents, forms and declarations provided for in the list of procedural instruction documents, completed incompletely or with missing or illegible information, or obsolete, without a certificate of conformity when applicable, or without clinical evidence for products with innovative technology or indication, leading to summary rejection of the petition. §5 There will be no technical analysis of notification and notification amendment petitions so that the products are considered regularized, without prejudice to the carrying out, at any time, of documentary or fiscal assessments on the notification processes and their amendments, and, if necessary, requesting additional information or clarification. §6 The processing of the notification of a medical device for in vitro diagnosis will occur within 30 (thirty) days after the protocol is submitted by the applicant.	ANVISA through REBLAS may be requested. Article 12 determines the validity of records set at 10 (ten) years, with revalidation for the same period. This period had already been practiced, but had not yet been determined in a specific RDC for IVDs.

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		§7 The maintenance of notification and registration is linked to compliance with the requirements of Good Manufacturing Practices, essential safety and performance requirements and specific regulations, when they exist. §8 When required, a preliminary analysis report considered satisfactory must be presented, carried out by a unit of the National Network of Public Health Laboratories as provided for in section IV, art. 16 of Law No. 6,360, of September 23, 1976. Art. 12. The registration of medical devices for in vitro diagnosis will be valid for 10 (ten) years, counting from the day of its publication in the Official Gazette of the Union, and may be revalidated successively for the same period.	
Section II IVD notification	Art. 19. To file petitions for registration or registration of in vitro diagnostic products, the applicant must present: I - proof of payment of the Health Surveillance Inspection Fee (TFVS), through the corresponding Union Collection Guide (GRU), or exemption guide; II - form made available by ANVISA in the electronic petition, duly completed; III - for products classified in risk classes II, III and IV, technical dossier containing the	**In vitro Diagnostic Medical Devices Notification** : Art. 13. To request notification of a medical device for in vitro diagnosis, the applicant must pay the corresponding fee and present the following documents to Anvisa: I - form for notification of medical device for in vitro diagnosis, duly completed, available on Anvisa's electronic portal; II - images of the product, its parts and accessories; III - images of the set of primary and secondary labels planned to be applied to products, in	Highlights : Section II of RDC 36/2015 was split into two Sections in RDC 830/2023, in order to separate the requirements for notification vs. registration. In RDC 830/2023, the “product images” requirement was included, which was already applied in the petition, but not documented in RDC 36/2015.

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	information required for the corresponding risk class; IV - for national products that have some outsourced manufacturing stage, a declaration informing the company name and postal address of the company(ies) involved and the corresponding stage(s) in the manufacturing process; V - for all imported products, consularized declaration , accompanied by a sworn translation, issued by the legal manufacturer for a maximum of two years, when there is no express validity indicated in the document, authorizing the importer to represent and market his product(s) in Brazil, containing at least the following information: a) legal name and full address of the manufacturer; b) company name and full address of the importer; c) express authorization for the importer to represent and sell the product(s) in Brazil; d) knowledge and compliance with the requirements of Good Manufacturing Practices for Health Products established in the Resolution of the Collegiate Board - RDC nº 16, of March 28, 2013.	accordance with the requirements indicated in articles 46 to 49 of this Resolution; IV - instructions for use, in accordance with the requirements indicated in articles 46 and 50 of this Resolution; V - for products classified in risk class II, technical dossier containing the information required for this risk class; VI - indication of the family corresponding to the product grouping, according to alternatives described in Normative Instruction - IN nº 3, of August 26, 2015, when applicable; VII - for imported in vitro diagnostic medical devices, a declaration issued by the legal manufacturer, consularized or apostilled, written in Portuguese, English or Spanish or accompanied by a sworn translation, a maximum of two years ago when there is no express validity indicated in the document, authorizing the company requesting to represent and sell its product(s) in Brazil; It is VIII - proof of compliance with the legal provisions determined in technical regulations, in accordance with the legislation that regulates specific in vitro diagnostic medical devices. Single paragraph. The declaration referred to in item VII of the caput of this article must contain the	An item was included to indicate the family corresponding to the product grouping, as recommended in IN 3/2015/ANVISA.

