Medical Software Regulation

Resolution of the Collegiate Board of Directors - RDC #657 03/24/2022

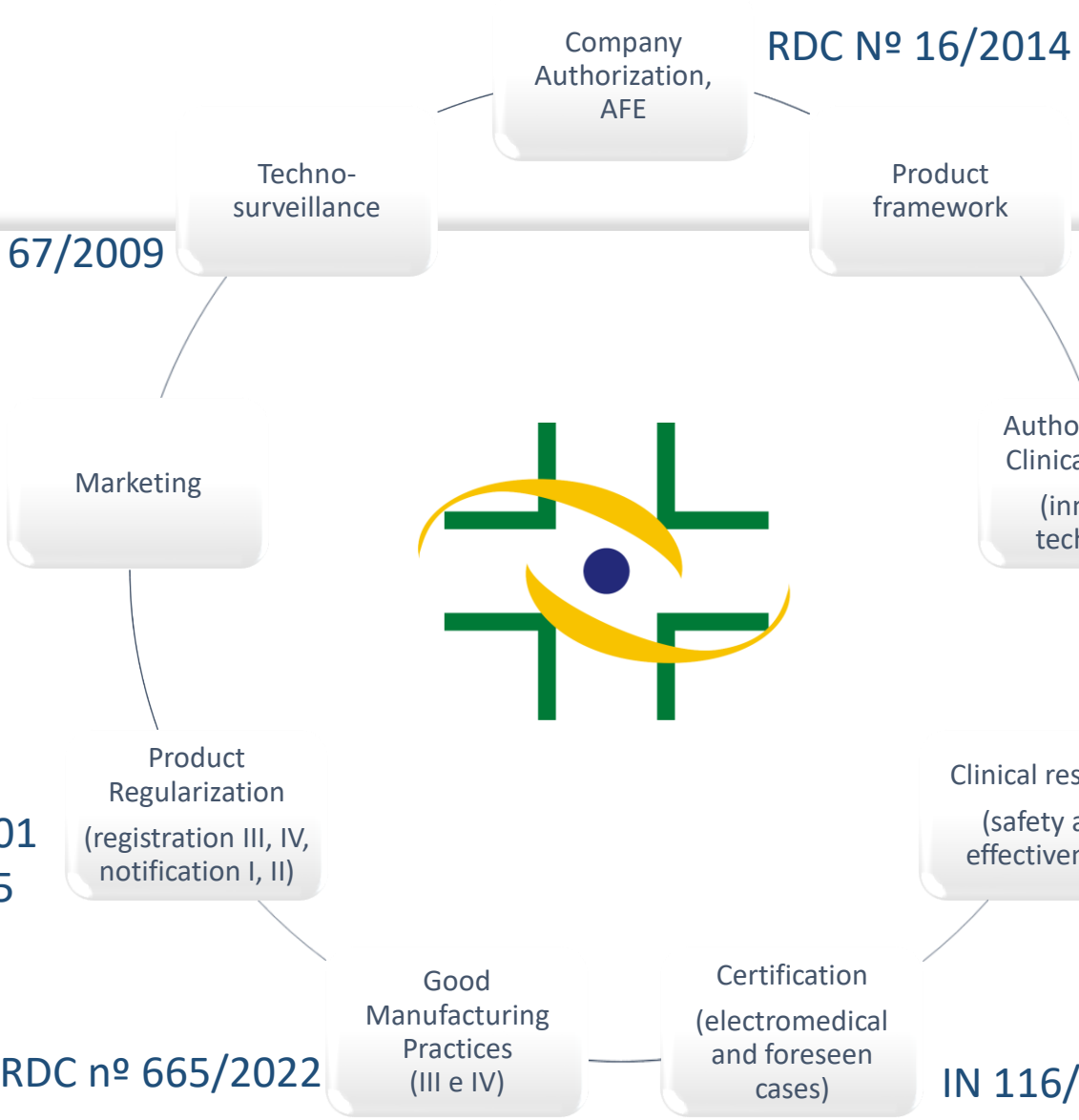
Office of Equipments - GQUIP

Medical Devices Office - GGTPS

Brasília, October 2022

ANVISA
Agência Nacional de Vigilância Sanitária

SANITARY CONTROL



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RDC #657/2022

- Subsidiary to RDC 185/2001 or its update.
- Regulates typical aspects of software as medical devices.
- Determines the scope of software that is considered medical devices subjected to regularization.
- International Harmonization (IMDRF, FDA, EC).

