COLLEGIATE BOARD RESOLUTION – RDC NO. 657 OF 24 MARCH 2022

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Provides for the regularization of Software as a Medical Device – SaMD.

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, item III of Law no. 9,782 of 26 January 1999, and item VI, paragraphs 1 and 3 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 23 March 2022, and I, Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Article 1. This Resolution provides for the regularization of Software as a Medical Device – SaMD.

Paragraph 1. For the purposes of this Resolution, the medical products and the products for *in vitro* diagnosis regulated by Collegiate Board Resolution – RDC no. 185, of 22 October 2001, Collegiate Board Resolution – RDC no. 36, of 26 August 2015, and Collegiate Board Resolution – RDC no. 40, of 26 August 2015, or successor regulations, are considered as medical devices.

Paragraph 2. This Resolution does not apply to the following software:

I – intended for welfare;

II – listed by the Brazilian Health Regulatory Agency (Anvisa) as non-regulated products;

III – used exclusively for administrative and financial management in health services;

IV – which processes medical demographic and epidemiological data, with no clinical diagnostic or therapeutical purpose; and

V – embedded in a medical device subjected to health surveillance.

Article 2. For the purposes of this Resolution, the following definitions are applicable:

I – valid clinical association or scientific validity: extension to which the SaMD output (concept, conclusions, measurements) is clinically acceptable or well-founded, based on an established scientific framework or evidence, and accurately corresponds in the real world to the health situation and conditions identified in the SaMD scope declaration;

II – clinical assessment: set of activities conducted in the assessment and analysis of clinical safety, effectiveness, and performance of a SaMD, according to the purpose intended by the manufacturer;

III – cybersecurity: a status in which information and systems are protected against unauthorized activities, such as access, use, disclosure, disruption, alteration, or destruction, to an extent where the risks related to confidentiality, integrity, and availability are kept at an acceptable level throughout their life cycle;

IV – compatibility: capability of a device, including software, to work without losing or jeopardizing its intended performance, integrate or work without the need for alteration or adaptation of any part of the devices combined, or be jointly used without conflict/ interference or adverse reaction, when used together with one or more devices according to its intended purpose;

V – visual identity alteration: any alteration that may have a significant impact on the software usability, or visual alteration that hinders the software recognition in accordance with its regularization;

VI – interoperability: capability of two or more devices, including software, of the same manufacturer or different manufacturers, to exchange information and use the information exchanged to correctly execute a specified function without altering data and communicate to each other, or to operate jointly as intended;

VII – software as a medical device – SaMD: software that meets the definition of medical device. It may be *in vitro* diagnosis (IVD) or not, intended to be used for one or more medical purposes that perform theses purposes without being part of a hardware medical device. It includes mobile applications and software with the purposes of *in vitro* analysis, if their indications are included in the general definition of medical device. This definition includes, among others, subscription-licensed software and hosted software service (or Software as a Service), which meet the definition of medical device;

VIII – embedded software: software developed to be incorporated into specific hardware devices with processors. Its development does not allow its use in different devices of general purposes, such as conventional computers, smartphones, tablets, or wearable devices;

IX – welfare software: software intended to encourage and maintain welfare, including healthy activities, such as physical exercise, or to encourage and maintain health control and a healthy lifestyle, which is not intended for prevention, diagnosis, treatment, rehabilitation, or anticonception;

X – validation: confirmation through analysis and objective evidence that the requirements defined for a particular purpose consistently lead to the expected result, and it may be analytical or clinical validation, depending on the SaMD indication of use;

XI – analytical validation: measurement of a SaMD capability to generate reliably and accurately the technical results intended from entry data; and

XII – clinical validation or clinical usefulness: measurement of a SaMD capability to produce a clinically significant output, related to the SaMD output target use in the situation or condition of target healthcare identified in the SaMD definition statement. Clinically significant means the positive impact of a SaMD on the health of a person or population, to be specified as relevant and measurable clinical results for the patient, including the result(s) related to the SaMD purpose (for example, diagnosis, treatment, risk forecasting, forecasting of response to treatment) or a positive impact in individual or public health.

