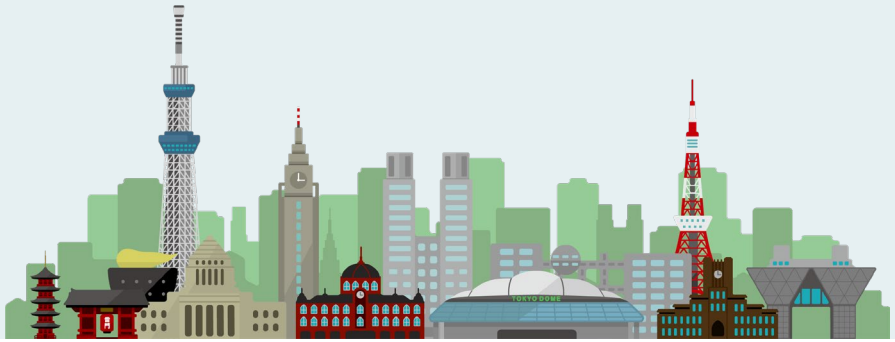
IMDRF International Medical Device Regulators Forum



# Anvisa- Brazil Regulatory Updates


Thiago Rezende P. Cunha
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Brazilian Health Regulatory Agency - ANVISA

# Brazilian Health Regulatory Agency

Brasília – Brazil

# Brazilian GMP Certificate

## Resolution RDC n°687/2022

- Compulsory for market authorization of medical devices Risk Class III and IV

- Valid for 2 years (general)
- Valid for 4 years (MDSAP)

MINISTÉRIO DA SAÚDE

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA

CERTIFICADO DE BOAS PRÁTICAS DE FABRICAÇÃO E CONTROLE DE PRODUTOS PARA SAÚDE

*Considerando o disposto na Lei n.º 9.782, de 26 de janeiro de 1999, o Decreto nº 3.029, de 16 de abril de 1999 e a publicação no Diário Oficial da União por meio da Resolução RE nº 1.843 na data de 29/05/2023certifico que a empresa, a seguir descrita, cumpre com a legislação sanitária vigente, quanto às Boas Práticas de Fabricação de produtos para saúde exigidas pela autoridade sanitária brasileira, estando sujeita a inspeções periódicas.*

Empresa: Labtest Diagnóstica S/A CNPJ: 16.516.296/0001-38

Endereço: Avenida Paulo Ferreira da Costa, nº 600, Distrito Industrial Vista Alegre, Lagoa Santa, Minas Gerais CEP: 33400-000

Autorização: 1000901 Expediente: 4873435/22-6

Certificado de Boas Práticas de Fabricação de Produtos para Saúde:

