IMDRF International Medical Device Regulators Forum

Anvisa- Brazil
Regulatory Updates

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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:

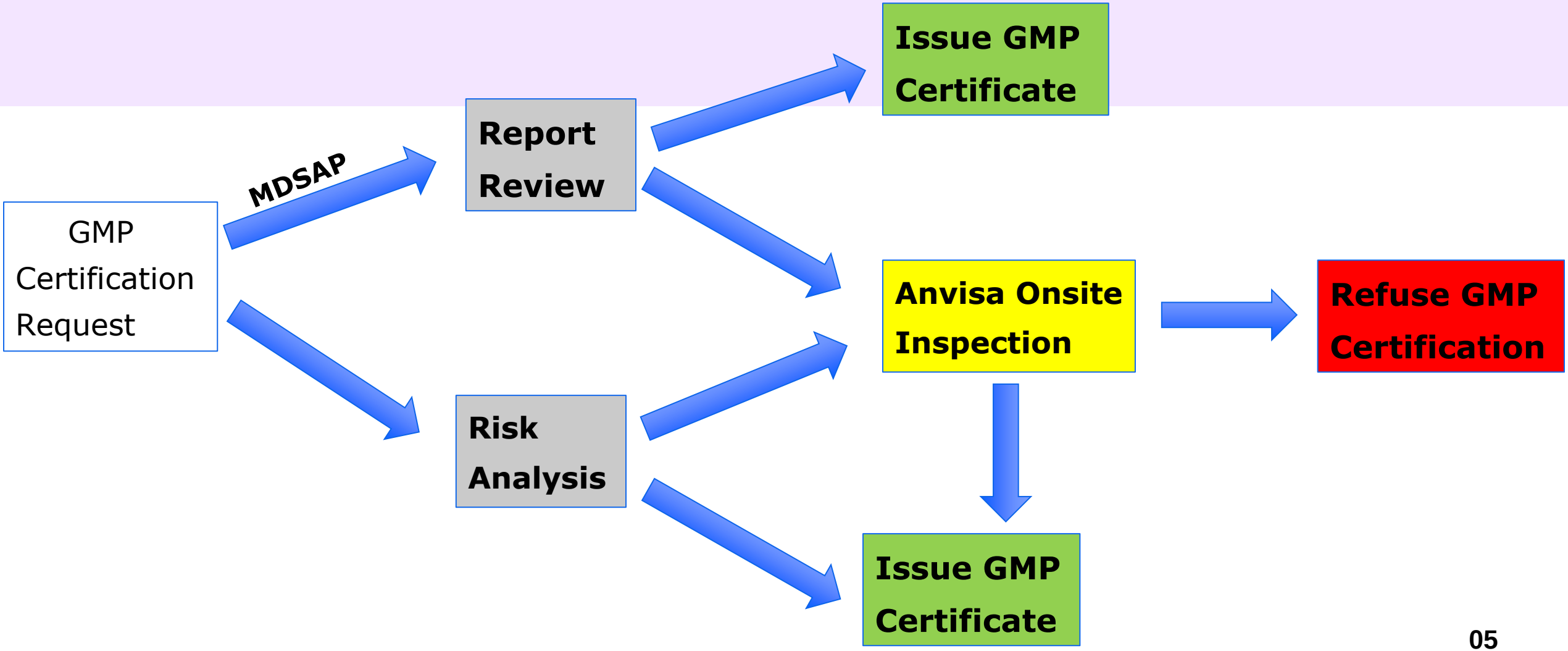
Produtos para diagnóstico de uso in vitro das classes III e IV.

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.

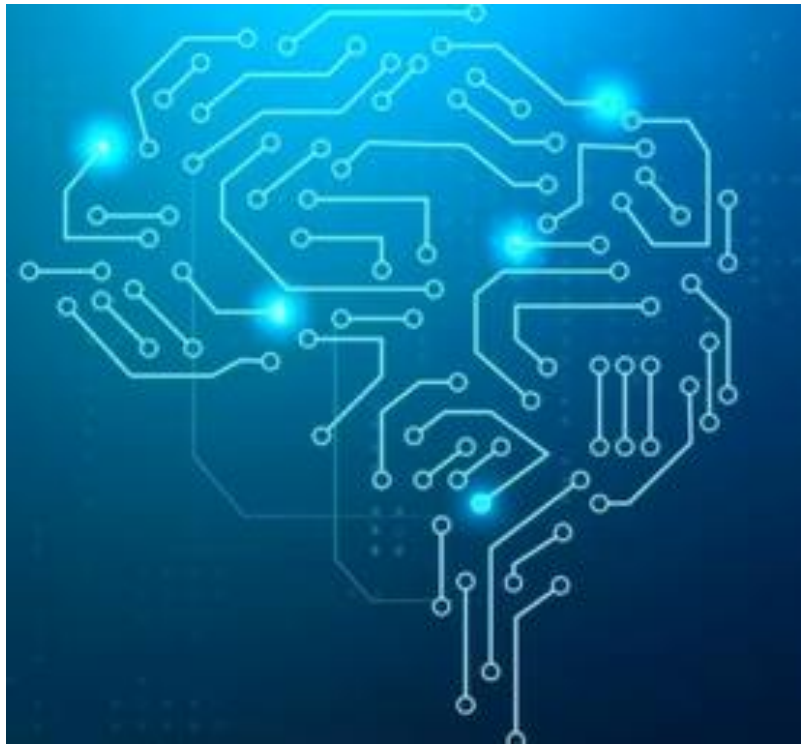
A autenticidade deste documento pode ser conferida no site https://sei.anvisa.gov.br/autenticidade, informando o código verificador **2406225** e o código CRC **B6355209**.