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		corporate name and full address of the legal manufacturer and the requesting company, the express authorization for the requesting company to represent and sell its products in Brazil, and the statement about the knowledge and compliance with the requirements of Good Manufacturing Practices for Health Products established in the Resolution of the Collegiate Board - RDC nº 665, of March 30, 2022, or regulation that replaces it. **Registration of Medical Devices for in vitro Diagnostics (Section III of the RDC)** Art. 14. To petition for registration of a medical device for in vitro diagnosis, the applicant must pay the corresponding fee and present the following documents to Anvisa: I - form for registration of medical device for in vitro diagnosis, duly completed, available on Anvisa's electronic portal; II - images of the set of primary and secondary labels planned to be applied to products, in accordance with the requirements indicated in articles 46 to 49 of this Resolution; III - instructions for use, in accordance with the requirements indicated in articles 46 and 50 of this Resolution;	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		IV - Technical dossier , as provided in Chapter VII of this Resolution; V - indication of the family corresponding to the product grouping, according to alternatives described in Normative Instruction - IN nº 3, of August 26, 2015, when applicable; VI - for imported in vitro diagnostic medical devices, declaration issued by the manufacturer legally consularized or apostilled, written in Portuguese, English or Spanish or accompanied by a sworn translation, a maximum of two years ago when there is no express validity indicated in the document, authorizing the company applicant to represent and market their product(s) in Brazil; VII - proof of compliance with the legal provisions determined in technical regulations applied to specific in vitro diagnostic medical devices; It is VIII - certificate of Good Manufacturing Practices issued by Anvisa or proof of protocol requesting a Certificate of Good Manufacturing Practices. §1º The protocol of the request for Certification of Good Manufacturing Practices will be accepted for the purpose of petitioning, as well as beginning the analysis of petitions for granting registration.	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		§2 The granting of requests for registration is subject to the publication of a valid Certificate of Good Manufacturing Practices issued by Anvisa and compliance with other requirements for registration of medical devices for in vitro diagnosis. §3º The declaration referred to in item VI of the caput of this article must contain the corporate name and full address of the legal manufacturer and the requesting company, the express authorization for the requesting company to represent and sell its products in Brazil, and the statement regarding knowledge and compliance with the requirements of Good Manufacturing Practices for Health Products established in the Resolution of the Collegiate Board - RDC nº 665, of March 30, 2022, or regulation that replaces it.	
Family Grouping	Art.20. In vitro diagnostic products can be registered or registered in groups as a family when: I - are from the same legal manufacturer, have similar technology, use the same methodology and are included in the family grouping list of in vitro diagnostic products, published in Normative Instruction No. 3, of August 26, 2015; or II - are from the same legal manufacturer, have similar technology, use the	Art. 4 XXI - family: grouping medical devices for in vitro diagnosis from the same legal manufacturer, for notification or registration purposes, with similar characteristics of technology, methodology and indication, within the same group established in specific regulation.	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	same methodology and are interdependent and exclusive for carrying out a specific test. §1 Reagents, calibrators and controls for a specific assay may be supplied separately as long as they are provided for in the product family registration or registration. §2 Products that can be used in multiple tests must be registered or registered separately, as súnicos products .		
Change of Notification or Registration	Section II: There was no information about changes to approval required	Section IV: Art. 16. Changes to information presented in the notification or registration process of medical devices are classified into: I - change of approval required; II - immediate implementation change ; It is III - non- reportable change . §1° The petition for changes contained in items I and II of this article must comply with the provisions of Normative Instruction - IN nº 74, of September 16, 2020, which details the applicable petition subjects. §2 Any minor changes not classified as requiring approval or immediate implementation are classified as non-reportable changes, and also: changes	Highlights : Change definitions for approval required, immediate implementation and non-reportable were included. Determines that the matters for change are defined by Normative Instruction - IN nº 74, of September 16, 2020.

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		to information that do not modify the design of the medical device; software bug fixes; non-technical changes such as images, formatting, layouts, symbols and text adjustments to documents without increasing risk; updates to Company Operating Authorization information; contact changes (e.g. telephone numbers or postal addresses), technical assistance and website. §3° The changes listed in §2° of this article must be controlled by the quality system of the regularization holder and be incorporated in subsequent petitions. §4 The request for change for in vitro diagnostic medical devices of risk classes I and II will be carried out under the immediate implementation regime, except when it is a non- reportable change .	
	<u>Out of stock of products after changes:</u> Art. 23. In cases of change, where there is a need to exhaust the stock of finished products, the simultaneous import and sale of the versions involved is permitted for up to 180 (one hundred and eighty) days, counting from the approval of the change by ANVISA	<u>Out of stock of products after changes:</u> Art. 25. If the stock of finished products needs to be exhausted as a result of a change, the simultaneous import and sale of the versions involved is permitted until the end of the product's expiration date or useful life. Art. 26. The stock of packaging, labels and instructions for use may be exhausted for a period of 120 (one hundred and twenty) days from the publication of the change.	Highlights : In RDC 36/2015, exhaustion should be done within 180 days after approval. According to RDC 830/2023, the deadline becomes the validity or useful life of the product in stock. It also includes running out of packaging, labels and instructions for use.

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
Revalidation of records	Section III: Art. 24. To file a petition for revalidation of the in vitro diagnostic product registration , the applicant must present: I - proof of payment of the Health Surveillance Inspection Fee (TFVS), through the corresponding Union Collection Guide (GRU) or exemption guide; II - form made available by ANVISA, duly completed; III - for imported products: certified copy of the legal document, as described in item V of art. 20; It is IV - proof of Certification in Good Manufacturing and Control Practices issued by ANVISA or proof of GMP Certificate request protocol.	Section V: Art. 27. To request the revalidation of the registration of a medical device for in vitro diagnosis, the applicant must pay the corresponding fee and present the following documents: I - for imported in vitro diagnostic medical devices, declaration issued by the manufacturer legally consularized or apostilled, written in Portuguese, English or Spanish or accompanied by a sworn translation, a maximum of two years ago when there is no express validity indicated in the document, authorizing the company applicant to represent and market their product(s) in Brazil; It is II - valid certificate of Good Manufacturing Practices issued by Anvisa. §1 The declaration referred to in item I of the caput of this article must contain the corporate name and full address of the legal manufacturer and the requesting company, the express authorization for the requesting company to represent and sell its products in Brazil, and the statement regarding knowledge and compliance with the requirements of Good Manufacturing Practices for Health Products established in the Resolution of the Collegiate Board - RDC nº 665, of March 30, 2022, or regulation that replaces it.	Highlights The main change in the revalidation documentation is, at first glance, the exemption from presenting the form and the removal of the option of presenting proof of the CBPF protocol, and from the new RDC coming into force, the presentation of the Good Practices certificate will be mandatory. .