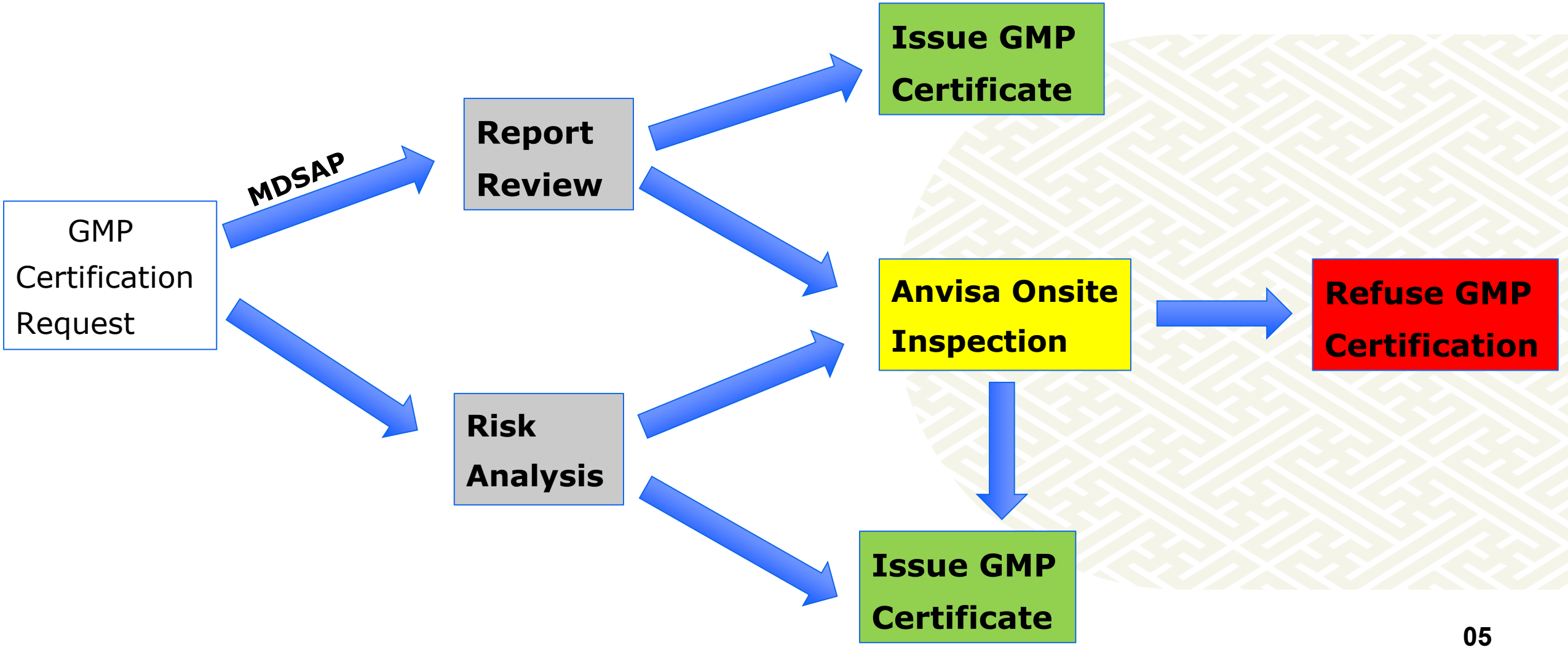
Produtos para diagnóstico de uso in vitro das classes III e IV.

Motivo: Publicado deferimento, subsidiado por critérios renovação automática

Validade até: 29/05/2025

Documento assinado eletronicamente por **Marcus Aurelio Miranda de Araujo, Gerente-Geral de Inspeção e Fiscalização Sanitária**, em 01/06/2023, às 14:55, conforme horário oficial de Brasília, com fundamento no § 3º do art. 4º do Decreto nº 10.543, de 13 de novembro de 2020 http://www.planalto.gov.br/ccivil_03/_ato2019-2022/2020/decreto/D10543.htm.