CHAPTER II

GENERAL PROVISIONS

Article 3. Software with medical applications that is considered accessories exclusively used by medical devices and embedded software with medical applications must be regularized together with the related medical devices subject to health surveillance.

Article 4. The SaMD must meet the rules and be organized in classes, in accordance with the Collegiate Board Resolution – RDC no. 185 of 22 October 2001, or later regulations.

Sole paragraph. Regardless of the SaMD risk classification for *in vitro* analysis, its regularization must meet the other rules according to Collegiate Board Resolution – RDC no. 185 of 22 October 2001, or later regulations.

Article 5. SaMD developed internally (in house) by the health service, exclusively used by the health service, headquarters or branches, classified as risk classes I and II, are not subject to regularization by Anvisa, as long as they do not interfere with the performance of medical devices subject to regularization.

Paragraph 1. The commercialization or donation of an in-house developed SaMD, without the due regularization by Anvisa, is forbidden.

Paragraph 2. The health service must have complete validation records of the in-house developed SaMD, including documentation that with evidence of its in-house development and the history of alterations.

Paragraph 3. In case the health service does not have the validation records referred to in Paragraph 2, for at least 10 (ten) years after the in-house developed SaMD disposal, it shall be considered as non-regularized, and it is subject to the applicable health and administrative penalties.

Paragraph 4. Validation evidence must be sufficient to ensure consistent accuracy, reliability, and intended performance, as well as the capability of distinguishing invalid or altered records.

Paragraph 5. Health services shall have a period of two years, counting from the date this Resolution is published, to conduct the validation of the in-house developed SaMD.

Article 6. The SaMD menus must be in Portuguese, preferably, and they may be alternatively in English or Spanish, as long as they meet the following requirements:

I – the meanings of each menu item and commands are explained in Portuguese in the use instructions;

II – it is not intended for use by lay persons or in a home environment;

III – it is considered as an acceptable risk by the company management risk system; and

IV – the need for fluency in the menu language is established as one of the pre-requirements the operators must meet.

CHAPTER III

LABELING AND USE INSTRUCTIONS REQUIREMENTS

Article 7. Use instructions and labeling must meet the provisions regarding medical devices, in accordance with Collegiate Board Resolution – RDC no. 185 of 22 October 2001 and Collegiate Board Resolution – RDC no. 431 of 13 October 2020, or later regulations. In addition, the company must add to the use instructions, or into the SaMD itself, the following information required for the safe and effective operation of the SaMD:

I – the SaMD update procedures;

II – the minimum hardware and software requirements;

III – operating principle, including generic descriptions of algorithms, routines, and formulas used to generate the clinical processing (prevention, diagnosis, treatment, rehabilitation, or anticonception) and its valid clinical associations;

IV – alerts and warnings;

V – interoperability specifications, indication of compatibilities and incompatibilities of software, hardware, and technological environment; and

VI – cybersecurity information.

Article 8. The information on the label and use instructions may be made available in the software itself, in an easily accessible location.

Paragraph 1. If software distribution is virtual, the company shall be exempted from presenting a hard copy of the label and use instructions.

Paragraph 2. The company must include in the information referred to in the caption of this article an identification of the product and its version, which allows for traceability of production in accordance with the Good Manufacturing Practices, instead of batch or serial number.

CHAPTER IV

REGULARIZATION OF SOFTWARE AS A MEDICAL DEVICE

Article 9. The regularization of a SaMD must meet the general provisions for medical devices, particularly Collegiate Board Resolution – RDC no. 185 of 22 October 2001 and Collegiate Board Resolution – RDC no. 40 of 26 August 2015, including their updates.

Article 10. In case of SaMD of risk classes I and II, the company must present a software notification petition form duly filled in, which is available on Anvisa website.