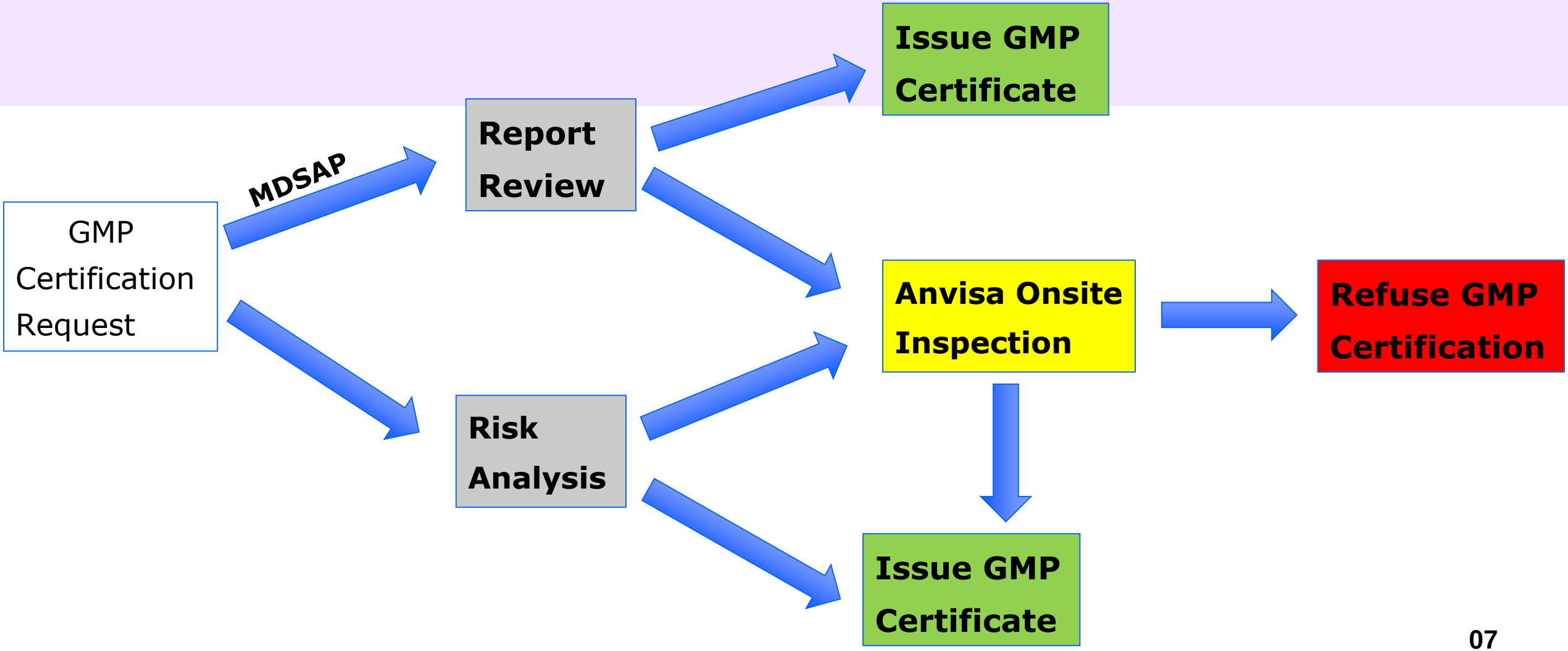

GMP Certification Request
MDSAP
Report Review
Risk Analysis
Issue GMP Certificate
Anvisa Onsite Inspection
Refuse GMP Certification
Issue GMP Certificate

Resolution RDC n° 982/2025

Compliance monitoring of medical devices manufacturers based on risk.

"Artificial Intelligence may be used in the process, as long as it meets Anvisa's technical standards of consistency, data protection, traceability and technical validation."

