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

(Published in DOU No. 61 of March 30, 2022)

It provides for the regulation of software as a medical device (Software as a Medical Device - SaMD).

The Collegiate Board of Directors of the National Health Surveillance Agency, in the use of the powers conferred on it by the arts. 7, item III, and 15, items III and IV, of Law No. 9,782, of January 26, 1999, and considering the provisions of article 187, item VI and §§ 1 and 3, of the Internal Regulations, approved by the Resolution of the Collegiate Board of Directors - RDC n° 585, of December 10, 2021, resolves to adopt the following Resolution of the Board of Executive Officers, as resolved at a meeting held on March 23, 2022, and I, the Chief Executive Officer, determine its publication:

CHAPTER I

INITIAL PROVISIONS

SECTION I

OBJECTIVE

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

§ 1 For the purposes of this Resolution, medical devices are considered medical devices and in vitro diagnostic products regulated by the 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;

1. - listed in a list made available by the National Health Surveillance Agency (Anvisa) of non-regulated products;
2. - used exclusively for administrative and financial management in health services;
3. - which processes demographic and epidemiological medical data without any diagnostic or therapeutic clinical purpose; and
4. - embarked on a medical device under a health surveillance regime.

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

- valid clinical association or scientific validity: The extent to which the output of the SaMD (concept, conclusion, measurements) is clinically accepted or well-founded, based on an established scientific framework or evidence, and corresponds accurately

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in the real world to the health situation and conditions identified in the SaMD scope statement;

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

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

- compatibility: The ability of a device, including software, to, when used in conjunction with one or more devices in accordance with its intended purpose: function without losing or compromising the ability to perform as intended, integrate or function without the need to alter or adapt any of the parts of the combined devices, or be used together without conflict/interference or adverse reaction;

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

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

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

- embedded software: Software designed to be embedded in 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;

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

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

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

- Clinical validation or clinical utility: Measurement of a SaMD's ability to produce a clinically meaningful output, associated with the target use of the SaMD output in the target healthcare situation or condition identified in the SaMD definition statement. Clinically significant 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 the function-related outcome(s) of the SaMD (e.g., diagnosis, treatment, risk prediction, treatment response prediction) or a positive impact on

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individual or public health.

CHAPTER II

GENERAL PROVISIONS

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

Art. 4 The SaMD must be framed in the rules and classes in accordance with the Collegiate Board Resolution - RDC No. 185, of October 22, 2001, or subsequent regulations.
Single paragraph. Notwithstanding the risk classification of the SaMD for in vitro, its regularization must follow the other rules in accordance with the Resolution of the Collegiate Board of Directors - RDC No. 185, of October 22, 2001, or subsequent regulations.

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

§1 It is forbidden to commercialize or donate the SaMD developed internally without due regularization in Anvisa.

§ 2 - 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 In the event that 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, being subject to the appropriate sanitary and administrative penalties.
(4) Evidence of validation shall be sufficient to ensure consistent accuracy, reliability and intended performance and the ability to discern invalid or altered records.

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

Art. 6 The SaMD menus must preferably be in Portuguese, and may alternatively be in English or Spanish, provided that they meet all the following requirements:

1. - be explained in the instructions for use, in Portuguese, the meaning of each menu item and commands;
2. - is not intended for use by laypeople or in a domestic environment;
3. - this approach is considered acceptable risk in the company's risk management; and
4. - the need for the level of fluency in the language is described in the instructions for use as one of the prerequisites for operators.

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CHAPTER III

LABELLING REQUIREMENTS AND INSTRUCTIONS FOR USE

Art. 7 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. In addition, 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 SaMD:

1. - the procedures for updating SaMD;
2. - minimum hardware and software requirements;
3. - working 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;
4. - warnings and warnings;
5. - Interoperability specifications, indication of compatibilities and incompatibilities of software, hardware and technological environment;
6. - cybersecurity information.

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

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

§ 2 - 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 A SOFTWARE AS A MEDICAL DEVICE

Art. 9 The regularization of a SaMD must follow the general provisions of medical devices, in particular the Resolution of the Collegiate Board of Directors - RDC No. 185, of October 22, 2001, and the Resolution of the Collegiate Board of Directors - RDC No. 40, of August 26, 2015, including its updates.
Art. 10. In the case of SaMD risk class I and II, a petition form for software notification must be submitted, duly completed, 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, shall 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 can be updated considering any 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

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accordance with the current health legislation for clinical trials conducted in Brazil, the Specific Special Communiqué must be submitted.