Article 11. The technical dossier of the SaMD notification regimen for risk classes I and II, which remains held by the notification holding company, must include:

SaMD Technical Dossier[1]	**Notification**	
	Class I	**Class II**
Chapter 1		
Administrative and Technical Information (forms available on Anvisa Website)	X	X

List of devices (Models/ Components/ Variants)	X	X
Chapter 2		
Software Detailed Description and Principles of Operation and Action	X	X
Intended Purpose (Use Purpose); Intended User; Use Indication	X	X
Environment/ Context of Intended Use	X	X
Use Contraindications	X	X
Global Commercialization History	-	X
Chapter 3		
Risk Management	X	X
List of Essential Security and Performance Requirements	-	X
List of Technical Regulations	X	X
Firmware Description	X	X
Software Development Plan and Software Maintenance Plan	-	X
Software Architecture	X	X
Tests of compatibility and interoperability with other software and hardware the medical software interacts with	X	X
List of residual anomalies (including known errors and defects) unsolved with risk analysis	X	X
Traceability Document for requirements, specifications, verification and validation tests, and related risks	-	X
Review history describing the alterations made	X	X
Description of versions (including components)	X	X
Cybersecurity architecture	-	X
Declaration of conformity with international regulations or their national versions (included in Articles 13, 14, and 15 of this Resolution)	-	X
Usability/ Human Factors	X	X
Chapter 4		
General Summary of Clinical Evidence[2]	X	X
Relevant Clinical Literature	-	X
Chapter 5		
Product Labeling	X	X
Use Instructions/ User Manual	X	X
Chapter 6		
General Manufacturing Information (Addresses of Manufacturing Plants)	X	X
Manufacturing Process (Flowchart)	X	X
Project and Development Information	X	X

Notes:

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

2 – Applicable only when clinical evidence is required to prove security and performance of technological innovations and new use indications, in accordance with the current health legislation for clinical trials conducted in Brazil, and the Specific Special Notification must be presented.

Article 12. The technical report of SaMD of risk classes III and IV, to be presented in the marketing authorization process, must also include:

I – software architecture;

II – hardware architecture and minimum and recommended technical requirements;

III – platform;

IV – compatibility, interoperability, and communication with other medical products, including other software or products for *in vitro* diagnosis;

V – architecture information and cybersecurity controls;

VI – verification and validation;

VII – risk management;

VIII – residual anomalies identified and ways to mitigate them;

IX – clinical assessment and valid clinical association, including the description of algorithms and/or routines used to generate the processing of suggestions for prevention, diagnosis, treatment, physiological monitoring, rehabilitation, or anticonception, and their clinical or scientific justifications; and

X – declaration of conformity with international regulations or their national versions.

Article 13. The declaration of conformity with international regulations or their national versions must include at least the following versions:

I – IEC 62304:2006 Medical device software – Software life cycle processes;

II – IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices; and

III – ISO 14971:2007 Medical devices – Application of risk management to medical devices.

Sole paragraph. More recent versions or versions equivalent to the regulations referred to in the items of Article 13 may be adopted.

Article 14. The declaration of conformity with international regulations or their national versions must include the product identification, models, identification code for each model, which allows for production traceability in accordance with the Good Manufacturing Practices, manufacturer identification, conformity regulations, identification of trials and tests conducted to justify conformity, manufacturer's signature.

Article 15. If the company does not present the declaration of a regulation referred to in the items of Article 13, it must present the technical justification and the following documents that prove the product safety and effectiveness corresponding to the missing regulation:

I – description of the product lifecycle;

II – report of the usability studies (human factors) for the SaMD; and

III – risk management report.

Sole paragraph. In case there are international or national specific Technical Regulations for the SaMD, their reports of tests and verifications may be used to prove the product safety and effectiveness, and its approval is subject to Anvisa technical analysis.

