Compliance & Risks

Medical Device Regulation Checklist: Brazil

13 February 2024

Further regulatory developments may have occurred after publication. To keep up-to-date with the latest compliance news, sign up to our newsletter.

Medical devices face their own unique regulatory landscape that has been increasingly complicated by several factors in recent years. The demand for more sustainable technology is being driven by both consumers and legislators, and as devices become more integrated with AI and internet connection, new cybersecurity and data protection legislation is racing to keep up.

We help you stay on top of your regulatory obligations in Brazil with this medical device checklist.

Your Checklist to Medical Device Regulation in Brazil

1. Overview and Classification

In Brazil, medical device regulation is overseen by the National Health Surveillance Agency (ANVISA). Medical device regulation in Brazil is tailored to a risk-based classification system with four classes:

- [ ] Class I (Low Risk)
- [ ] Class II (Moderate Risk)
- [ ] Class III (High Risk)
- [ ] Class IV (Very High Risk)

---

2. Major Regulations

Regulation RDC No. 751/2022, published by ANVISA and effective from 1 March 2023, includes the rules for risk classification, labeling requirements and instructions for use, and the procedures for notification and registration of medical devices:

Risk Classification

- [ ] Categorization based on risk levels, from class I to class IV.
- [ ] Medical devices classified in risk classes I and II are subject to notification.
- [ ] Medical devices falling into risk classes III and IV are subject to registration.

Labeling Requirements

- [ ] Information contained on the labels and instructions for use must be in Portuguese.
- [ ] Medical devices must include instructions for use in their packaging or reference how to access these documents.

Notification or Registration of Medical Devices

- [ ] Documents are submitted to Anvisa for notification, registration, amendment, revalidation or cancellation of notification or registration of the medical device.

Extension of the Validity Period for Medical Device Registrations

- [ ] 10 years, with the possibility of successive revalidation for the same duration (previously 5 years).

Resolution RDC No. 777/2023, amends Collegiate Board Resolution RDC No. 751, which came into effect on 1 March 2023, among other things, the following amendments were made:

- [ ] Exemption for Custom-Made Devices.
- [ ] Compliance Declaration for Importation required.
- [ ] Suspension and Cancellation Authority - ANVISA is granted the authority to suspend the manufacture, import, distribution, commercialization, and use of medical devices in the event of health risks arising from irregularities in the product, manufacturing process, or absence of a compulsory certificate of conformity.

Resolution RDC No. 665/2022 on Good Manufacturing Practices (GMP) for Medical Products and In Vitro Diagnostic Products

- [ ] Applies to manufacturers, distributors, stockers, and importers of medical products and in vitro diagnostic products marketed in Brazil.
- [ ] Quality Management System (QMS) requirements.
- [ ] Obligations covering documents and quality records, process and production controls, handling, storage, distribution, and traceability and corrective and preventive actions.

Resolution RDC No. 687/2022 - Good Manufacturing Practices Certification granting and renewal

- [ ] Good Manufacturing Medical Devices Manufacturing Practices Certification apply to class III and IV devices in cases where:

- [ ] The manufacturing unit that produces a final product on its own behalf or for another company.
- [ ] The manufacturing unit that performs the final release of the final product, associated with at least one production stage, excluding the stages of design, distribution sterilization, packaging and labeling.
- [ ] The manufacturing unit of medical software (Software as a Medical Device - SaMD).

- [ ] Deadline of 180 days for applicable manufacturing units to apply for Good Manufacturing Practices Certification.

---

3. B-GMP Certificate Application Process

Steps required to obtain a Brazilian Good Manufacturing Practice (B-GMP) certificate:

- [ ] Initiation: The Brazilian Registration Holder (BRH) starts the B-GMP certification request on behalf of the manufacturer.
- [ ] Submission of Certificates: The BRH can submit certificates from the Medical Device Single Audit Program (MDSAP) or authorized third-party organizations.
- [ ] Evaluation: ANVISA reviews MDSAP reports and other organization-issued audit reports, assessing them thoroughly before issuing the B-GMP certificate.
- [ ] Submission for Device Registration: The obtained B-GMP certificate, along with the device dossier file, is submitted to ANVISA as part of the device registration process.
- [ ] Commercialization Approval: Upon successful registration completion, medical devices are legally permitted for commercialization in the Brazilian market.

Required Documents for B-GMP Certification which the BRH must submit:

- [ ] Completed B-GMP certification request form and proof of payment.
- [ ] List and full details of devices produced.

- [ ] Manufacturing process flow chart and manufacturing site layout, quality manual.
- [ ] Recent relevant audit reports.

Validity of B-GMP Certificate issued by ANVISA:

- [ ] Valid for 2 years and renewal every 2 years.

References

- Regulation RDC No. 751/2022
- Resolution RDC No. 810, 2023
- Resolution RDC No. 777/2023
- Resolution RDC No. 665/2022
- Resolution RDC No. 687/2022
- Instruction No. 13/2009
- Resolution RDC No. 185/ 2001