Practical Implementation of Conformity Assessment of Medical Devices in Brazil

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MEDICAL DEVICES OFFICE

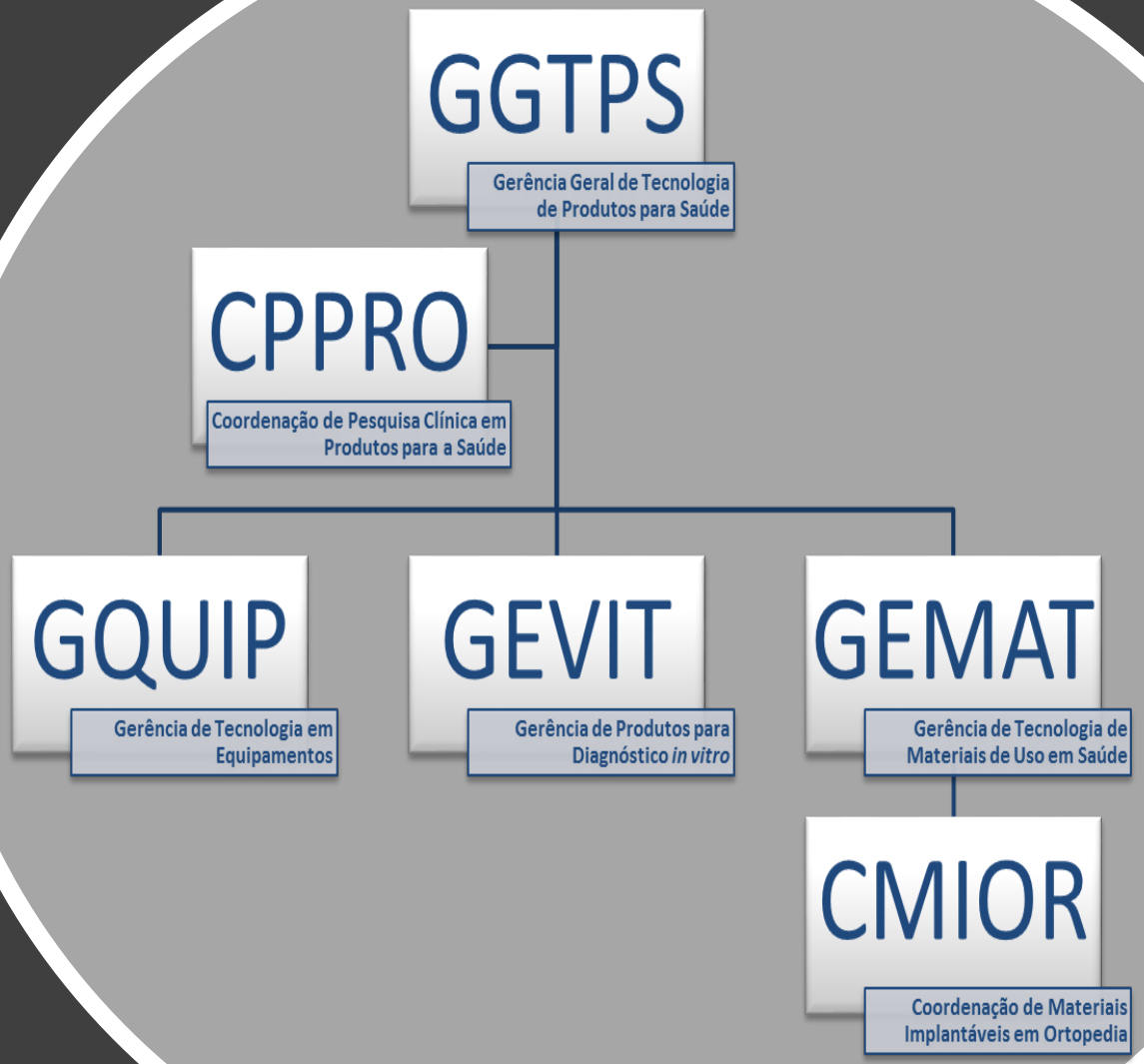
Brazilian Health Regulatory Agency

Agência Nacional de Vigilância Sanitária – ANVISA

Medical Devices Office

- Analysis of submissions for registration, notification, renewal, changes and cancellation of Medical Devices (MD)
- Issuance of MD registration requirements and guidance’s
- Provide information regarding the status of regulated products
- Support to Good Manufacturing Practices inspections for enforcement and certification processes
- Participation in international regulatory forums

