



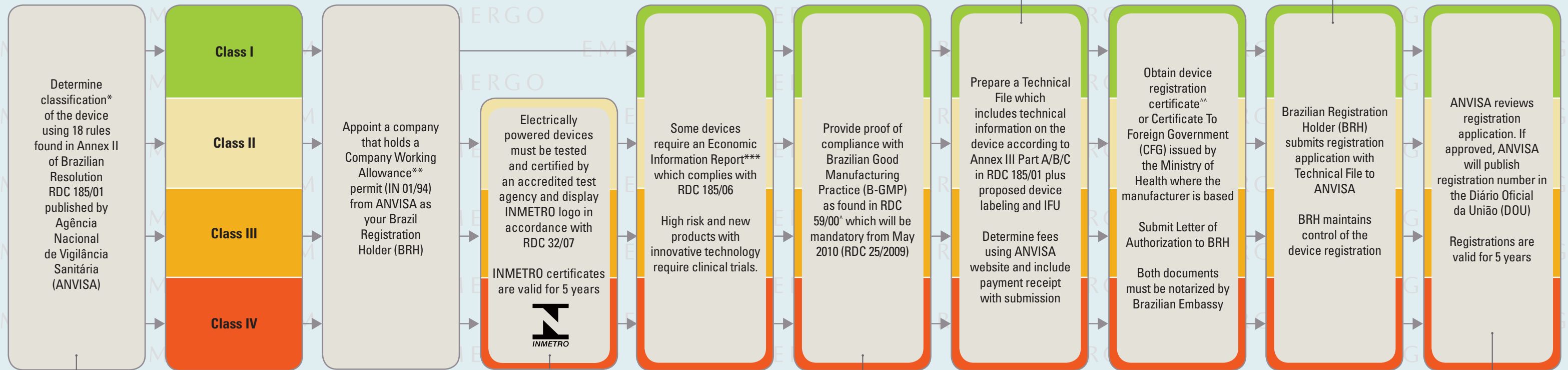
Emergo Group has been assisting medical device and IVD companies with international regulatory issues and quality management system compliance since 1997. Whether you are entering the Brazilian market for the first time or introducing another new device, we can assist with every step of the process from device classification and ANVISA registration to distributor selection. With offices in Brazil and worldwide, Emergo Group can help you obtain regulatory clearance, maintain compliance and increase sales in the world's largest and fastest growing medical device markets.

### Preparation of your Technical File

Our Brazilian consulting team 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.

### Independent Registration Holder representation

Having an independent firm control the registration for your device(s) is critical if you will not have a direct sales office in Brazil. Emergo can assist you with representation through our offices in Brazil.



### Proper device classification is critical

Determining the proper classification for your medical device is critical to ensuring a smooth registration process. Our team has many years of experience with medical device classification.

### Assistance with INMETRO certification

If you manufacture an electro-medical device, electrical safety testing 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.

### Compliance with Brazilian quality system requirements

Brazilian QMS requirements are similar to ISO 13485 and US FDA QSR, but not the same. Our consultants will advise you on what modifications must be made to your existing quality system to ensure ongoing compliance with ANVISA requirements.

### Finding and qualifying distributors

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

\* Brazilian Resolution RDC 185/01 is similar to the European Medical Devices Directive (93/42/EEC) and classification is very similar. 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.

\*\*\* The Economic Information Report must include pricing comparisons for other countries, patient/user information, marketing materials, and other data.

^ Brazilian Good Manufacturing Practice (B-GMP) is similar to the US FDA quality system regulations.

^^ The device registration certificate proves that your product is approved for sale in your home market.

IMPORTANT NOTE: Risk management in compliance with ISO 14971:2007 is required for all implants, intrauterine devices and blood bags.