Ministry of Health - MS

National Health Surveillance Agency – ANVISA

COLLEGIATE BOARD RESOLUTION - RDC No. 657, OF MARCH 24, 2022

(Published in the Official Gazette No. 61, dated March 30, 2022)

Provides for the regularization of software as a medical device (Software as a Medical Device - SaMD).

The **Collegiate Board of the National Health Surveillance Agency,** in exercise of the powers conferred upon it by arts. 7, paragraph III, and 15, paragraphs III and IV, of Law No. 9,782, of January 26, 1999, and considering the provisions of art. 187, paragraph VI and §§ 1º and 3º, of the Internal Regulations, approved by Collegiate Board Resolution - RDC No. 585, of December 10, 2021, resolves to adopt the following Collegiate Board Resolution, as deliberated at a meeting held on March 23, 2022, and I, the Chief Executive Officer, determine its publication:

CHAPTER I

INITIAL PROVISIONS

Art. 1 This Resolution provides for the regularization of software as medical device (Software as a Medical Device - SaMD).

§ 1º For the purposes of this Resolution, medical devices are considered to be medical products and in vitro diagnostic products regulated by Collegiate Board Resolution - RDC No. 185, of October 22, 2001, Collegiate Board Resolution - RDC No. 36, of August 26, 2015, and Collegiate Board Resolution - RDC No. 40, of August 26, 2015, or subsequent regulations.

§ 2 This Resolution does not apply to the following software:

I - for well-being;

II - related in a list made available by the National Surveillance Agency Sanitary (Anvisa) of unregulated products;

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

IV - which processes demographic and epidemiological medical data, without any clinical diagnostic or therapeutic purpose; and

V - shipped in a medical device under health surveillance.

Art. 2 For the purposes of this Resolution, the following definitions apply:

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

II - clinical evaluation: Set of activities carried out in the evaluation and analysis of the clinical safety, efficacy and performance of a SaMD, according to the purpose intended by the manufacturer;

III - cybersecurity: A state in which information and systems are protected against unauthorized activities, such as access, use, disclosure, disruption, modification or destruction, to a level in which risks related to confidentiality, integrity and availability are maintained at an acceptable level throughout the life cycle;

IV - compatibility: Ability of a device, including software, to, when used together with one or more devices in accordance with their intended purpose: function without loss or compromise of the ability to perform as intended, integrate or function without the need for alteration or adaptation of any of the parts of the combined devices, or be used together without conflict/interference or adverse reaction;

V - distortion of visual identity: Any change that has a significant impact on the usability of the software or visual change that prevents the recognition of the software as it had been regularized;

VI - interoperability: Ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to exchange information and use the exchanged information for the correct execution of a specified function without altering the content of the data and to communicate with each other, or to function together as intended;

VII - Software as a Medical Device
SaMD): Software that meets the definition of a medical device, which may or may not be in vitro diagnostic (IVD), intended for one or more medical indications, and which performs these purposes without being part of the medical device hardware.
Includes mobile applications and software for in vitro purposes, if their indications are included in the general definition of medical devices. This definition includes, among others, software licensed by subscription and centrally hosted (Software as a Service), which falls within the definition of medical devices;

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

IX - well-being software: Software intended to encourage and maintain well-being, including healthy activities such as physical exercise, or to encourage and maintain health control and a healthy lifestyle that are not intended for prevention, diagnosis, treatment, rehabilitation or contraception;

X - validation: Confirmation through analysis and objective evidence that the requirements defined for a given purpose consistently lead to the expected result, which may consist of analytical or clinical validation depending on the indication for use of SaMD;

XI - analytical validation: Measurement of the ability of a SaMD to reliably and accurately generate the intended technical result from the input data; and

XII - clinical validation or clinical utility: Measurement of the ability of a SaMD to produce a clinically meaningful output, associated with the target use of the SaMD output in the target health care situation or condition identified in the SaMD definition statement. Clinically meaningful means the positive impact of a SaMD on the health of an individual or population, to be specified as relevant, measurable and patient-relevant clinical outcomes, including outcome(s) related to the function of the SaMD (e.g. diagnosis, treatment, risk prediction, prediction of response to treatment) or a positive impact on individual or public health.

CHAPTER II

GENERAL PROVISIONS

Art. 3 Software with medical applications that are considered accessories for exclusive use of medical devices and software with embedded medical applications must be regularized together with the associated medical devices under health surveillance.

Art. 4º SaMD must be classified under the rules and classes in accordance with the Collegiate Board Resolution - RDC No. 185, of October 22, 2001, or subsequent regulations.

Sole paragraph. Notwithstanding the risk classification of SaMD for in vitro, its regularization must follow the other rules in accordance with the Collegiate Board Resolution - RDC No. 185, of October 22, 2001, or subsequent regulations.

Art. 5º SaMD developed internally (in house) by the health service and for the exclusive use of the health service, head office or branches, which fall into risk classes I and II, will not be subject to regularization by Anvisa, as long as they do not interfere with the operation of medical devices subject to regularization.

§1º The commercialization or donation of SaMD developed internally is prohibited without due regularization with Anvisa.

