



**IMDRF**

International Medical  
Device Regulators Forum

# Regulatory and Policy Updates ANVISA

Leandro Rodrigues Pereira  
General Manager  
Medical Devices Office



## Regulatory Updates

- **Resolution RDC n° 270/2019** - Simplification of the regulatory process for the lowest-risk medical devices (Class I).
- The regulatory process changed from Cadastro (simplified approval) to a simple Notification for class I devices



**IMDRF**

International Medical  
Device Regulators Forum

## **New Regulation for Personalized Medical Devices**

- Approved on September, 12, 2019
- Establishes new procedure for authorizing custom-made medical device
- Fully aligned with IMDRF/PMD WG/N49 FINAL:2018



## New Regulation for Personalized Medical Devices

- **Key Points:**
- Company Authorization for custom made devices: Manufacturers must demonstrate technology mastery and comply with Brazilian GMP
- Authorized Companies must notify ANVISA of the manufacturing or importing of each individual custom-made device



# IMDRF

International Medical  
Device Regulators Forum

## New regulation for Personalized Medical Devices

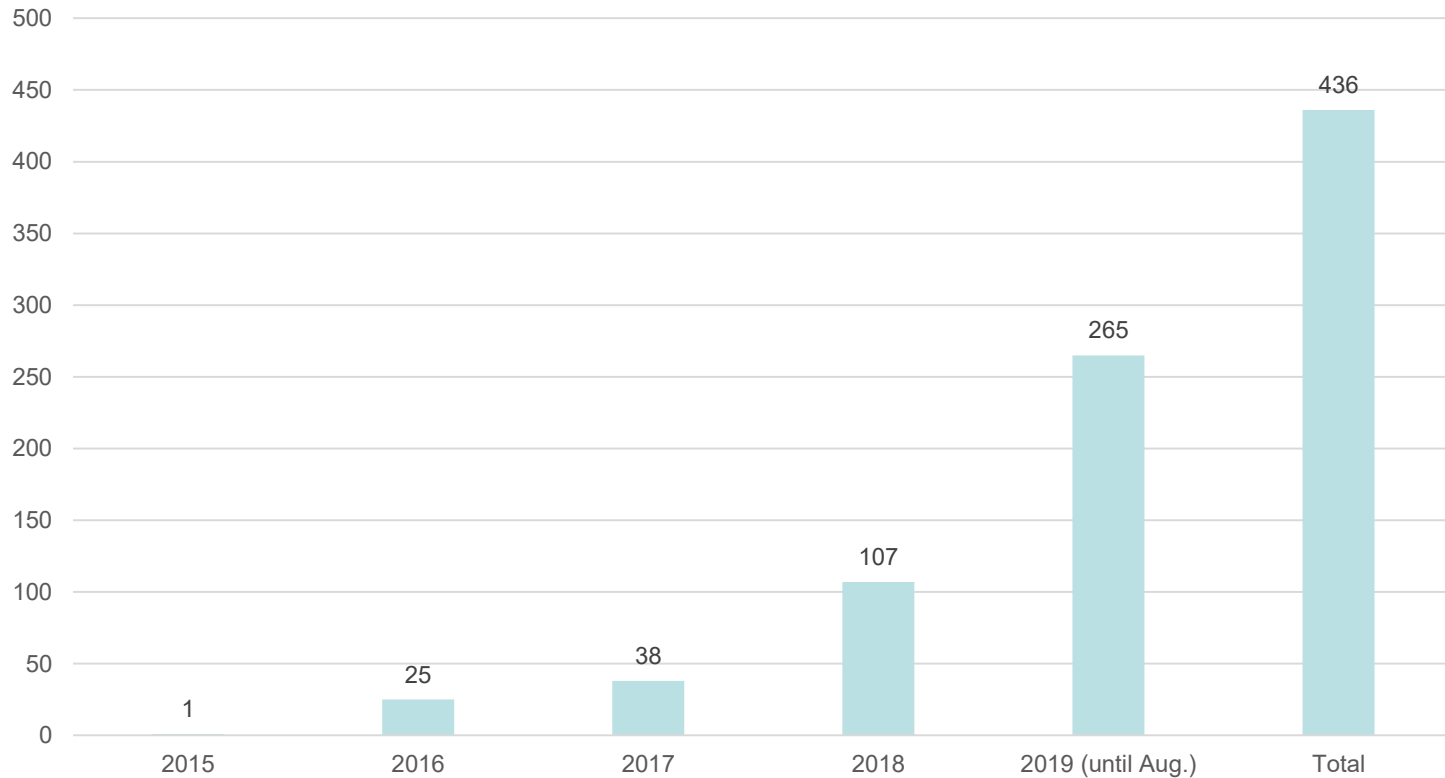
- **Key Points:**
- Labelling must contain patient and physician information
- Implant Card Requirements