Art. 12. In the technical report of SaMD risk class III and IV, to be presented in the registration process, it should be included, additionally:

1. - software architecture;
2. - Hardware architecture and minimum and recommended technical requirements;
3. -platform;
4. - compatibility, interoperability and communication with other medical products, including other software or products for in vitro diagnostics;
5. - information on cybersecurity architecture and controls; VI - verification and validation;
6. - risk management;
7. - identified residual anomalies and ways to mitigate them;
8. - clinical evaluation and valid clinical association, including a 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
9. Declaration of conformity with international standards or their national versions.

Art. 13. The declaration of conformity with international standards or their national versions shall include at least the following versions:

1 - IEC 62304:2006 - Medical device software -- Software life cycle processes;

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

3 - ISO 14971:2007 Medical devices -- Application of risk management to medical devices.

Single paragraph. More current or equivalent versions of the above standards may be adopted;

Art. 14. The declaration of conformity with international standards or their national versions must bring 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 conformity, 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 mentioned in the items of article 13 is not presented, the technical justification and the following documents that demonstrate the safety and efficacy of the product corresponding to the missing standard must be presented:

1. - Descriptive of the life cycle of the product;
2. - Report of usability studies (human factors) for SaMD; and III - Risk

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management report.

Single paragraph. In the event that there are specific Technical Standards for SaMD, international or national, their test and verification reports can be used to demonstrate the safety and efficacy of the product, and their acceptance is subject to the technical analysis of Anvisa.

CHAPTER VI

POST-REGULARISATION AMENDMENTS

Art. 16. Changes to the information of a SaMD must follow the general provisions contained in the Collegiate Board Resolution - RDC No. 340, of March 6, 2020, including its updates. In addition, modifications are subject to the amendment petition which:

1. - create new functionalities or clinical indications for use;
2. - significantly affect the clinical functionalities, clinical safety and efficacy or performance associated with the purposes set out above; and
3. - mischaracterize the visual identity, so that the software is no longer recognizable in the face of the images sent to Anvisa.

Single paragraph. Modifications for simple maintenance, such as visual changes that do not alter the visual identity, error corrections, revisions in the programming, or only information security modifications that do not affect the indications for use, the effectiveness of SaMD or other aspect of patient safety, are not subject to petitioning at Anvisa.

CHAPTER VII

SAFETY AND EFFECTIVENESS OF A SOFTWARE AS A MEDICAL DEVICE

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

1. - The risks associated with the possible negative interaction between the software and the Information Technology environment in which it operates and interacts;
2. - Devices incorporating programmable electronic systems, including software, or software constituting a medical device in its own right, shall be designed to ensure repeatability, reliability and performance in accordance with their intended use. In the event of a single failure condition, appropriate measures shall be taken to eliminate or reduce, as far as possible, the risks or performance impairments that may result therefrom;
3. - With respect to devices incorporating software or software that itself constitutes a medical device, the software shall be developed and manufactured in accordance with the current state of knowledge, taking into account the principles of the development lifecycle, risk management, including information security, verification and validation;
4. - Software constituting a medical device which is intended to be used in

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conjunction with mobile platforms shall 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 the level of light or noise); and

5. - Manufacturers should indicate the minimum hardware requirements, characteristics of computer networks and cybersecurity measures, including protection against unauthorised access, necessary for the software to function as intended.

CHAPTER VIII

FINAL AND TRANSITIONAL PROVISIONS

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

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

Art. 20. The regularization processes granted prior to the validity of this Resolution shall be adequate or complemented in the acts of its future amendments.

Art. 21. The maintenance of compliance between the information related to SaMD and those 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 its current updates.

Art. 23. The regularized product is subject to audit, market monitoring and inspection by the competent sanitary authority and, if irregularity is found, may have its regularization suspended until the correction of the identified problem, or canceled, without prejudice to the applicable administrative, civil and criminal responsibilities.

Art. 24. The monitoring of SaMD's behavior in the post-market, as well as the notification of adverse event, technical complaint and field action, must be done in accordance with the legal and regulatory order in force, and through the channels indicated by Anvisa.

Art. 25. This Resolution enters into force on July 1st, 2022.

ANTONIO BARRA TORRES