- **<u>PROMOTE REGULATORY CONVERGENCE</u>**



Organization Chart

Medical Devices Office (GGTPS)

- **Office of Equipments** (GQUIP)
  - medical equipment (e.g. electromedical equipment) and software
- **Office of Healthcare Materials** (GEMAT)
  - materials, articles (e.g. catheters, syringes, blood bags)
- **Office of *In Vitro* Diagnostics** (GEVIT)
  - reagents, calibrators, controls, instruments (e.g. COVID-19, Syphilis, HIV assays, glucosemeters)
- **Orthopedic Implants Coordination** (CMIOR)
  - orthopedic implants
- **Clinical Trials Coordination** (CPPRO)
  - approval of clinical trials conducted in Brazil with medical devices

Medical Devices Regulation

Main RDC's for MD

- **RDC 185/2001** – Premarket approval process for medical devices (non-IVDs)
- **RDC 36/2015** – Premarket approval process for IVDs
- **RDC 56/2001 (RDC 546/2021)** – Essential Requirements of Safety and Performance
- **RDC 665/2022 (update from RDC 16/2013)** – Good Manufacturing Practices Requirements for MD
- **RDC 40/2015** – MD Notification (Low risk non-IVDs)
- There are also other RDCs which defines additional requirements for specific devices

Medical Device Market Authorization

RDC 185/2001; RDC 40/2015; RDC 36/2015

- **Notification** (classes I and II)
  - No renewal
  - Simplified technical dossier
  - GMP must be followed (no need for certification)

- **Registration** (classes III and IV)
  - Valid for 10 years (since 2018)
  - Must be renewed
  - Full technical dossier must be submitted
  - GMP certification is required

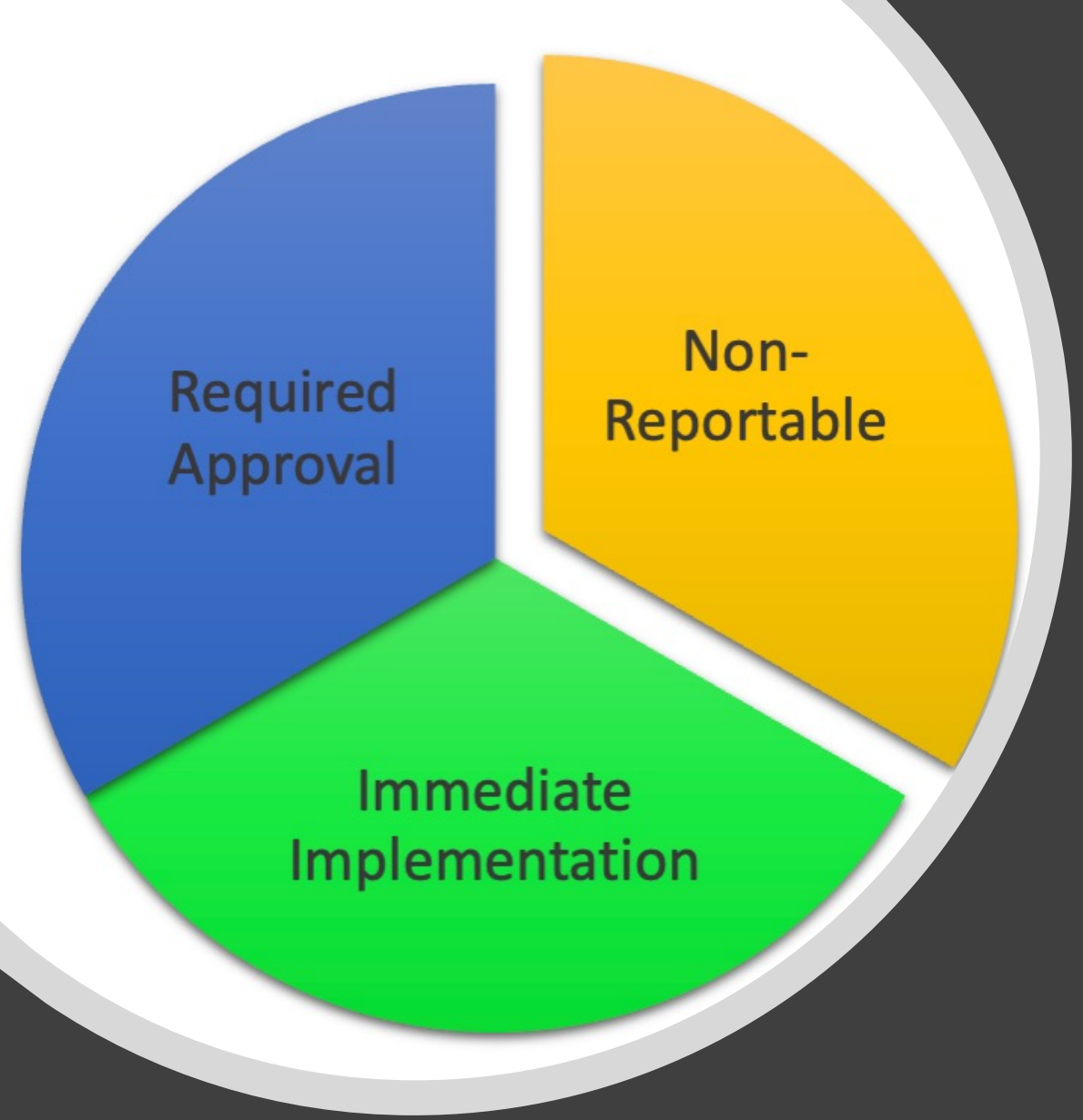
- Submitted by domestic manufacturer or importer (this last, on behalf of the foreign manufacturer)
- GMP Certification shall be obtained before registration final decision
- For both schemes an authorization number is issued