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
Information Compliance	Item not included in RDC 36/2015	Art. 30. Changes made by the manufacturer to the information relating to the in vitro diagnostic medical device contained in the notification or registration must be communicated by the holder to Anvisa, in accordance with the requirements set out in Section IV of Chapter III of this Resolution. Art. 31. Changes relating to a medical device for in vitro diagnosis that require prior approval by Anvisa may only be disclosed to the consumer market after publication of said change in the Official Gazette of the Union and Anvisa's electronic portal Art. 32. All communication or advertising of a medical device for in vitro diagnosis published on the consumer market must be in strict accordance with the information presented by the holder of notification or registration to Anvisa.	Highlights : New item in RDC. Although it was already carried out in practice, it was not yet included in the regulations.
Documentary Repository of Medical Devices	Item not included in RDC 36/2015	Art. 33. Uploading instructions for use in the Documentary Repository of Medical Devices corresponds to the insertion and updating of these documents linked to the processes of notification or registration of medical devices for in vitro diagnosis. §1 In the case of a medical device that does not have instructions for use (such as a specific document), the labeling model must be uploaded in the	Highlights : Another practice that was already defined by ANVISA, but was not documented in the IVD RDC, as the information regarding the Documentary Repository was defined in (RDC) 431/2020, subsequent to RDC 36/2013, having been incorporated into RDC 830/ 2023.

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		instructions for use field, also including the information provided for in Chapter VI of this Resolution. §2 The loading of instructions for use must occur through the applicable petition subjects, identified as "Availability of Instructions for Use on the Anvisa Portal". §3 The loading of instructions for use is the responsibility of the holder of the notification or registration and must be controlled by him for possible audits. §4 Uploading instructions for use is mandatory and must be carried out by the company responsible for notifying or registering the product, which certifies that its content is in accordance with current legislation and consistent with the regularized product. §5 For new notified or registered products and for changes to previously notified or registered products, instructions for use must be uploaded within 30 (thirty) days after publication in the Official Gazette of the Union. §6º For non-reportable changes to those products previously notified or registered, the upload of instructions for use must be carried out within 180 (one hundred and eighty) days after the implementation of	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		the change that implies a change in the instructions for use. Art. 34. The instructions for use will be made available exclusively on Anvisa's electronic portal, at the time of finalizing the respective petition protocol, regardless of documentary analysis by the Agency. §1 The update is carried out by inserting new instructions for use. §2º If there is a new upload of instructions for use in the notification or registration process, only those recently uploaded will be kept public. §3 Instructions for use uploaded over time will be kept in a database for control and auditing by Anvisa. Art. 35. The instructions for use uploaded or their absence under the terms of this Resolution may be subject to documentary or fiscal assessment at any time by Anvisa and, if necessary, the Agency may: I - request information, additional clarification or upload of appropriate instructions for use from the company; and/or II - remove the instructions for use or restore a previous version, when there is justification for such measures.	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		Art. 36. Companies that insert information that do not comply with current legislation and consistency with the regularized product are subject to the penalties provided for in Law No. 6,437, of 1977.	
Section IX : Procedural Reassessment Procedure	Item not included in RDC 36/2015	Art. 37. The notification and registration processes for in vitro diagnostic medical devices are subject to procedural reassessment, audit, market monitoring and inspection by the competent health authority. Art. 38. In cases where inconsistencies or the need to supplement information are evident, holders will be urged to adapt their processes. §1 Adjustments must be responded to by the holder of the notification or registration within 30 (thirty) days from the date of confirmation of receipt. §2 Situations that require correction of previously presented information must be addressed through a specific petition. §3º The lack of response to the notification of adequacy referred to in the caput within a period of up to 30 (thirty) days, counting from its issuance, will lead to the cancellation of the notification, registration or amendment.	Highlights : Another practice that has already been carried out by ANVISA in other Medical Devices and from now on is documented for IVD devices.