Document available on Anvisa's website:

<http://portal.anvisa.gov.br/2017-2020/temas>

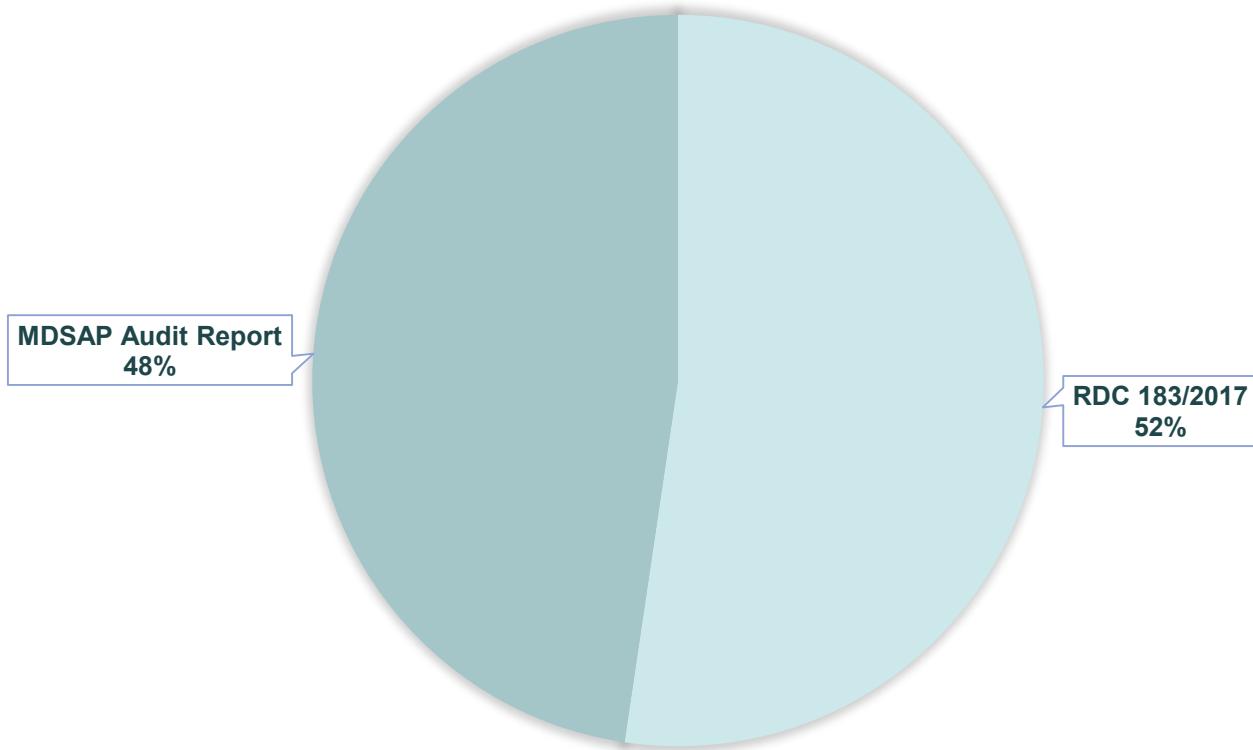


Anvisa's GMP Certification using MDSAP Audit Report per year





## ANVISA'S GMP CERTIFICATIONS 2019 until August





# IMDRF

International Medical  
Device Regulators Forum

## Software as a Medical Device (SaMD) Forum

- September, 18, 2019 – Brasília –DF
- This is an event that marks the beginning of the regulatory process for internalizing the IMDRF SaMD documents in Brazil.





**IMDRF**

International Medical  
Device Regulators Forum

**Спасибо!**  
**Thank you!**

Leandro Rodrigues Pereira  
General Manager  
Medical Devices Office  
ANVISA