RDC 185/2001 defines 4 risk classes: I, II, II, IV.

Rules similar to 93/42/EEC (EU) 2017/745

RDC 185/2001 is in the final stage of revision and its successor will be published soon.

Similarity with European Union rules will be maintained, but updated to 2017/735 EC.



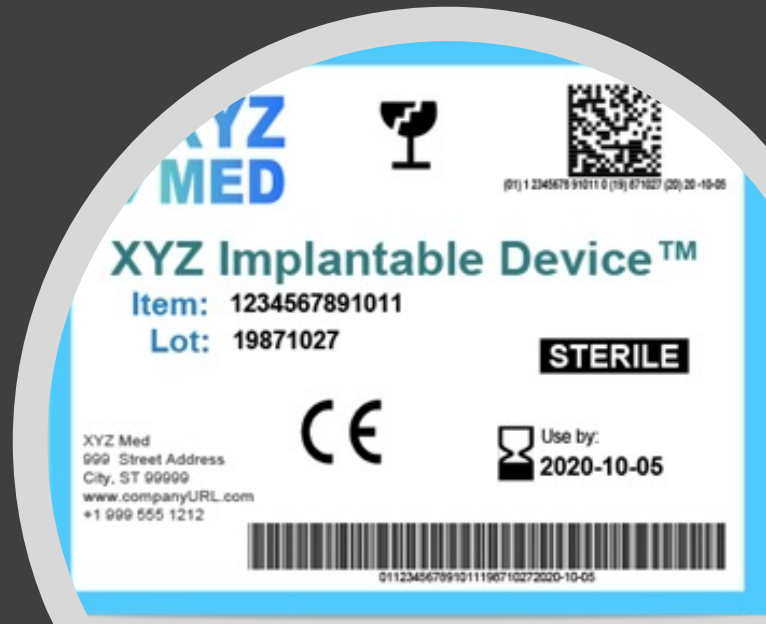
MD Modifications

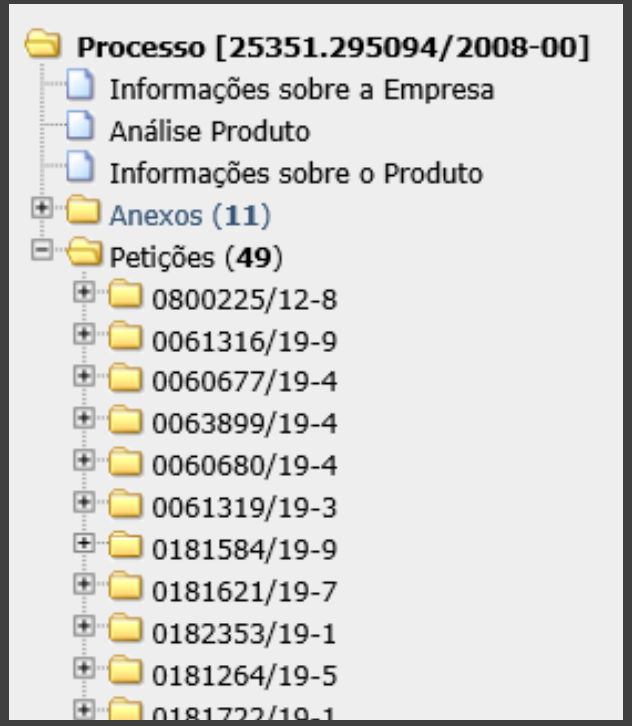
Recently Implemented Regulation

- **RDC 370/2020** and **IN 74/2020** – Rules for modifications of MD
  - Modifications are classified as:
    - Required approval
    - Immediate implementation
    - Non-reportable
  - Immediate implementation modifications may be assessed later by Anvisa

Labelling Requirements

- **Requirements for labelling** of nIVD's are established on RDC 185/2001 and of IVD's on RDC 36/2015
- All labelling must be in **Portuguese-Brasil (PT-BR)**
- For imported devices it is allowed the importation without labels in Portuguese. However, all labels and companion documents must be translated into Portuguese-Brasil (PT-BR) before distribution
- **E-labelling** is allowed according to requirements of IN 4/2012, except for some types of devices (e.g. the ones indicated for domestic use and/or operation by lay user)





Nome da Empresa	EMPRESA DE TESTE LTDA. (VS01)		
CNPJ	11.111.111/0001-91	**Autorização**	8.99.999-9
Produto	Produto de Teste da GGTPS		

Apresentação/Modelo
Apresentação A
Apresentação C
Apresentação B