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
CHAPTER VI – CANCELLATION OF REGISTRATION OR REGISTRATION		***Chapter IV – ADMINISTRATIVE SANCTIONS***	
Administrative sanctions	Art. 36. ANVISA will cancel the registration or registration of the in vitro diagnostic product in cases where: I - the information provided is proven to be false or any of the documents indicated in Chapter III are canceled, or II - it is proven that the product or manufacturing process may present a risk to the health of the consumer, patient, operator or third parties involved.	Art. 39. Anvisa may suspend the manufacture, import, distribution, commercialization and use of the medical device in the event of a health risk arising from irregularities in the product, irregularities in its manufacturing process, absence of a compulsory certificate of conformity or conditions different from those approved with Anvisa. Art. 40. Anvisa may apply the penalties provided for in Law No. 6,437, of August 20, 1977, in cases where companies or medical devices are not in compliance with current legislation and the regularization process. Art. 41. Anvisa may cancel the notification or registration of the medical device for in vitro diagnosis in cases where: I - the information provided in any of the documents requested in this Resolution is proven to be false, or any of these documents are canceled by the competent health authority ; II - in case of proof that the product or manufacturing process may present a risk to the health of the user, patient, operator or third parties involved; III - a lack of information or documents is identified in the product processes subject to notification;	Highlights : ANVISA expanded the scope of sanctions and included in the new RDC those that are already standard, according to Art. 39 and 40 (RDC 830/2023). Regarding cancellations , the scope was expanded and publication in the Official Gazette of the Union was included.

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		IV - an error is identified in the health framework in the notification processes; or V - when the demands for procedural reassessment presented by Anvisa are not met. Art. 42. Anvisa may order the cancellation of changes that result in incorrect information or irregularity of a medical device for in vitro diagnosis. Art. 43. Anvisa may, at its discretion and at any time, request information or clarifications before deciding to cancel the notification or irregular registration of a medical device for in vitro diagnosis. Art. 44. The cancellation of notification or registration of a medical device for in vitro diagnosis will be published in the Official Gazette of the Union.	
Secondary Labeling (external)	Art. 34 §1 The secondary (external) labeling of in vitro diagnostic products must contain the following information: I - technical name or commercial name of the product; II - details necessary to allow the user to identify the product and its use; III - company name and address of the legal manufacturer;	Art. 47. The secondary (external) labeling of medical devices for in vitro diagnosis must contain the following information: I - commercial name of the product; II - details necessary to allow the user to identify the product and its use; III - legal name and address of the manufacturer, preceded by the term "manufacturer" or equivalent symbols;	Highlights : RDC 36/2015 allowed technical name OR commercial name; now only the commercial name. In RDC 830/2023: The mention of the legal manufacturer must now be preceded by the term “manufacturer” or equivalent symbolism.

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	IV - company name , address and CNPJ of the applicant; V - name of the technical person responsible, with acronym and registration number with the professional authority; VI - registration or registration number with ANVISA preceded by the acronym MS; VII - indication that the product is for "in vitro diagnostic use"; VIII - when intended for the lay public, the expressions "Carefully read the instructions for use before carrying out the test" and "Self-test for (specify, parameter or condition for which the test is proposed), without diagnostic purposes"; IX - number , batch code or serial number, preceded by the term that identifies it, or equivalent symbols; X - unequivocal indication of the date until which the product can be used, except for instruments; XI - indication of storage conditions, and specific transport and/or handling conditions may also be mentioned;	IV - company name , address and CNPJ of the holder of the notification or registration, preceded by the expression "regularized by"; V - name of the technical person responsible, with acronym and registration number with the professional authority; VI - notification or registration number with Anvisa, preceded by the acronym "Anvisa"; VII - indication that the product is for "in vitro diagnostic use" or "IVD"; VIII - when the product is intended for the lay public, the expressions "Carefully read the instructions for use before carrying out the test" and "Self-test for (specify, parameter or condition for which the test is proposed), without diagnostic purposes"; IX - batch number , batch code or serial number, preceded by the term that identifies it, or equivalent symbols; X - unequivocal indication of the product's expiration date, except for instruments; XI - indication of storage conditions, and specific transport and/or handling conditions may also be mentioned; XII - if the product is supplied sterile, indication of its condition and the sterilization method;	The holder's data (formerly “applicant”) must be preceded by the expression “regularized by”. The acronym “MS” has fallen off the labels, preceding the registration number, and should be replaced by “ANVISA”

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	XII- if the product is supplied sterile, indication of its condition and the sterilization method; XIII - alerts or precautions to be adopted by the product user; XIV - when relevant, if the product is for single use and if there is a potential risk of reuse, indication of this fact; It is XV - list of the components that make up the product as a whole, informing the respective quantities.	XIII - alerts or precautions to be adopted by the product user; XIV - if the product is for single use and there is a potential risk of inadvertent reuse, indication of this fact; It is XV - list of the components that make up the product as a whole, informing the respective quantities/volumes.	
Primary (internal) labeling	Art. 34: §2 The primary labeling of in vitro diagnostic products, except instruments, must contain the following information: I - technical name or commercial name of the product and indication of the component; II - batch number or code preceded by the term that identifies it, or equivalent symbols; III - unequivocal indication of the date until which the product can be used safely; IV - indication of appropriate storage conditions for the product.	Art. 48. The primary labeling of medical devices for in vitro diagnosis, except instruments, must contain the following information: I - product name and component indication; II - batch number or code preceded by the term that identifies it, or equivalent symbols; III - unequivocal indication of the validity period; It is IV - indication of appropriate storage conditions for the product.	Highlights : In the new RDC, it is no longer necessary to include a technical name or commercial name on the primary labeling, but only the name of the product. The other requirements remain the same.