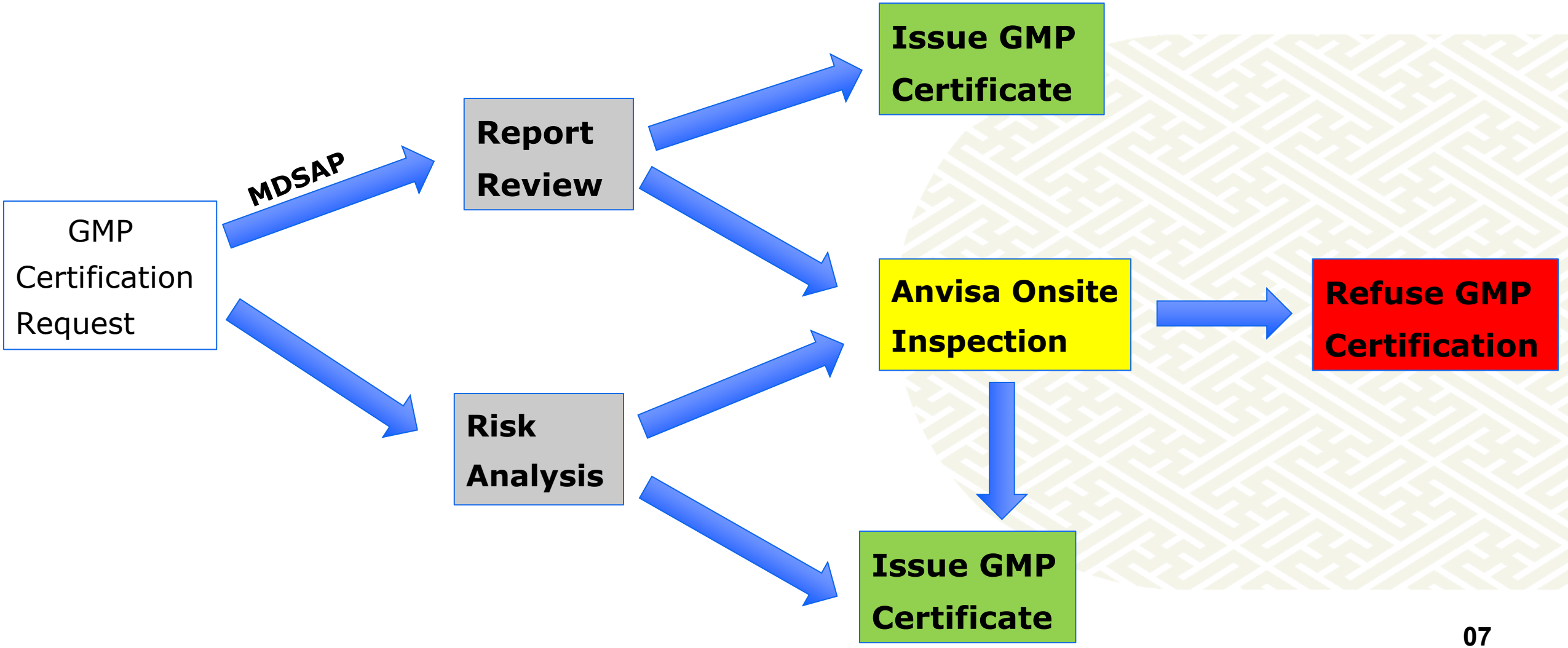
A autenticidade deste documento pode ser conferida no site https://sei.anvisa.gov.br/autenticidade, informando o código verificador **2406225** e o código CRC **B6355209**.


GMP Certification Request
MDSAP
Report Review
Risk Analysis
Issue GMP Certificate
Anvisa Onsite Inspection
Refuse GMP Certification
Issue GMP Certificate

# Public Consultation n°1.303 – December 2024

**Risk management and monitoring the compliance of companies applied to GMP Certification**

*"The risk result based on **Artificial Intelligence** models may be used in the GMP Certification process"*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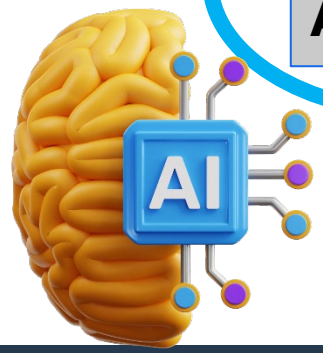



Issue GMP Certificate

Anvisa Onsite Inspection

Refuse GMP Certification

Issue GMP Certificate

# Use of MDSAP by Anvisa

**MDSAP reports for granting Anvisa initial GMP certifications**

- The audit reports are reviewed by an Anvisa inspector
- Must cover all requirements from RDC 665/2022
- MDSAP Certificates used for Anvisa GMP Recertification

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

# Use of MDSAP by Anvisa

## Validity of GMP Certificate

**RDC 850/2024** – Validity of Anvisa GMP certificates issued through MDSAP extended from 2 to 4 years

Validity is conditioned upon the manufacturer's permanence in the program during the whole validity period of the certificate

