



Emergo Group assists medical device companies worldwide with registration, representation and distribution in China as shown below.

### SFDA medical device classification

Device classification in China is not a straightforward process. Class II devices in Europe or the USA might be Class III in China, dramatically changing the cost and time needed for registration. Our team in Beijing knows how to decipher SFDA Order No. 15 and other documents needed for the proper classification of your device.

### Chinese Registration Standard preparation

If you wish to import a medical device into China, a specific Registration Standard document must be prepared and submitted along with product samples for testing. We can prepare the documentation and work with the designated test site in China to coordinate registration and monitor progress.

### Clinical trials for medical devices in China

New SFDA rules require some manufacturers of higher risk devices to submit clinical data as part of the device registration application. The clinical trials required to produce the data must be conducted in China. Our office in Beijing offers full service clinical trial support for medical device manufacturers.

### China Legal Agent and After Sales Agent representation

Companies selling in China are required to appoint a Legal Agent and After Sales Agent. While it is possible to ask a distributor to fulfill the Legal Agent role, doing so severely limits your flexibility to switch distributors since the Legal Agent controls your device approval in China. Our office in Beijing is a fully licensed independent Legal Agent and After Sales Agent. We will ensure that your regulatory responsibilities are fulfilled while giving you complete control over distribution.

### Chinese QMS requirements

If you can demonstrate compliance with the quality system requirements of the US FDA, Europe or Canada (with an ISO 13485:2003 certificate) this will be accepted in China. If you do not have a quality management system in place, we can help you implement ISO 13485 and/or FDA GMP.

### Import license application support

A significant amount of information is needed to obtain an Import Medical Device Registration Certificate (IMDRC) from the SFDA. We have the experience and understanding of the system to prepare your license application. Translation of all documentation into Chinese can also be coordinated.

\* Clinical trials may need to be conducted in China for Class II/III devices that do NOT already have regulatory approval elsewhere in the world, as well as certain high risk devices. If clinical trials have been conducted outside China and the device has US, European or other national approval, the data will likely be accepted by the SFDA. Long-term implantable devices, however, require clinical trials in China regardless of whether any trials have already been conducted for them elsewhere in the world.

\*\* The SFDA Medical Device Quality Supervision and Inspection Center conducts testing on products.

\*\*\* Certification validity may change from 4 years to 5 years in the near future.