IMDRF International Medical Device Regulators Forum

Regulatory and Policy Updates ANVISA

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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

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

New regulation for Personalized Medical Devices

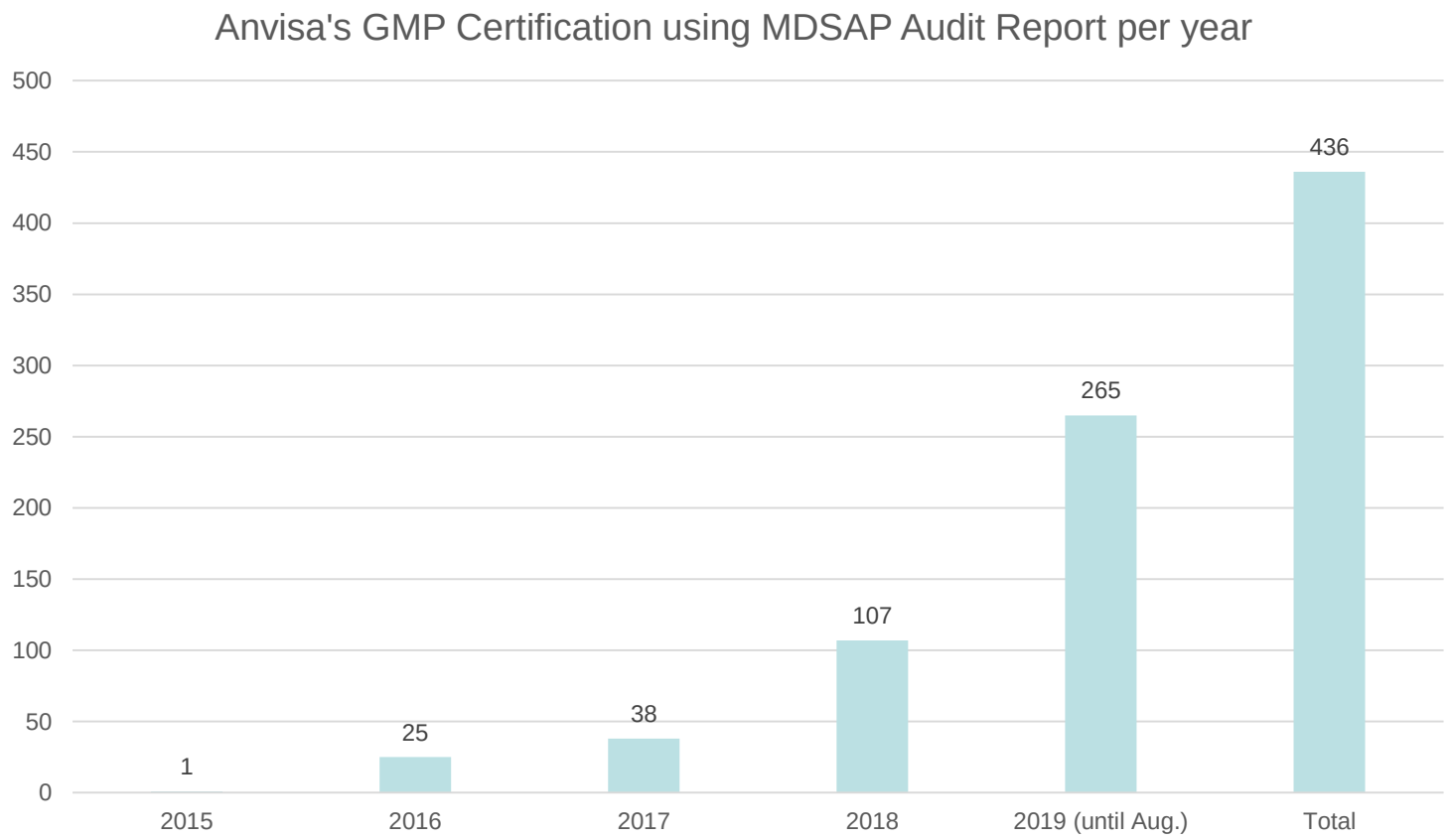
- **Key Points**:

- Labelling must contain patient and physician information

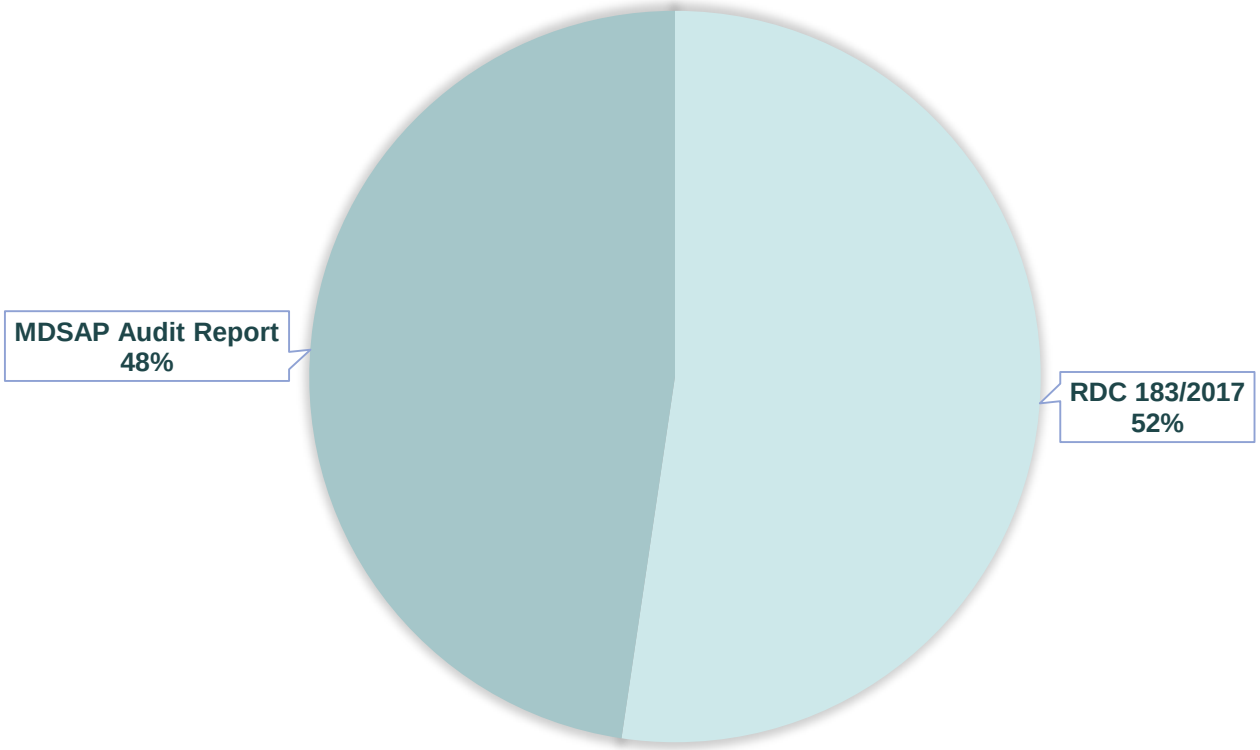
- Implant Card Requirements

Document available on Anvisa's website:

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


Anvisa's GMP Certification using MDSAP Audit Report per year
500
450
400
350
300
250
200
150
100
50
0
1
25
38
107
265
436
2015
2016
2017
2018
2019 (until Aug.)
Total

ANVISA'S GMP CERTIFICATIONS 2019 until August



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.

Спасибо!

Thank you!

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