Encourage manufacturers in joining MDSAP

| Year | # GMP Certificates Issued Based on MDSAP Reports (% of total) |
|---|---|
| **2017** | 38 (4.7%) |
| **2018** | 107 (19.3%) |
| **2019** | 374 (48.7%) |
| **2020** | 544 (49.1%) |
| **2021** | 529 (51.4%) |
| **2022** | 621 (59.7%) |
| **2023** | 659 (59.1%) |
| **2024** | 708 (62.2%) |

# Unique Device Identification

Pilot 1 (May 2024) → 10 companies


Pilot 2 (Nov 2024) → 10 companies

**Pilot 3 (Feb 2025)** → **10 companies**

Pilot 4 (May 2025) → Open

**RDC 591/2021 and RDC 884/2024**

- Final phase of development
- Public Consultation to be published (March / April)
- **Launching (July 2025)** ←

# Reliance mechanisms for pre-market authorizations

## IN 290/2024 - effective since Jun / 2024

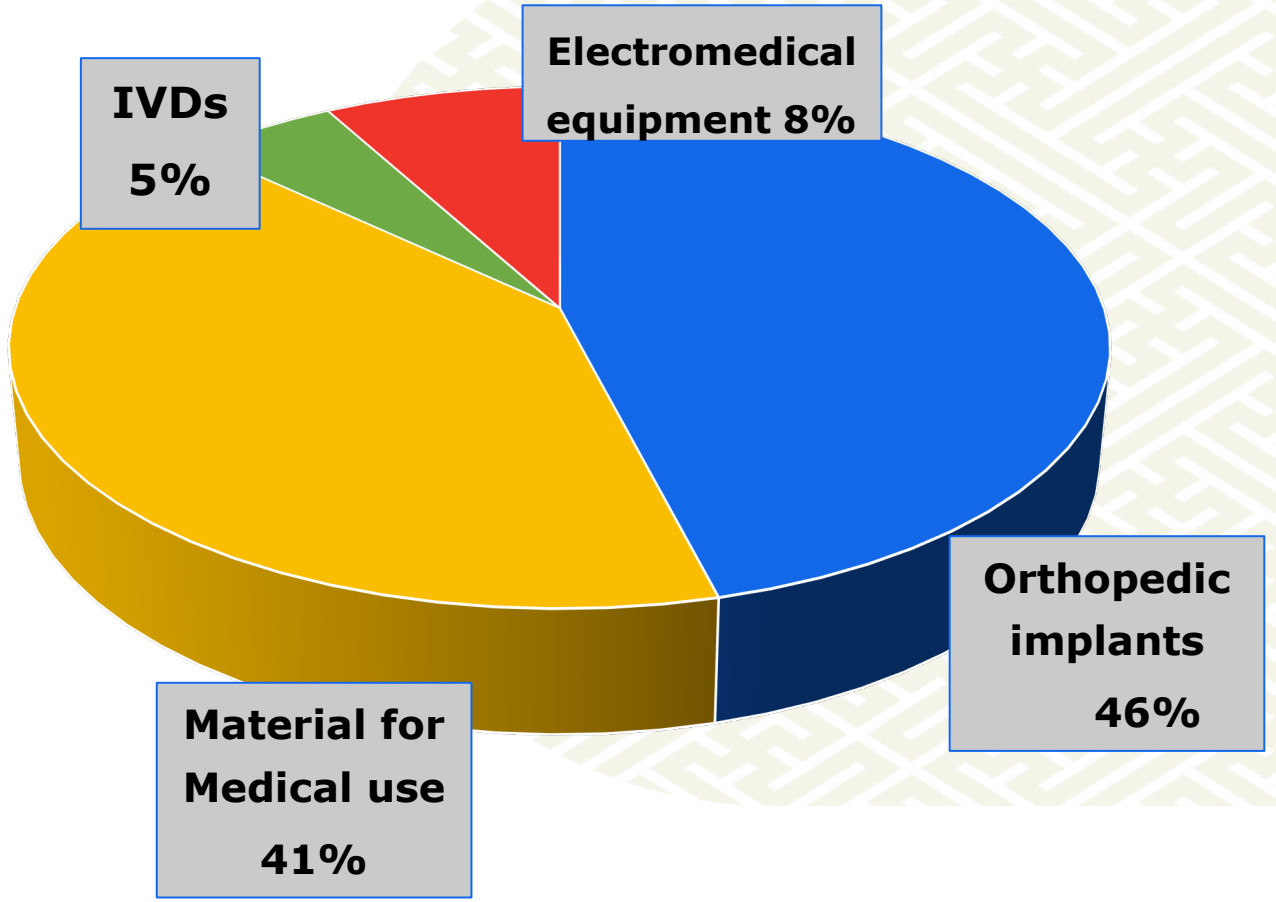
- Product registration certificates from Equivalent Foreign Regulatory Authorities used for market authorization in Brazil
- Initially from the official member authorities of MDSAP (AUS, CAN, JAP, USA)