Tipo de Arquivo	**Arquivos**	**Expediente, data e hora de inclusão**
IMAGENS DO(S) PRODUTO(S)	Imagem - Produto Teste.jpg	0649158/20-2 - 03/03/2020 - 07:55
FORMULÁRIO DE NOTIFICAÇÃO OU CADASTRO	Formulário de Cadastro - Produto Teste.doc	0649158/20-2 - 03/03/2020 - 07:55
ROTULAGEM OU MODELO DE ROTULAGEM	Rotulagem - Produto Teste.jpg	0649096/20-7 - 03/03/2020 - 07:40
INSTRUÇÕES DE USO OU MANUAL DO USUÁRIO DO PRODUTO	Instruções de uso - Produto Teste.png	0649096/20-7 - 03/03/2020 - 07:40

Nome Técnico	Bomba de Infusão Implantável
Registro	12345678900
Processo	25351.295094/2008-00

Instructions for Use Repository

RDC 431/2021

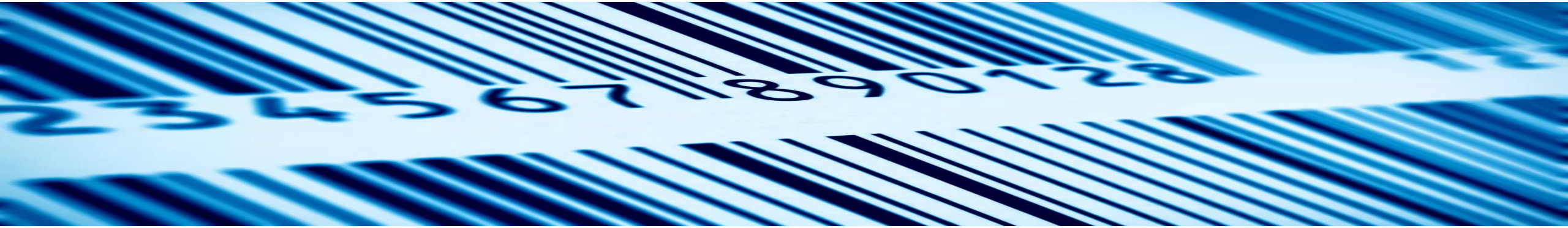
- Applicant must upload the IFU's to Anvisa webpage
- IFU's are available in the registered MD searching tool
- Useful for users and buyers
- Important tool to help the user to identify counterfeit products and specific characteristics
- https://consultas.anvisa.gov.br/#/saude/

Used and Refurbished Medical Equipment

RDC 579/2021

- Regulation for the import, sale and donation of used and refurbished medical equipment
- Maintains the prohibition of importation of used equipment
- Allows the importation of refurbished equipment by the manufacturer or authorized by the manufacturer
- Allows the sale and donation of used equipment in Brazil, when the technical safety is guaranteed through the Technical Report and Technical Responsibility Note
- Valid since January 2022

