



Emergo Group assists medical device companies worldwide with registration, representation, quality system compliance and distribution in Brazil as shown below.

### Device classification in Brazil

Determining the proper classification for your medical device is critical to ensuring a smooth registration process. Our office in Brasilia is staffed by experts with many years of experience with Brazil medical device classification.

### INMETRO electrical safety certification

If you manufacture an electro-medical device, electrical safety testing and INMETRO certification may be required in Brazil. We can help coordinate this testing on your behalf as the results are critical to the completion of the registration documents.

### Brazilian Registration Holder representation

Companies without an establishment in Brazil are required to appoint a Brazilian Registration Holder as an in-country representative and liaison with ANVISA. Having an independent firm control the registration for your device(s) is critical if you will not have a direct sales office in Brazil. Once the Brazil Registration Holder role is appointed, it cannot be transferred. We can act as your Registration Holder through our office in Brasilia.

### Brazil ANVISA Technical File preparation

Like a US FDA 510(k) submission, the Brazilian Technical File provides proof that your product is safe and effective. Our Brazilian office will prepare your Technical File and assist with document and IFU translation into Portuguese. We will also advise you on device labeling requirements in accordance with Brazilian regulations.

### Brazilian Good Manufacturing Practices (BGMP)

Brazilian quality system requirements are very similar to US FDA 21 CFR Part 820. Our consultants will advise you on what modifications must be made to your existing quality system to prepare for your biennial ANVISA quality system certification audit.

### BGMP quality system audits

ANVISA conducts biennial audits of medical device manufacturers selling in Brazil. Emergo Group is available to conduct pre-assessment audits to ensure that you, or your major suppliers, are ready for the audits. Internal auditor training is also available.

### Medical distributor qualification in Brazil

While your registration is being finalized, our distribution specialists can help you find and evaluate Brazilian distributors in São Paulo, Rio de Janeiro, Salvador and other Brazilian cities as needed. Having a local resource to evaluate distribution partners will increase the chances of finding a partner who is qualified and able to effectively market your products in Brazil.

\* Brazilian Resolution RDC 185/01 is similar to the European Medical Devices Directive (93/42/EEC) and classification is very similar. Generally, Class I/II/III/IV in Brazil = Class I/IIa/IIb/III in Europe.  
 \*\* The Company Working Allowance permit, called an "Autorização de Funcionamento," allows the company to import, distribute, store and sell the product in Brazil. The manufacturer only needs to secure this permit if they will be importing and distributing their own products in Brazil. Otherwise, a distributor or registration holder will already have this permit.  
 \*\*\* Testing performed outside Brazil is usually acceptable if performed by an ILAC certified lab.  
 \*\*\*\* The Economic Information Report must include pricing comparisons for other countries, patient/user information, marketing materials, and other data.  
<sup>^</sup> Class I and II devices not listed on the IN 2/2011 list do not need to comply with BGMP and also go through an abbreviated cadaster process.  
<sup>^^</sup> Brazilian Good Manufacturing Practice (B-GMP) is very similar to the US FDA Quality System Regulations (21 CFR Part 820).  
<sup>^^^</sup> The device registration certificate proves that your product is approved for sale in your home market.  
 IMPORTANT NOTE: Risk management in compliance with ISO 14971 is required for all implants, intrauterine devices and blood bags.