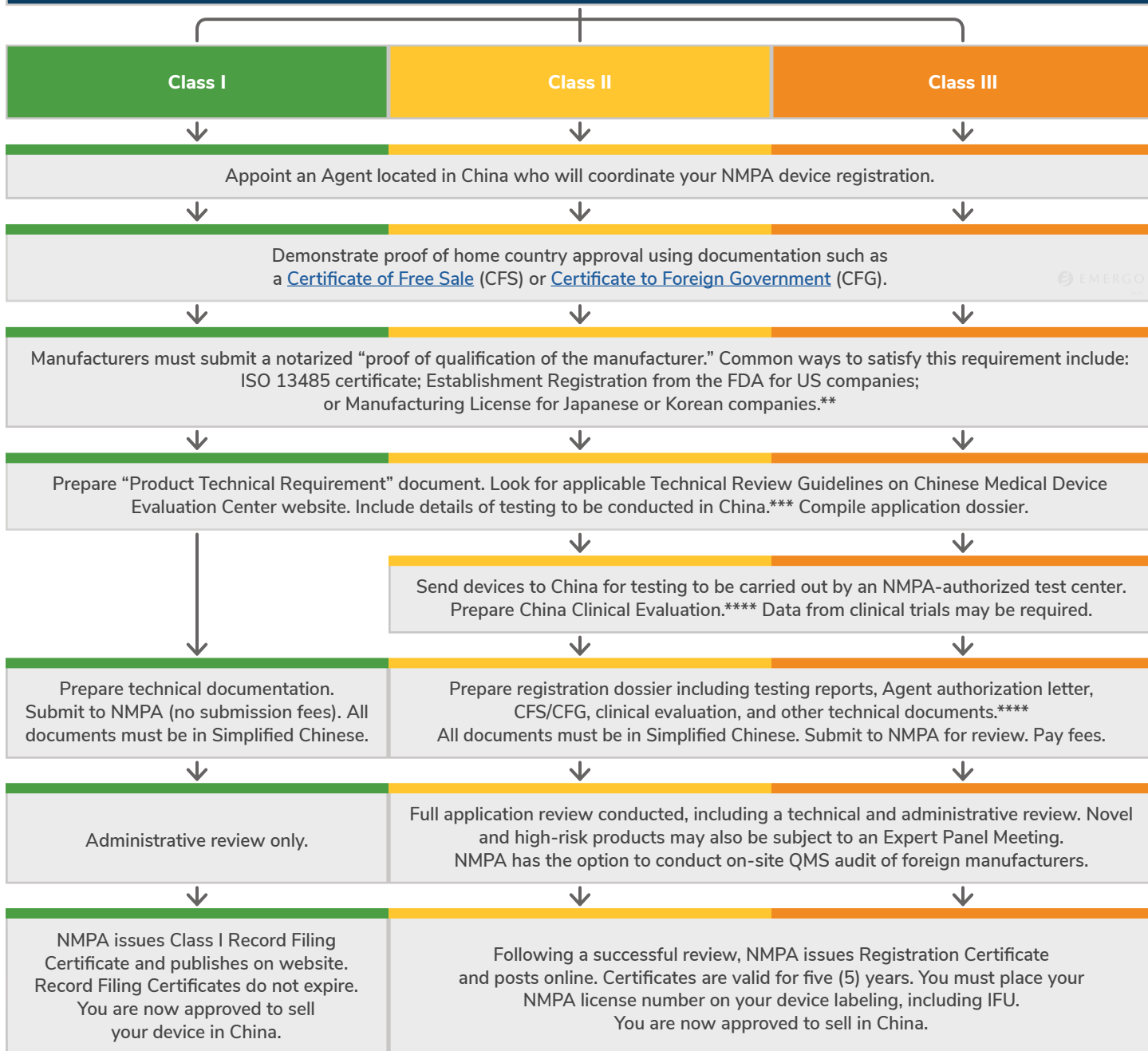


# China

## The Regulatory Process for Medical Devices

Determine classification of your medical device in China using the [National Medical Products Administration \(NMPA\) Medical Device Classification Catalog \(Announcement No. 104/2017\)](#),\* or the rules in Order No. 15 for novel devices. Class II and III device manufacturers should also identify predicates, and determine the clinical data requirements for their device and how to satisfy them.



\* Only devices that are listed in the Catalog and match the exact device description are confirmed as Class I, II, or III devices under the corresponding product code. Aside from Announcement No. 104/2017, there are a few additional classification lists that remain valid. If classification cannot be determined, it is possible to apply for an NMPA classification determination.

\*\* All manufacturers must also comply with the China-specific GMP requirements (Announcement No. 64/2014). There are also additional Appendices that are specific to certain product categories, such as sterile and implantable devices.

\*\*\* Foreign test reports are generally accepted for Class I devices; Class II and III devices require a combination of foreign and local test reports.

\*\*\*\* The NMPA requires a Clinical Evaluation for all Class II and III devices. There is a list of exempted devices (Announcement No. 94/2018) that only require a simplified CER, while a full China Clinical Evaluation is required for all other devices. The China Clinical Evaluation is unique and requires comprehensive comparison to an equivalent product already approved in China, where available. It differs significantly from a CER submitted for European CE Marking. Ask us for details.

This is a simplified overview of the process. Additional steps may be required depending on the classification of your device and quality of technical documentation.