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
Primary labeling of IVD instruments	Art. 34: §3 The primary labeling of instruments must be indelible and contain the following information: I - technical name or commercial name of the product and commercial model; II - serial number preceded by the term that identifies it or equivalent symbols; III - identification of the legal manufacturer; IV - registration or registration number with ANVISA.	Art. 49. The primary labeling of instruments must be indelible and contain the following information: I - commercial name of the product and commercial model; II - serial number preceded by the term that identifies it or equivalent symbols; III - identification of the legal manufacturer; It is IV - notification or registration number with Anvisa, preceded by the acronym "Anvisa".	Highlights : For instruments, on primary labeling there is no longer a need to include the technical name OR commercial name, only the commercial name.
Instructions for use	Art. 35. Instructions for use of in vitro diagnostic products must be in Portuguese and contain the data listed below: I - technical name or commercial name of the product; II - legal name and address of the manufacturer, together with a telephone or fax number or website address where technical assistance can be obtained (Consumer Service);	Art. 50. Instructions for use of medical devices for in vitro diagnosis must contain the data listed below: I - commercial name of the product; II - company name and address of the legal manufacturer; III - telephone number or website address where technical assistance can be obtained (Consumer Service);	Highlights : In the new RDC, it is only mandatory to mention the commercial name of the product in the Instructions for Use. SAC options for maintenance were reduced to telephone and website. The performance characteristics, in RDC 36/2015, were detailed. In the new RDC, ANVISA removed this

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	III - purpose and method of use of the product, including indication that it is for "in vitro diagnostic use"; IV - intended user , when applicable; V - indications of applicable storage or handling conditions; VI - operating principle of the test or instrument; VII- types of samples or matrices to be used, when applicable; VIII- conditions for collection, handling, preparation and preservation of samples; IX - description of the product, including accessories and any limitations on their use, such as the use of a dedicated instrument, and if applicable, software version; X - stability in use of the product, except for instruments, including storage conditions after opening primary packaging, as well as storage conditions and stability of working solutions, when relevant; XI - details of any treatment or handling of the products before they are ready for use, such as installation, reconstitution, calibration, among others;	IV - purpose and method of use of the product, including indication that it is for "in vitro diagnostic use" or "IVD"; V - intended user , when applicable; VI - indications of applicable storage or handling conditions; VII - operating principle of the test or instrument; VIII - types of samples or matrices to be used, when applicable; IX - conditions for collection, handling, preparation and preservation of samples; X - product description , including accessories and any limitations for its use, such as the use of a dedicated instrument, and if applicable, software version; XI - stability in use of the product, except for instruments, including storage conditions after opening primary packaging, as well as storage conditions and stability of working solutions, when relevant; XII - details of any treatment or handling of the products before they are ready for use, such as installation, reconstitution, calibration, among others;	detail, although it is still mandatory to mention the product's performance.

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	XII - when applicable, recommendations for quality control procedures; XIII - test procedure, including calculations and interpretation of results; XIV - information on interfering substances or limitations that may affect the performance of the test; XV - performance characteristics , such as sensitivity, specificity, accuracy and precision, except for instruments; XVI - residual risks identified; XVII - reference intervals, when applicable; XVIII - where relevant, requirements for special facilities (such as a clean room) or special training (such as in radiation safety) or specific qualifications of the product user; XIX - if the product is supplied sterile, instructions on how to act if the packaging is damaged before use; XX - information on other products, materials or instruments necessary to carry out the test or reaction; XXI - warnings or precautions to be taken regarding the disposal of the product, its	XIII - when applicable, recommendations for quality control procedures; XIV - test procedure, including calculations and interpretation of results; XV - information on interfering substances or limitations that may affect test performance; XVI - applicable performance characteristics; XVII - residual risks identified; XVIII - reference intervals, when applicable; XIX - requirements for special facilities or special training or specific qualifications of the product user, when applicable; XX - if the product is supplied sterile, instructions on how to act if the packaging is damaged before use; XXI - information on other products, materials or instruments necessary to carry out the test or reaction; XXII - warnings or precautions to be taken regarding the disposal of the product, its accessories and consumables used, including biological, environmental and physical risks;	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	accessories and consumables used, including risks of infection or microbiological, environmental and physical; XXII - for products intended for lay users, the circumstances in which the user must consult a healthcare professional; XXIII - date of issue or last revision of the instructions for use and, when appropriate, a numerical identification; It is XXIV - indication of the terms and conditions guaranteeing the quality of the product.	XXIII - for products intended for lay users, the circumstances in which the user must consult a healthcare professional; XXIV - indication of version control of instructions for use; It is XXV - indication of the terms and conditions guaranteeing the quality of the product. Single paragraph. When the dimensions of the product packaging allow, information about instructions for use may appear on its label.	
Instructions for Use in non-printed format	Art.33. The use of instructions for use in non-printed format must comply with the provisions of Normative Instruction No. 4, of June 15, 2012:	Art. 51. 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. Art. 52. The following are requirements for the availability of instructions for use in non-printed format: I - 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 Service Service where the printed format of instructions for use can be requested at no additional cost (including shipping);	Highlights : RDC 830/2023, in this item, incorporated the text of IN nº4, of June 15, 2012, only adding the section of Art. 55, which concerns PoCT (Point of Care Testing), in addition to the permission of Instructions for Use in printed format also for Controls and Calibrators

