Regulatory Update from Anvisa - Brazil

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Anvisa - Brazilian Heath Regulatory Agency
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Headquarter in Brasília
Requirements for Market Authorization of In Vitro Diagnostic Medical Devices

- Final text approved by Anvisa Collegiate Board on 6 December 2023
  - Harmonized within Mercosur
  - RDC 830/2023
  - Effective on 1st June 2024
  - Update of the documentation required for submission
  - Electronic Instructions for Use requirements
  - Updated definitions and classification rules
  - IMDRF/IVD WG/N64 FINAL:2021 - Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
Clinical Investigations Requirements

- Final text approved by Anvisa Collegiate Board on 13 December 2023
  - RDC 837/2023
  - Effective since 15 December 2023
  - Alignment of the Brazilian regulatory scenario with international practices
  - Simplification of the process of submitting documentation
  - Adoption of a convergent terminology in relation to the development of medical devices
EP of Safety and Performance

• **Final text approved by Anvisa Collegiate Board on 6 March 2024**
  • Harmonized within Mercosur
  • RDC XYZ/2024
  • Effective 180 days after its publication
  • Based on IMDRF document - Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47FINAL:2018)
Medical Device Licenses in Brazil

### Number of MD Market Authorizations per Year

<table>
<thead>
<tr>
<th></th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Notification</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class I</td>
<td>3102</td>
<td>2718</td>
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<tr>
<td>Class II</td>
<td>3443</td>
<td>3751</td>
<td>4162</td>
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<td><strong>Registration</strong></td>
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<tr>
<td>Class III</td>
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<td>1014</td>
<td>718</td>
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<td>Class IV</td>
<td>254</td>
<td>328</td>
<td>300</td>
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<tr>
<td><strong>Total</strong></td>
<td>7737</td>
<td>7811</td>
<td>7891</td>
</tr>
</tbody>
</table>

Active Licenses of Medical Devices

**87,758**

(31 December 2023)
Reliance Mechanisms for Market Authorizations

• **Pathway for abridged review of initial submissions**
  - Public Consultation 1200/2023 closed on 25 October 2023
  - Normative Instruction proposal submitted to the Reporting Director

• **Main objectives**
  - Market authorization certificates from Equivalent Foreign Regulatory Authorities will be accepted for expedited review for the grant of Market Authorization in Brazil (registration)
  - Initially from the founding members authorities of MDSAP

• **Expectation to be published and made effective by the second quarter of 2024**
Use of MDSAP by Anvisa

• MDSAP Audit Reports are accepted for granting Anvisa GMP Certificates
  • The Audit Reports are reviewed and they need to cover all requirements in RDC 665/2022

• MDSAP Certificates started to be accepted for the renewal of Anvisa GMP Certificates (pilot programme started late 2023)
  • Simple review of the Certificate to optimizes the renewal process

• Increase in the GMP Certificate validity from 2 to 4 years if based on MDSAP documents
  • Revision in process after Public Consultation 1208/2023 - expectation to publish the RDC in the first quarter of 2024
Use of MDSAP by Anvisa

Anvisa GMP Certificates Issued using MDSAP

<table>
<thead>
<tr>
<th>Year</th>
<th># GMP Certificates Issued Based on MDSAP Reports (% of total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>38 (4.7%)</td>
</tr>
<tr>
<td>2018</td>
<td>107 (19.3%)</td>
</tr>
<tr>
<td>2019</td>
<td>374 (48.7%)</td>
</tr>
<tr>
<td>2020</td>
<td>544 (49.1%)</td>
</tr>
<tr>
<td>2021</td>
<td>529 (51.4%)</td>
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<tr>
<td>2022</td>
<td>621 (59.7%)</td>
</tr>
<tr>
<td>2023</td>
<td>659 (59.1%)</td>
</tr>
</tbody>
</table>
MDSAP Forum hosted by Anvisa
Brasília, 23 - 27 October 2023
Data Transparency

- **GMP Certification Database**
  - Relevant search criteria
  - Geographic distribution views available
  - Certification status filters
  - Constantly updated (weekly basis)
  - Widely helpful to management

Dashboard link:
Data Transparency

• Data Dashboard of issued GMP Certificates
  https://app.powerbi.com/view?r=eyJrIjoiYTYzNDM0ZDEtNzkxNC00ODNILTkwNDAtMjZjMTFjOWVjMTkwIiwidCI6ImI2N2FmMjNmLWMzZjMtNGQzNS04MGM3LWI3MDg1ZjVlZGQ4MSJ9

• Data Dashboard of Anvisa Inspections – Medical Devices
  Microsoft Power BI
Anvisa’s 25th Anniversary Celebration

The Agency celebrates 25 years of contributions to public health and to the quality of life of Brazilian citizens.