



IMDRF International Medical
Device Regulators Forum

IMDRF Stakerholder Open Forum

Regulatory Updates Brazil

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Australia

Ana Carolina Moreira Marino Araujo
General Manager – Office of Inspection and Law Enforcement
Brazilian Health Regulatory Agency
ANVISA



Software as Medical Device Regulation

Resolution RDC No. [657/2022](#)

Provides guidance for regularization of Software as a Medical Device (SaMD).

Resolution came into force on 1 July 2022

Based on IMDRF documents:

- Software as a Medical Device (SaMD): Key Definitions (IMDRF/SaMD WG/N10FINAL:2013) (IMDRF, 2013)
- Software as a Medical Device (SaMD): Possible Framework for Risk Categorization and Corresponding Considerations (IMDRF/SaMD WG/N12FINAL:2014) (IMDRF, 2014)
- Software as a Medical Device (SaMD): Application of Quality Management System (IMDRF/SaMD WG/N23 FINAL:2015) (IMDRF, 2015)
- Software as a Medical Device (SaMD): Clinical Evaluation (SaMD WG (PD1)/N41R3) (IMDRF, 2017)
- Principles and Practices for Medical Device Cybersecurity (IMDRF/CYBER WG/N60FINAL:2020)



Software as Medical Device Regulation

Resolution RDC No. [657/2022](#)

Provides requirements for regularization of Softwares a Medical Device (SaMD), including:

- Software updating procedures as well as minimal hardware and software requirements
- Interoperability specifications, compatibilities and incompatibilities, as well as technology environments
- Cybersecurity information

The new RDC 657/2022 makes clear which software types do not fall under the new regulation, such as:

- Software for well-being of users
- Software used only for administrative and financial purposes within healthcare organizations
- Software to process demographic and epidemiological medical data without providing any diagnostic or therapeutic function



Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

Public Consultation will be opened in the following days, it was approved August 31st
Contribution period will be 60 days counting from the publication date
Expected approval of the final document: Q1 2023

Based on IMDRF documents:

- Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47FINAL:2018) (IMDRF, 2018)

Main objectives:

- The purpose is to update safety and performance requirements of MD and IVDMD and to restructure the previous regulation in line with the Good Regulatory Practices
- Inclusion of specific requirements for new technologies
- Alignment of requirements for Mercosur jurisdictions



Clinical Investigations Requirements Revision

The Revision Procedure of RDC No. 10/2015 has been approved.

Main objectives:

- Decrease regulatory cost
- Adoption of definitions converging with ISO14155:2020
- Clarification about clinical investigations that must be submitted to Anvisa for approval before the start of study activities

Public Consultation is expected in the coming months.



Regulatory Updates

Resolution RDC No. [665/2022](#)

Brazilian Technical Regulation for Good Manufacturing Practices of Medical Devices and In Vitro Diagnostic Devices

No Major Changes, it was published to attend a Presidential Decret for harmonization of the format of legislation.

- Revoked RDC N° 16/2013
- No changes in the Requirements
- Only editorial changes



Regulatory Updates

Resolution RDC No. [687/2022](#)







Establishes criteria for issuing and renewing Good Manufacturing Practices for Medical Devices Certificates

Major Changes:

- Revoked RDC Nº 183/2017
- Simplified the documentation that should be presented
- Adds additional Facilities that requires GMP Certification, for example: IVD manufacturing unit that perform specific manufacturing steps, such as cutting, impregnation or lamination of immunochromatography strips
- 3 possible pathways for granting GMP Certification
- Risk Matrix that defines desk review certification or the need for an in-person inspection is now publicly available at [Anvisa's website](#)



Use of MDSAP Reports by ANVISA

2017		38 Certificates Issued (4.7%)
2018		107 Certificates Issued (19,3%)
2019		374 Certificates Issued (48,7%)
2020		544 Certificates Issued (49,1%)
2021		529 Certificates Issued (51,4%)
2022		389 Certificates Issued (until July 31 th)



THANK YOU!

Ana Carolina Moreira Marino Araujo
General Manager
Office of Inspection and Law Enforcement

Agência Nacional de Vigilância Sanitária - Anvisa
SIA Trecho 5 - Área Especial 57 - Lote 200
CEP: 71205-050
Brasília – DF – Brasil

www.anvisa.gov.br

www.twitter.com/anvisa_oficial

Anvisa Atende: 0800-642-9782

ouvidoria@anvisa.gov.br



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