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		III - ensure the availability of instructions for use throughout the period in which the supplied product is on the market; It is IV - specify the resources necessary for the user to read the instructions for use. §1 When the dimensions of the external labeling do not allow it, the information required in this article may be included in a document attached to the product. §2 The manufacturer or holder of the notification or registration of instruments must consider the period indicated in item III of the caput of this article as the useful life specified for the product, counting from the last unit sold of the product. Art. 53. Instructions for use provided in non-printed format must contain: I - all information required in this Chapter and, when applicable, in regulations dedicated to specific in vitro diagnostic medical devices; II - identification of the version of the instructions for use corresponding to the respective product; III - an alert to the user so that the correlation between the version of the instructions for use indicated with the product purchased, as provided by the manufacturer, is observed; It is	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		IV - indication of how to obtain, at no additional cost (including shipping), instructions for using the product in printed format. Art. 54. To provide instructions for use via the internet, in addition to what is established in articles 52 and 53 of this Resolution, the following requirements must also be met: I - provide , with the product, clear guidance on how to find the corresponding and updated instructions for use at the electronic address available on the internet; II - guarantee the basic security requirements of the electronic address; III - make the file of instructions for use available on the electronic address in a non-editable readable format; IV - provide free access to the tool necessary to read the instructions for use on the website; It is V - ensure that the file made available and printed in this way is identical to that provided by the manufacturer or holder of the notification or registration, when requested, in printed format. Art. 55. The exclusive availability of instructions for use in non-printed format for the following medical devices for in vitro diagnosis is prohibited: I - instruments that are indicated for general domestic use, including those for use in home care services - SAD;	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		II- instruments that are indicated for operation by laypeople, regardless of the place of use; III- self-test products; It is IV- Point of type products Care Testing (PoCT), that is, devices for professional use that have been designed to be operated outside the physical environment of the clinical laboratory, usually close to or next to the patient.	
CHAPTER IV – REGISTRATION DOSSIER		***Chapter VI – TECHNICAL DOSSIER***	
	Art. 27. The technical manager will assume responsibility for the information provided in the product's technical dossier.	Art. 56. The legal and technical managers of the requesting company are responsible for the information and documents presented.	Highlights : As of RDC 830/2023, responsibility for the information submitted will be joint with those legally and technically responsible.
	There was no corresponding item in RDC 36/2015	Art. 57: §2º The Technical Dossier may be arranged in a single physical or electronic file, containing all the information described in this chapter, or be composed of references to documents and information that make up other files or records of the company's Quality System, which must be available for inspection by the National Health Surveillance System. §3 In specific cases, when inquiries and investigations are necessary, the Technical Dossier may be requested to be sent to Anvisa.	This article concerns the technical dossier that remains in the possession of the holder.

Brazil Import Healthcare Solutions

BIHS

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
Items contained in the Technical Dossier:	I - product description , containing the data listed below: a) indication of use or intended use: 1. analyte or measurement; 2. functionality (screening, monitoring, diagnosis or diagnostic assistance); 3. specific situation, condition or risk factor of interest that is intended to be detected, defined or differentiated; 4. intended user (professional or lay user); 5. environment or place of use; 6. whether it is for single or multiple use; 7. whether it is automated, semi-automated or non-automated; 8.whether it is qualitative or quantitative; 9. type(s) of sample(s) required; 10. when applicable, target population for the test;	I - product description , containing the data listed below: a) indication of use or intended use: 1. analyte or measurement; 2. functionality (screening, monitoring, diagnosis or diagnostic assistance); 3. specific situation, condition or risk factor of interest that is intended to be detected, defined or differentiated; 4. intended user (professional or lay user); 5. environment or place of use; 6. whether it is for single or multiple use; 7. whether it is automated, semi-automated or non-automated; 8. whether it is qualitative, quantitative or semi-quantitative; 9. type(s) of sample(s) required; It is 10. when applicable, target population of the test. b) detailed description of the principle of the test method or operating principles of the instrument;	Highlights : Item II – Product Images RDC 36/2015 allowed product images to consist of diagrams or drawings. The new RDC 830/2023 eliminates these options and only determines that photographs are sent. Item III – Risk Management RDC 36/2015 recommended that Risk Management should contain analysis and risk reduction measures. RDC 830/2023 recommends that the document must contain identification, analysis, risk reduction measures and acceptability criteria.

