

An overview of China's regulatory process for medical devices and how we can help.

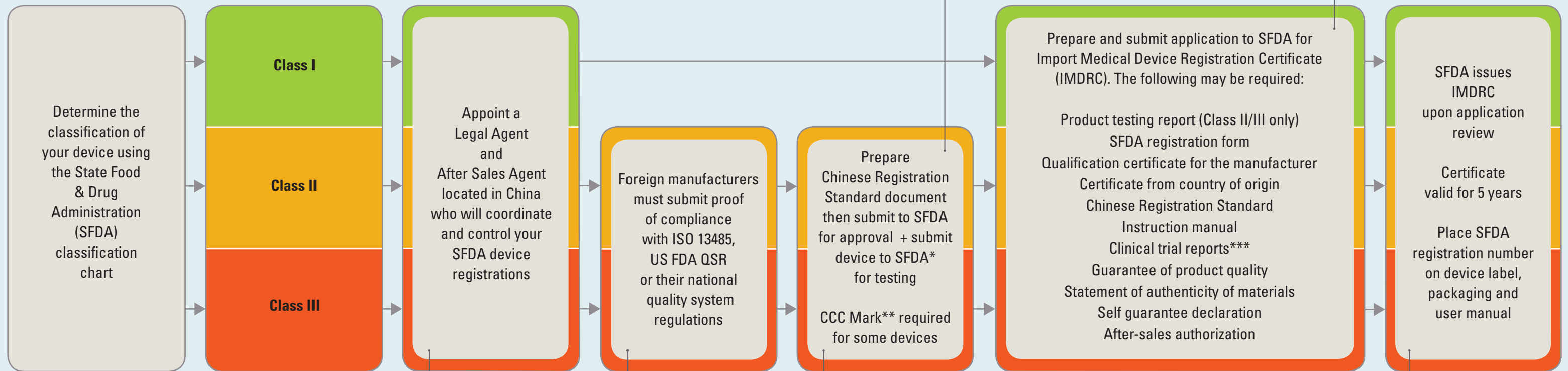
Emergo Group has been assisting medical device and IVD companies with international regulatory and quality assurance issues since 1997. Whether you are entering the Chinese market for the first time or introducing another new device, we can assist with everything from quality system compliance and audits, to Chinese Registration Standard preparation and approvals. With offices in North America, Europe, Asia and Australia, Emergo can help you obtain regulatory approval, maintain compliance and increase your sales in the world's largest and fastest growing medical device markets.

Emergo can prepare your Chinese Registration Standard

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.

License application support

A significant amount of information is needed to obtain a IMDRC (license) from the SFDA and we can prepare your license application. Translation of all documentation into Chinese will also be provided.



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Professional, independent regulatory representation

Companies selling in China are required to appoint a Legal Agent (LA) and After Sales Agent (ASA). While it is possible to ask a distributor to fulfill this role, doing so severely limits your flexibility to switch distributors since the Agent controls your device approval in China. Hiring an independent Agent ensures that your regulatory responsibilities will be maintained while giving you complete control over distribution.

Meeting Chinese QMS requirements

If you can demonstrate compliance with the quality system requirements of the US FDA, Europe, Canada, Japan or another country, this will be accepted in China. If you do not have a quality management system in place, we can help you do so.

Application for CCC Mark

Currently, several categories of (mostly) electrical devices require the CCC Mark certification. If your device requires CCC, we will prepare the necessary application and coordinate testing as needed. The SFDA may also require a facility audit.

Ongoing regulatory compliance and auditing

If you appoint us as your Legal Agent (and After Sales Agent), we will keep you updated on the constantly changing Chinese regulatory landscape to ensure you stay in full compliance. We are also available to conduct quality system audits of critical suppliers located in China, if necessary.

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

** CCC Mark = China Compulsory Certificate. Required for several categories of devices, most of which have an electrical component. A CCC Mark application must be submitted prior to product registration and a facility inspection is required for CCC Mark approval.

*** 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, long term implantable devices or certain other 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.