Implementation Schedule for the Unique Device Identification in Brazil



RDC 591/2021

- UDI Carrier shall be on the label or on the device itself and on all higher levels of device packaging
- Higher levels does not include shipping containers

D_0 = January 10, 2022

RDC 591/2021 into effect

January 10, 2025 (D_0 + 3 years)

Class III (medium to high-risk devices)

January 10, 2028 (D_0 + 6 years)

Class I (low-risk devices)

Class IV (high-risk devices)

July 10, 2024 (D_0 + 2,5 years)

Class II (low to medium-risk devices)

January 10, 2026 (D_0 + 4 years)

The term for each class can be extended in +2 years if the device is reusable and the UDI is placed on the device itself (direct marking)

Software as Medical Device

RDC 657/2022

- Minimum requirements for pre-market authorization of SaMD (Software as Medical Device) within ANVISA
- Specific definitions
- Clarifies the non-applicability of the RDC for software for well-being, software exclusively for administrative and financial management in health services, software embedded in medical equipment and software that process demographic and epidemiological medical data, without any clinical, diagnostic or therapeutic purpose
- IMDRF reference documents:
  - IMDRF/SaMD WG/N10FINAL:2013 - Software as a Medical Device (SaMD): Key Definitions
  - IMDRF/SaMD WG/N12FINAL:2014 - Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations
  - IMDRF/SaMD WG/N23FINAL:2015 - Software as a Medical Device (SaMD): Application of Quality Management System
- Valid from July 2022

Good Manufacturing Practices Requirements for the Brazilian Market

- **GMP certificate is required for registration of class III and class IV medical devices**
- GMP rules are provided on RDC 665/2022 (update from RDC 16/2013) – “Mercosul” harmonization
- Inspection and certificate issuance by Anvisa will take place ~ 6 months after submission
- **GMP audit reports from other Regulatory Authorities (agreements) or from recognized Auditing Organizations may be used to issue Anvisa GMP certificate – RDC 687/2022**
  - When a MDSAP audit report is available in the repository (REPs) the Anvisa GMP Certificate can be issued approximately 20 days after submission

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

MERCOSUL

Medical Device Single Audit Program

MDSAP Members





MDSAP Official Observers



MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

MDSAP Affiliate Members




Regulatory Convergence

IMDRF International Medical Device Regulators Forum

MERCOSUL

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

World Health Organization

Bilateral agreements

ISO

IEC

Main Regulatory Convergence Challenges for the Near Future

Implementation and a “really global” adoption of an “unique” MD NOMENCLATURE

Medical Device Single Review Program (MDSRP)

- **Considered by Anvisa as the best chance to streamline MD regulation globally – Benefits to regulators and industry**
- **IMDRF Good Regulatory Review Practices WG**

Implementation of IMDRF Documents

Anvisa continues to make constant efforts to implement IMDRF documents in local regulations

- **Unique Device Identification** – RDC 591/2021 (Long-term project)
- **Update of the Essential Requirements of Safety and Performance of MD** – Public Consultation (soon)
- **Update of medical devices classification rules –** GHTF basis
- **Development of an electronic submission platform (web based) –** Regulated Product Submission (RPS)
- **Regulation for Software as Medical Device** – RDC 657/2022 (recently published)
- **Regulation for Personalized Medical Devices –** RDC 305/2019 (Aligned with IMDRF)
- **Participation on international standards developments** – Standards WG
- **MD Clinical Investigation, Clinical Evidences and Clinical Evaluation –** Guidances
- **MD Cybersecurity Guide –** Guia 38/2020
- **Medical Device Single Review Program (MDSRP)** – Document available for IMDRF public comments

Simple, but Very Important Tips for Applicants

Submission Form

- Do not leave any field unfilled.
- If there is any information that is not applicable, please justify.

Free Sale Certificate and Authorization Letter

- Remember that these documents must be presented consularized or with an apostille of the same country of the legal manufacturer.
- Information about the manufacturer such as the company name and full address must be clear and identical in both documents.

Intended Use

- The original intended use must be preserved.

Technical Dossier

- The technical dossier must cover all applicable essential safety and performance requirements.
- If the manufacturer considers that something does not apply, this must be justified.

General

- All information presented must correspond to the same version/configuration that will be made available to the Brazilian market.

THANK YOU!

OBRIGADO!

MEDICAL DEVICES OFFICE

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