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	b) detailed description of the principle of the test method or operating principles of the instrument; c) the risk class in which the product falls; d) description of the product components and, where appropriate, description of the active ingredients of the components; e) description of the commercial presentation and packaging (primary and secondary); f) when applicable, for automated tests, description of the characteristics of the necessary instrument or dedicated instrument; g) when applicable, indication of the software to be used as an in vitro diagnostic product; h) where applicable, description or complete list of in vitro diagnostic product configurations/variations that will be available; i) when applicable, description of accessories, other in vitro diagnostic products and any other products, which must be used in combination with the target product; It is	c) the risk class and classification rule in which the product falls; d) description of the items that make up the product and its compositions; e) description of the commercial presentation and packaging (primary and secondary); f) for automated tests, description of the characteristics of the required instrument or dedicated instrument; g) when applicable, indication of the software to be used with the medical device for in vitro diagnosis; h) where applicable, description or complete list of configurations/variations of the in vitro diagnostic medical device that will be available; i) where applicable, description of accessories, other medical devices for in vitro diagnosis and any other products, which must be used in combination with the target product; It is j) indication of the country(ies) in which the product(s) is authorized or approved for sale. II - images of the products (photographs of the product and all of its constituents);	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	j) indication of the country(ies) in which the product(s) is authorized or approved for sale; II - images of the products (photographs, drawings or diagrams of the product or all of its components); III - product risk management report (risk analysis and risk reduction measures); IV - when applicable, list of adopted technical standards; V - Certificate of Conformity issued within the scope of the Brazilian Conformity Assessment System (SBAC), for instruments with compulsory certification, listed by ANVISA in specific regulations; VI - performance studies , containing, when applicable: a) biological samples: 1. characterization and validation of clinical samples used; It is 2. storage conditions and sample stability; b) determination of metrological traceability of calibrator and control values;	III - product risk management report (identification, analysis of risk reduction measures and acceptability criteria); IV - when applicable, list of adopted technical standards; V - Certificate of Conformity for instruments with compulsory certification, listed by Anvisa in specific regulations; VI - performance studies , containing, when applicable: a) biological samples: 1. characterization and validation of clinical samples used; It is 2. storage conditions and sample stability; b) determination of metrological traceability of calibrator and control values; c) measurement accuracy; d) measurement accuracy, including: 1. repeatability; It is 2. reproducibility; e) analytical sensitivity or detection limit; f) analytical specificity;	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	c) measurement accuracy; d) measurement accuracy, including: 1. repeatability; It is 2. reproducibility; e) analytical sensitivity or detection limit; f) analytical specificity; g) high dose pro-zone effect; h) measurement range (limits) or linearity; i) definition of cut -off value; j) test procedure validation report; k) report on the validation of the cleaning and disinfection procedure for instruments that require direct contact with the patient or lay user; It is l) usability report for products intended for lay users; VII - product stability (except instruments), including: a) expiration date established from a study with at least 3 (three) batches of product	g) high dose pro-zone effect; h) measurement range (limits) or linearity; i) definition of cut -off value; j) test procedure validation report; k) report on the validation of the cleaning and disinfection procedure for instruments that require direct contact with the patient or lay user; It is l) usability report for products intended for lay users. VII - product stability (except instruments), including: a) expiration date established from a real-time study, or accelerated with data from the real study in progress, with at least 3 (three) batches (protocol, acceptability criteria, results, conclusion and recommended storage conditions); b) stability in use - after opening or installing in an instrument (protocol, acceptability criteria, results and conclusion); It is c) transport or dispatch stability (protocol, acceptability criteria, completion and recommended transport conditions), when transport or dispatch is carried out under conditions different from storage conditions.	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	(protocol, acceptability criteria, results, conclusion and recommended storage conditions); b) stability of the product in use - after opening or installed in an instrument (protocol, acceptability criteria, results and conclusion); It is c) transport or dispatch stability (protocol, acceptability criteria, completion and recommended transport conditions), when transport or dispatch is carried out under conditions different from storage conditions; VIII - clinical performance, when applicable, including: a) general summary of clinical evidence, covering clinical sensitivity and clinical specificity; b) expected values or reference values; c) clinical evidence assessment report; IX - labeling and instructions for use, containing: a) images of the set of primary and secondary labels planned to be applied to products, in accordance with the requirements indicated in Chapter V of this Resolution;	VIII - clinical performance, when applicable, including: a) general summary of clinical evidence, covering clinical sensitivity and clinical specificity; b) expected values or reference values; It is c) clinical evidence assessment report (protocol, acceptability criteria, results, conclusion). IX - labeling and instructions for use, containing: a) images of the set of primary and secondary labels planned to be applied to products, in accordance with the requirements indicated in articles 46 to 49 of this Resolution; b) instructions for use of the product, in accordance with the requirements indicated in articles 46 and 50 of this Resolution; It is c) for instruments, operator's manual. X - name and addresses of manufacturing units, identifying the respective manufacturing stages, including outsourced companies; It is XI - description of the manufacturing process, including in-process control steps, finished product testing and production flowchart.	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	b) instructions for use of the product, in accordance with the requirements indicated in Chapter V of this Resolution; It is c) for instruments, technical or operator manual. X - addresses of manufacturing units, including those of outsourced stages or those contracted by the legal manufacturer; It is XI - manufacturing processes, containing the flowchart of the production process describing the phases or stages of manufacturing until obtaining the finished product, including stages of in-process control and testing of the finished product, identifying the manufacturing units, when applicable. Single paragraph. For cases where stability studies are presented using the accelerated model, real-time study data must be presented upon registration revalidation.		
Final and Transitional Provisions	Art. 37. Maintaining the regularization of all in vitro diagnostic products is linked to compliance with the requirements of Good Manufacturing Practices, applicable technical standards and specific standards, when they exist. Art. 38. The registration processes for in vitro diagnostic products granted prior to the validity of	combinations associated with them as in force for the registration regime for medical devices for in vitro diagnosis apply to the notification regime . Art. 61. Notifications and records of medical devices for in vitro diagnosis, their amendments and other acts will be published in the Official Gazette of the Union and will	Highlights : ANVISA provides more specifics in this section in the new RDC 830/2023. It typifies health infractions and vehemently determines that import and commercialization can only be