CHAPTER VI

POST-REGULARIZATION ALTERATIONS

Article 16. The alterations of a SaMD information must meet the general provisions of Collegiate Board Resolution – RDC no. 340 of 6 March 2020, including its updates. In addition, the following alterations are subject to alteration petition:

I – alterations that create new functionalities or clinical use indications;

II – alterations that may significantly affect clinical functionalities, clinical safety and effectiveness, or performance related to previously intended purposes; and

III – alterations that may change visual identity, in such a way that the software is no longer recognized with the images sent to Anvisa.

Sole paragraph. Alterations intended for simple maintenance are not subject to petitioning with Anvisa. Examples of such alterations include visual changes that do not alter visual identity, error corrections, programming reviews, or just information security alterations that do not affect indications of use, SaMD effectiveness, or another patient safety factor.

CHAPTER VII

SAFETY AND EFFECTIVENESS OF SOFTWARE AS MEDICAL DEVICE

Article 17. The regularization of a SaMD, related to the essential requirements of safety and effectiveness for health products, must follow the general provisions of Collegiate Board Resolution – RDC no. 546 of 30 August 2021 and its updates, complemented by the following information:

I – The risks associated with the eventual negative interaction between the software and the Information Technology environment in which it operates and interacts;

II – The devices incorporating programmable electronic systems, including software, or software that constitutes a medical device on its own, must be designed to ensure repeatability, reliability, and performance according to its intended use. In case of single failure, adequate measures must be taken to eliminate or reduce, as far as possible, potential risks or performance decrease rising from such failure;

III – Regarding devices incorporating software, or software that constitutes a medical device on its own, the software may be developed and manufactured in accordance with current knowledge, considering the principles of development lifecycle, risk management (including information security), verification, and validation;

IV – Software that constitutes a medical device on its own, which is intended to be used jointly with mobile platforms, must be designed and manufactured compatible with the specific

characteristics of the mobile platform (for example, size, resolution, and screen contrast) and the external factors related to its use (variable environment regarding the level of light or noise); and

V – Manufacturers must indicate the minimum hardware requirements, computer network characteristics, and cybersecurity measures (that is, protection against unauthorized access), which are necessary for the software to operate as intended.

CHAPTER VIII

FINAL AND TRANSITIONAL PROVISIONS

Article 18. The manufacturer shall not commercialize the SaMD or its updates, as licensing or equivalent form, or make it available to new users, in case its regularization is expired or cancelled.

Article 19. In case of doubt related to the classification resulting from the enforcement of health regulations in applicable resolutions, the company may request the SaMD classification through the communication channels available, by filling the software classification form, available on Anvisa website.

Article 20. The regularization processes granted before this Resolution enters into force must be made adequate or complemented in their future alterations.

Article 21. The requesting company is responsible for maintaining conformity between SaMD information and the information declared in regularization processes.

Article 22. This Resolution complements Collegiate Board Resolution – RDC no. 185/2001, Collegiate Board Resolution – RDC no. 36/2015, Collegiate Board Resolution – RDC no. 40/2015, Collegiate Board Resolution – RDC no. 15/2014, Collegiate Board Resolution – RDC no. 431/2020, Collegiate Board Resolution – RDC no. 546/2001, Collegiate Board Resolution – RDC no. 340/2020, Collegiate Board Resolution – RDC no. 551/2021, Collegiate Board Resolution – RDC no. 67/2009, and their updates in force.

Article 23. The regularized product is subject to audit, marketing monitoring, and inspection by the competent health authorities. In case of irregularities, its regularization may be suspended until the problem identified is resolved, or it may be cancelled, without prejudice to the applicable administrative, civil, and criminal responsibilities.

Article 24. The post-marketing monitoring of the SaMD behavior, as well as adverse event notification, technical complaint, and field action, must be carried out in accordance with the legislation and regulations in force, and through the channels indicated by Anvisa.

Article 25. This Resolution enters into force on 1 July 2022.

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