“Software subjected to the Sanitary surveillance regime are those intended for the **prevention, diagnosis, treatment, rehabilitation or contraception of human beings**”

RDC #657/2022 – does not apply

- For well-being;
- Related in a list made available by Anvisa of unregulated products;
- Used exclusively for administrative and financial management in health services;
- That processes demographic and epidemiological medical data, without any diagnostic or therapeutic clinical purpose;
- Embedded in a medical device under sanitary surveillance regime (on-board).

Risk classification is not defined in RDC #657/2022

- The software currently must be framed in the rules presented in RDC 185/2001.
- In the near future there will be a specific rule for software in the resolution that will replace RDC 185/2001.
- RDC 657/2022 will remain valid.
- Risk class I and II - regularization by notification, RDC 40/2015.
- Risk class III and IV -regularization by registration, RDC 185/2001.

- The most common rules that software currently falls under are:
  - Any rule if it performs the function or influences equipment that falls within it. I, II, III or IV.
  - Rule 10 – software that makes or helps in diagnosis and monitoring. II or III.
  - Rule 9 – software that makes or helps in the treatment. II or III.
  - Rule 12 – software with other indications. I.
  - Internal procedure demands to confirm the risk using the IMDRF table.

State of Healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

RDC #657/2022 – define

- Software as a medical device;
- On-board software;
- Clinical evaluation of software;
- Software validations;
- Decharacterization of visual identity;
- Compatibility;
- Interoperability;
- Cybersecurity;
- other terms.

RDC #657/2022 – allows

- Instructions for use and label in digital format in the software itself;
- Menu in English or Spanish as long as it is not of lay use, requirements are met and the risk is analysed;
- SaMD developed internally (in house) by the health service risk classes I and II do not need to be regularized. Health services must validate them internally and they cannot be marketed.

RDC #657/2022 – requires in the software

- Procedures for updating SaMD;
- Minimum hardware and software requirements;
- Operating principle, algorithms, routines and formulas used;
- Alerts and warnings;
- Specifications of interoperability, indication of compatibilities;
- Cybersecurity information.

RDC #657/2022 – establishes

- Need for compliance with standards IEC 62304:2006 - Medical device software -- Software life cycle processes, IEC 62366-1:2015 Medical devices -- Part 1: Application of usability, engineering to medical devices, e - ISO 14971:2007 Medical devices -- Application of risk management to medical devices.
- Situations in which changes to the software regularization process should be submitted to ANVISA if they change indications of use or functionality and/or change the visual identification of the product.

RDC #657/2022 – **essential requirements safety and efficacy**

- In addition to the RDC nº 546/2021:
  - negative interaction between the software and the Information Technology environment;
  - designed to ensure repeatability, reliability and performance;
  - manufactured in accordance with the current state of knowledge, including the security of information;
  - used in conjunction with mobile platforms, should be designed and manufactured in a compatible manner including external factors;
  - minimum hardware, network and cybersecurity requirements.

RDC #657/2022 – Required Documentation

- Indication and use purpose, description of the software (general characteristics and operating environment);
- Operating principles (algorithms used);
- Software architecture, hardware architecture, operating platform, target audience, compatibility (interoperability and communication) with other medical products including other software;
- Security features (access controls and protection - cybersecurity);
- Operational training required.

RDC #657/2022 – Required Documentation

- Infrastructure requirements;
- Verification tests (including success or failure criteria, integration and system tests), resolved and unresolved anomalies or bugs;
- Risk management;
- Warnings and precautions, adverse events;
- Technical standards used in development, manual versions, design and software.

RDC #657/2022 – Required Documentation

Software that uses artificial intelligence (AI) to achieve its medical purpose or to help the software achieve this purpose need to clarify a few more details by presenting:

Report containing rational justifying applied AI technique, size of the bases used and reporting training history;

Description of the information bases used for learning activities, training, verification, etc. of AI, containing origin, amount of data and description of data;

RDC #657/2022 – reaffirms ban

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

RDC #657/2022 – Does not address

- Good manufacturing practices - defined in RDC #665/2022;
- Framework and health risk - defined by RDC #185/2001 and its subsequent updates;
- Requirements for the Efficacy and Safety of Medical Devices - Resolution RDC #546/2021;
- Clinical trials with medical devices - Resolution RDC #548/2021 .

Thank you

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