| Month 2024 | Registration Submissions (Reliance Applications) | |
|---|---|---|
| **May** | 201 | (0) |
| **Jun** | 125 | (33) |
| **Jul** | 151 | (17) |
| **Aug** | 169 | (19) |
| **Sep** | 171 | (20) |
| **Oct** | 230 | (31) |
| **Nov** | 164 | (37) |
| **Dec** | 265 | (45) |

# Reliance mechanisms for pre-market authorizations

**IN 290/2024**
**effective since Jun / 2024**

- Time and resources saving in pre-market authorizations review



# Number of MD Market Authorizations per Year in Brazil

| | | 2021 | 2022 | 2023 | 2024 |
|---|---|---|---|---|---|
| **Notification** | Class I | 3102 | 2718 | 2711 | 2797 |
| | Class II | 3443 | 3751 | 4162 | 4205 |
| **Registration** | Class III | 938 | 1014 | 718 | 921 |
| | Class IV | 254 | 328 | 300 | 393 |
| **Total** | | **7737** | **7811** | **7891** | **8320** |

Active Authorizations of Medical Devices

**91.707**

(31 dec 2024)

# Education

## “Safe Aesthetics” Program

- Aware the population about the risks involved in aesthetic procedures
- Disseminate information on the Anvisa website and social media
- Increase the oversight of aesthetic products, including the manufacturing, distribution and use
- Unannounced inspections

National Health Surveillance Agency - Anvisa

What are you looking for?

Are you going to undergo cosmetic surgery? Pay attention to these three points for a safe procedure:

- Authorized location
- Approved product
- Qualified professional

Click here and learn more about how to have a safe procedure.

# Conclusion

## Key points for 2025

- Safety of the population
- Optimization of resources
- Reliance and regulatory convergence
- Use of innovation

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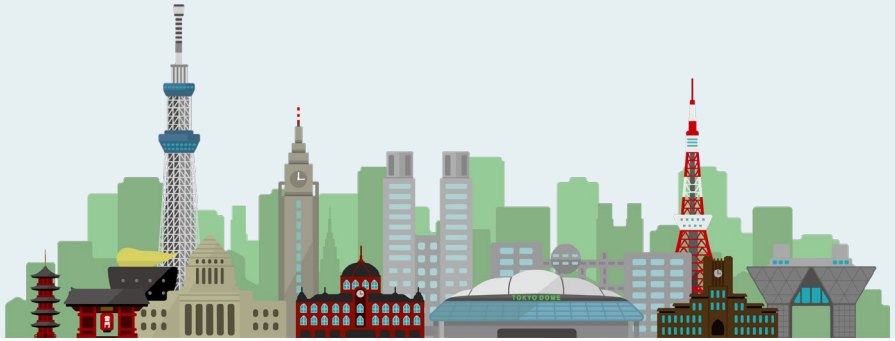

# Thank you!

# Obrigado!

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ANVISA

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