§ 2º The health service must have complete records of the validation of the SaMD developed internally, including documentation that demonstrates its internal development and the history of changes.

§ 3 If the health service does not have the validation records described for at least 10 (ten) years after the disposal of the SaMD developed internally, it will be considered non-regularized and will be subject to the applicable health and administrative penalties.

§ 4º Validation evidence must be sufficient to ensure consistent accuracy, reliability, and intended performance and the ability to discern invalid or altered records.

§ 5º Health services will have a term of two years, from the publication of this Resolution, to carry out the validation of the SaMD developed internally.

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

I - be explained in the instructions for use, in Portuguese, meaning of each menu item and commands;

II - is not intended for use by lay people or in a domestic environment;

III - this approach is considered an acceptable risk in the company's risk management; and

IV - the need for the level of fluency is described in the instructions for use in the language as one of the prerequisites for operators.

CHAPTER III

LABELING REQUIREMENTS AND INSTRUCTIONS FOR USE

Art. 7º The instructions for use and labeling must follow the provisions for medical devices in accordance with the Collegiate Board Resolutions - RDC No. 185, of October 22, 2001 and Collegiate Board Resolution - RDC No. 431, of October 13, 2020, or subsequent regulations. Additionally, the company must add, in the instructions for use or in the SaMD itself, the following information necessary for the safe and effective operation of the SaMD:

I - the procedures for updating SaMD;

II - minimum hardware and software requirements;

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

IV - alerts and warnings;

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

VI - cybersecurity information.

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

§ 1º If the software distribution is virtual, the company is exempt the physical presentation of the label and instructions for use.

§ 2º The company must include in this information an identification of the product and version, which allows the traceability of production in accordance with good manufacturing practices, instead of the batch or serial number.

CHAPTER IV

REGULARIZATION OF SOFTWARE AS A MEDICAL DEVICE

Art. 9 The regularization of a SaMD must follow the general provisions of medical devices, in particular the Collegiate Board Resolution - RDC No. 185, of October 22, 2001, and the Collegiate Board Resolution - RDC No. 40, of August 26, 2015, including their updates.

Art. 10. In the case of SaMD risk class I and II, a duly completed software notification petition form must be submitted, available on Anvisa's electronic portal.

Art. 11. The technical dossier, of the SaMD notification regime, risk class I and II, which remains in the possession of the company holding the notification, must contain:

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Dossiê Técnico de Dispositivo Médico[1] – SaMD	Notificação	
	Classe I	Classe II
Capítulo 1		
Informações Administrativas e Técnicas (formulários disponíveis no Portal da Anvisa)	X	X
Lista dos dispositivos (Modelos / Componentes / Variantes)	X	X
Capítulo 2		
Descrição Detalhada do Software e Fundamentos de Funcionamento e Ação	X	X
Finalidade Pretendida (Finalidade de Uso); Propósito de Uso; Usuário Pretendido; Indicação de Uso	X	X
Ambiente / Contexto de Uso Pretendido	X	X
Contraindicações de Uso	X	X
Histórico Global de Comercialização	-	X
Capítulo 3		
Gerenciamento de Risco	X	X
Lista dos Requisitos Essenciais de Segurança e Desempenho	-	X
Lista de Normas Técnicas	X	X
Descrição do Firmware	X	X
Plano de desenvolvimento de software e plano de manutenção de software	--	X
Arquitetura de Software	X	X
Testes de compatibilidade e interoperabilidade com os outros softwares e hardware que o software médico interage	X	X
Lista de anomalias residuais (incluindo os erros e defeitos conhecidos) não resolvidos com análise de risco	X	X
Documento de Rastreabilidade dos requisitos, especificações, testes de verificação e validação e riscos associados.	--	X
Histórico de revisão com descrição das mudanças realizadas	X	X
Descritivos das versões (incluindo os componentes)	X	X
Arquitetura de cibersegurança	--	X
Declaração de conformidade com normas internacionais ou suas versões nacionais (constante nos Art. 13., 14. e 15. desta resolução)	--	X
Usabilidade / Fatores Humanos	X	X
Capítulo 4		
Resumo Geral da Evidência Clínica[2]	X	X
Literatura Clínica Relevante	-	X
Capítulo 5		
Rotulagem do Produto	X	X
Instruções de Uso / Manual do Usuário	X	X
Capítulo 6		
Informações Gerais de Fabricação (Endereços das Unidades Fabris)	X	X
Processo de Fabricação (Fluxograma)	X	X
Informações de Projeto e Desenvolvimento	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 possible future editions.

2-Applicable only when clinical evidence is required as a result of demonstration of safety and performance, technological innovations and new indications for use. In accordance with current health legislation for clinical trials conducted in Brazil, a Specific Special Communication must be presented.

Art. 12. The technical report of SaMD risk class III and IV, to be presented in the registration process, must additionally 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 diagnostic use;

V - information on cybersecurity architecture and controls;

VI - verification and validation;

VII - risk management;

VIII - residual anomalies identified and ways to mitigate them;

IX - clinical evaluation and valid clinical association, including the description of the algorithms and/or routines used to generate the processing of suggestions for prevention, diagnosis, treatment, physiological monitoring, rehabilitation or contraception and their clinical or scientific foundations; and

X - declaration of conformity with international standards or their national versions.