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MDSAP

Report Review

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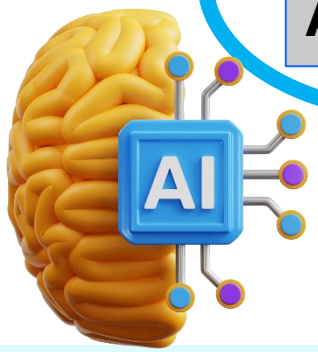
Risk Analysis



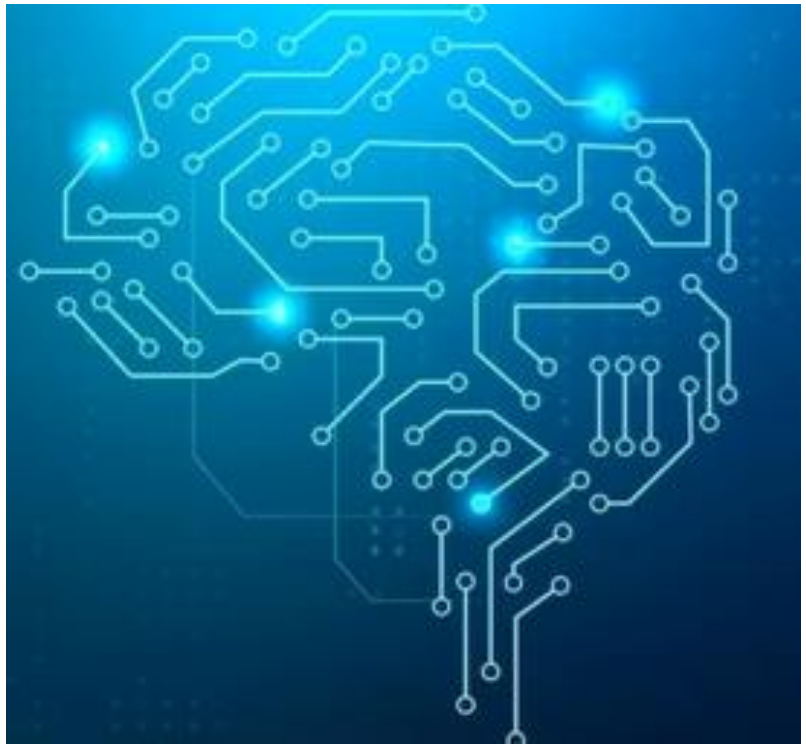
Anvisa Onsite Inspection

Refuse GMP Certification

Issue GMP Certificate

Criteria for risk classification

- Risk class of the products
- Complexity of the facility and activities
- Compliance history with GMP standards
- Marketing complaints
- Major Changes (if applicable)
- Time since last Anvisa inspection

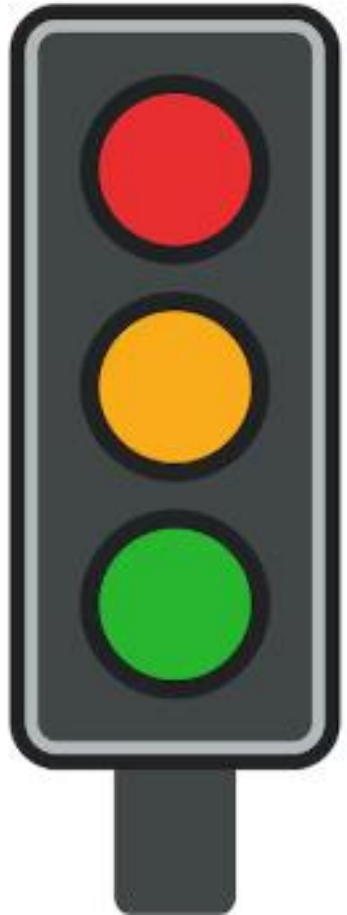


Manufacturers Classification

High Risk Manufacturers
- **Perform on-site inspection**

Medium Risk Manufacturers
- **Technical review**

Low risk companies
- **Certificate issue / Monitoring**



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 (61.2%)
***2025**	637 (64.7%)

*Until August 31st

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https://www.mdsap.global/

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Eligibility of Medical Device Organizations (MDOs) to apply for MDSAP certification

Code: MDSAP AU P0038.001 **Version date:** 28 July 2025 **Effective date:** 1 August 2025

Category: Audit procedures and forms

The purpose of this procedure is to establish a voluntary pilot program allowing eligible Medical Device Organizations (MDOs) to voluntarily participate in and apply for MDSAP certification.

We aim to provide documents in an accessible format. If you're having problems using a document with your accessibility tools, please contact us for help.

Unique Device Identification

RDC 591/2021 and RDC 884/2024

- Final phase of development
- Launching (Q3-2025)
- Fully populated until 2031.

BRAZIL

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)

Market Authorizations in Brazil

Country	Products
Brazil	31,3%
China	18,0%
USA	16,6%
Germany	8,9%
Italy	2,4%
France	2,2%
Korea	1,9%
India	1,9%
Rest of the world	16,8%

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)

Reliance Data	Results
Requests	382
Concluded	184
Approved	169
Not approved	15
Percentage of total requests	15,5%

Conclusion

Our values (2025/2026)

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

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Thank you! Obrigado! ありがとう

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