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	this Resolution must be adequate or complemented in the acts of their revalidation. Single paragraph. Products registered in risk class II until the date of entry into force of this Resolution are now considered registered, maintaining the same registration identification number, without the need for revalidation. Art. 39. The documents indicated in items III, IV and V of art. 19 must be added to processes containing petitions pending analysis. Art. 40. Maintaining conformity between information relating to products and that declared in the registration or registration processes is the responsibility of the requesting company. Art. 41. The documents mentioned in this Resolution that are issued in a foreign language must be translated into Portuguese. Single paragraph. The documents that form part of the technical dossier, indicated in art. 29, according to the rules defined in the Collegiate Board Resolutions - RDC nº 25, of June 16, 2011, and RDC nº 50, of November 6, 2013. Art. 42. Failure to comply with the provisions contained in this Resolution constitutes a health infraction, under the terms of Law No. 6,437, of	remain available for consultation on Anvisa's electronic portal. §1 Devices subject to notification and registration may only be manufactured or imported for delivery for consumption and display for sale after publication of the notification or registration number. §2 Products manufactured in national territory exclusively for export purposes do not require notification or registration with Anvisa. §3 The import of medical devices for in vitro diagnosis, including their accessories, whose industrialization dates precede the notification or registration publication dates is permitted, provided that the time period does not exceed 5 (five) years, and that such products maintain strict compliance with the approval conditions with Anvisa. § 4 For the import of medical devices for in vitro diagnosis under the terms of § 3, the import processes must be accompanied by a declaration issued by the notification or registration holder attesting to compliance with both requirements. § 5 The medical device for in vitro diagnosis to be imported under the terms of § 3 must be, as applicable, within its validity in compliance with current legislation.	carried out after the publication of the registration/notification number. It also defines that products manufactured in Brazil and intended exclusively for export do not require notification/registration. It allows registered products that were manufactured up to 5 years before the publication of the registration can be imported, as long as the same conditions stated in the submission are maintained. Informs that IVD products subject to SBAC certification can only be manufactured during the validity of the certificate of conformity. In the next revalidation of devices registered before October 26, 2015, the complete technical dossier must be presented, different from that recommended for revalidations after the aforementioned date. The following are now subject to regularization: Control devices without assigned quantitative or qualitative values and products for extracting

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
	August 20, 1977, without prejudice to applicable civil, administrative and criminal responsibilities.	Art. 62. Medical devices subject to certification of conformity within the scope of the Brazilian Conformity Assessment System (SBAC) may only be manufactured during the validity of the Certificate of Conformity. Single paragraph. The import, distribution and commercialization of stock produced within the validity of the certification is permitted until the end of the validity period or useful life of the product, provided that the cancellation or termination of the certificate was not motivated by safety or performance problems of the medical device . Art. 63. Request forms, instructions for use or user/operator manuals and labeling models must be presented in the Portuguese language. Single paragraph. The other documents that make up the petitions for medical devices for in vitro diagnosis can be presented in Portuguese, Spanish or English, according to the rules defined in the Collegiate Board Resolution - RDC nº 25 of June 16, 2011. Art. 64. In the first petition for revalidation of devices registered before October 26, 2015, the complete and updated technical dossier must be presented. Art. 65. A period of 365 days is established, counting from the entry into force of this Resolution, for holders of notifications of medical devices for in vitro diagnosis to file petitions for sanitary reclassification of products that	deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), auxiliary to in vitro diagnostic procedures .

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		have had their notification regime modified to registration according to classification rules. §1 The petition must be accompanied by the same documentation required for new product registration. §2º The protocol of the request for Certification of Good Manufacturing Practices will be accepted for the purpose of petitioning, as well as beginning the analysis of petitions for sanitary reframing. §3 The granting of requests for sanitary classification is subject to the publication of a valid Certificate of Good Manufacturing Practices issued by Anvisa and compliance with other requirements for registration of medical devices for in vitro diagnosis. §4 Failure to comply with the provisions of the caput will result in the cancellation of the product notification. Art. 66. Registration processes whose products have had their regularization regime modified from registration to notification in accordance with the classification rules will be handled through an Anvisa rectification petition. Art. 67. Control devices without assigned quantitative or qualitative values are now classified as medical devices for in vitro diagnosis and must be duly regularized within 365 days from the entry into force of this Resolution.	

GAP ANALYSIS REPORT – RDC 36/2015 *versus* RDC 830/2023

RDC Item or Subject	RDC 36/2015	RDC 830/2023	Gap Analysis
		Art. 68. Products for the extraction of deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), auxiliary to in vitro diagnostic procedures, must be duly regularized within 365 days from the entry into force of this Resolution.	