Art. 13. The declaration of conformity with international standards 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 current or equivalent versions may be adopted.

of the aforementioned standards;

Art. 14. The declaration of conformity with international standards or their national versions must include the identification of the product, models, identification coding of each model, which allows the traceability of production in accordance with good manufacturing practices, identification of the manufacturer, standards in compliance, identification of the tests and examinations carried out to justify conformity, signature of the manufacturer;

Art. 15. If the declaration of any of the standards cited in the items of art. 13 is not presented, a technical justification and the following documents demonstrating the safety and effectiveness of the product corresponding to the missing standard must be presented:

I - Description of the product life cycle;

II - Report on usability studies (human factors) for SaMD; and

III - Risk management report.

Sole paragraph. In the event that there are specific Technical Standards for SaMD, whether international or national, their test and verification reports may be used to demonstrate the safety and efficacy of the product, with their acceptance being subject to technical analysis by Anvisa.

CHAPTER VI

POST-REGULARIZATION CHANGES

Art. 16. Changes to information in a SaMD must follow the general provisions set forth in the Collegiate Board Resolution - RDC No. 340, of March 6, 2020, including its updates. Additionally, the following modifications are subject to a change request:

I - create new functionalities or clinical indications for use;

II - significantly affect clinical functionality, safety and clinical efficacy or performance associated with the purposes set out above; and

III - distort the visual identity, so that it is no longer the software is recognizable from the images sent to Anvisa.

Sole paragraph. Modifications for simple maintenance purposes, such as visual changes that do not alter the visual identity, error corrections, programming revisions, or just information security modifications that do not affect the indications for use, the effectiveness of SaMD or other aspects of patient safety, are not subject to petition to Anvisa.

CHAPTER VII

SAFETY AND EFFICACY OF SOFTWARE AS A MEDICAL DEVICE

Art. 17. The regularization of a SaMD, referring to essential safety and efficacy requirements of health products, must follow the general provisions of the Collegiate Board Resolution - RDC No. 546, of August 30, 2021, and its updates, supplemented by the information below:

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

II - Devices incorporating programmable electronic systems, including software, or software which in itself constitutes a medical device, must be designed to ensure repeatability, reliability and performance in accordance with their intended use. In the event of a single failure condition, appropriate measures must be taken to eliminate or reduce, as far as possible, the risks or reduced performance that may arise from it;

III - With regard to devices incorporating software or software that constitutes, in itself, a medical device, the software must be developed and manufactured in accordance with the current state of knowledge, taking into account the principles of the development life cycle, risk management, including information security, verification and validation;

IV - Software that constitutes, in itself, a medical device and is intended to be used in conjunction with mobile platforms must be designed and manufactured in a manner compatible with the specific characteristics of the mobile platform (e.g. screen size, resolution and contrast) and the external factors related to its use (variable environment with regard to light or noise level); and

V - Manufacturers must indicate the minimum hardware requirements, computer network characteristics and cybersecurity measures, namely protection against unauthorized access, necessary for the software to function as intended.

CHAPTER VIII

FINAL AND TRANSITORY PROVISIONS

Art. 18. The manufacturer may not commercialize, in the form of licensing or equivalent, or make available to new users SaMD or its updates with expired or canceled regularization.

Art. 19. In case of doubt in the classification resulting from the application of the health classification rules contained in the applicable resolutions, the company may request the classification of SaMD through the available communication channels by completing the software classification form, available at
Anvisa electronic portal.

Art. 20. Regularization processes granted prior to the validity of this Resolution must be adapted or supplemented in acts of future amendments.

Art. 21. Maintaining compliance between the information relating to SaMD and that declared in the regularization processes is the responsibility of the requesting company.

Art. 22. This Resolution is complementary to the Collegiate Board Resolutions - RDC No. 185, of 2001, Collegiate Board Resolution - RDC No. 36, of 2015, Collegiate Board Resolution - RDC No. 40, of 2015, Collegiate Board Resolution - RDC No. 15, of 2014, Collegiate Board Resolution - RDC No. 431, of 2020 and Collegiate Board Resolution - RDC No. 546, of 2001, Collegiate Board Resolution - RDC No. 340, of 2020, Collegiate Board Resolution - RDC No. 551, of 2021 and Collegiate Board Resolution - RDC No. 67, of 2009 and their current updates.

Art. 23. The regularized product is subject to audit, market monitoring and inspection by the competent health authority and, if an irregularity is found, its regularization may be suspended until the identified problem is corrected, or cancelled, without prejudice to the applicable administrative, civil and criminal liabilities.

Art. 24. Monitoring of SaMD behavior in the post-market, as well as notification of adverse events, technical complaints and field actions, must be carried out in accordance with current legal and regulatory provisions, and through the channels indicated by Anvisa.

Art. 25. This Resolution shall come into force on July 1, 2022.

ANTONIO BARRA TORRES