



Medical Device Regulations in China

Meeting NMPA requirements



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Getting to market in China

Medical devices commercially distributed in China are regulated under the [Regulation on Supervision and Administration of Medical Devices](#). The regulation, published in 2021, introduced significant changes to the medical device regulatory environment.

While the regulation simplified the approval process for low-risk medical devices, manufacturers of higher-risk medical devices now need to provide more extensive technical and clinical information to meet pre-market approval requirements.

The cost of regulatory approvals for Class II and III medical devices increased significantly due to the [implementation of registration fees](#). While many manufacturers may find it challenging to access the market in China under these circumstances, those with innovative devices may benefit from the “Green Channel” registration process for an [expedited approval](#).

Overview of the NMPA regulatory structure

Medical devices in China are regulated by the National Medical Products Administration (NMPA). The NMPA is responsible for establishing and implementing medical device regulation, technical standards and device classification, as well as medical device registration and post-market surveillance policies.

The primary legislation in China governing medical devices is the Regulations on the Supervision and Administration of Medical Devices (State Order No. 739), implemented in 2021. Supplemental rules and guidelines have additionally been released to support this regulation.

Medical device manufacturers must register their devices before commercialization in China. Levels of control apply to medical devices based on the risks, from low to high. Medical devices may fall under Class I, II or III. While Class I medical devices only require notification to the NMPA, Class II and III medical devices require registration, including testing, formal technical review, and possible clinical trials before approval. The NMPA's [classification catalog](#) and online databases are available to help manufacturers identify the correct class of their devices. In cases where the classification is unclear, manufacturers must submit a formal classification application to the NMPA to obtain an official classification.

Class I notifications do not expire. Registration certificates for Class II and III devices are valid for five years. Manufacturers can apply for registration extensions (renewals), which must be submitted at least six months before expiration. When changes are made to an approved product, a modification application should be submitted.

Imported medical devices require proof of marketing approval from their country of origin for registration in China. For example, a U.S. manufacturer must have a listing, clearance or approval from the U.S. Food and Drug Administration (FDA). Where the device is not regulated as a medical device in its home country, the NMPA applicant must provide proof of such non-medical designation.

Foreign manufacturers must appoint an in-country representative, known as an Agent, who will act as a local regulatory contact for the device in China. The foreign manufacturer controls the registration in China; however, the Agent is responsible for communication with the NMPA during the device registration process and for maintenance of the certificate after approval, including post-market surveillance and registration extensions. Also, devices/IVDs that qualify for registration under the Innovative Device Registration Route (Green Channel) do not require home country approval. Notably, a Chinese invention patent is required to qualify for the Innovative Route.

Manufacturers must also appoint a After Sales Service Provider, who will be responsible for the products on the market from a servicing and maintenance perspective. This role is typically assigned to a distributor and must be identified in the Instructions for Use (IFU).



Class I

Manufacturers of Class I medical devices must first determine the applicable product code for their device. This can be confirmed by reviewing the NMPA's classification catalog, existing [Class I medical device list](#), and the NMPA classification announcements. If the product code is not clear via those methods, manufacturers can submit a formal classification application to confirm that the device is Class I.



Class I applicants must prepare a submission dossier called a Class I Record Filing. The record filing will include items such as a risk analysis report, Clinical Evaluation Report, the product Technical Requirement, corresponding test reports, and documentation regarding the product design and manufacturing process.

Class I Record Filings undergo only a completeness check upon submission, instead of a full technical review. The applications are either accepted or rejected upon submission.

Upon approval, the NMPA will issue a Class I voucher with a Record Number. This number must be placed on the Instructions for Use (IFU) and the product labeling. The NMPA will also publish the Record Number and product information on its website.

Class I Record Filings do not expire. However, if changes made to the device result in changes to the published filing information or the product Technical Requirement, manufacturers must notify the NMPA by submitting a modification application with supporting documents.

Class II and III

Manufacturers of Class II and III medical devices must submit more extensive documentation for which the NMPA will perform a comprehensive technical review. Submission dossiers should include:

- Product technical requirement (PTR)
- Test reports
- Clinical data, where applicable
- Biocompatibility evaluation reports, where applicable
- Risk analysis reports
- Manufacturing information
- Proof of quality management system (QMS), such as an ISO 13485 certificate
- Additional files prepared specifically for the NMPA, such as a research report including product performance and biocompatibility data

Before initiating the registration, manufacturers must confirm the appropriate [device code and classification](#). The device code corresponds to each product category, similar to U.S. FDA Product Codes associated with specific product groups. For example, China code 01-02- 01 is for medical laser instruments and 13-07-04 is for vascular prosthesis.

Once this is confirmed, manufacturers must develop the product technical requirement (PTR) based on testing data already completed by the manufacturer for international authorization, applicable Chinese national and industrial standards and the performance characteristics of the product itself. The PTR essentially outlines the specific criteria the product should meet to be commercialized in China and will serve as the testing protocol for device registration, as well as post-market inspection.

In-country testing

Test reports must be submitted as part of the NMPA application to demonstrate compliance with the requirements outlined in the PTR document. Under the previous State Council Order No. 680, in-country testing by a recognized laboratory was required for the registration of all Class II and III devices. However, State Council Order No. 739 states that a self-testing report from the manufacturer can also be accepted by the NMPA instead of in-country device testing and the NMPA has published the Regulations for Management of Medical Device Registration Self-Testing (Announcement No. 126/2021), which sets out the requirements for device testing to be conducted by the registration applicant (“self-testing”).

With that said, the regulation states that the NMPA will focus on inspection records, quality control capabilities, inspector operating skills, inspector qualification requirements, facilities and environment and inspection equipment during the QMS audit of the manufacturer performing the self-testing. However, the NMPA does not typically conduct a QMS audit for foreign manufacturers and the regulation does not address specific requirements for foreign manufacturers. Therefore, for manufacturers located outside of China, completing local product testing at an authorized lab in China would still generally be the most straightforward route, due to the NMPA’s qualification requirements for acceptance of a self-testing report.

There are many test laboratories in China authorized to test medical devices for registration purposes. Each test laboratory has a scope that is approved by the NMPA, which should be referenced when selecting the appropriate center to perform testing.

The fees for in-country testing generally range from \$5,000 (USD)-\$20,000 (USD) per device family. Upon initiation of the in-country testing process, the test center will provide a testing schedule detailing the testing timeline. The total timeframe for in-country testing is estimated at six months, although some products take longer.

The product technical requirement (PTR), together with testing sample(s) that represent the product family, should be provided to the test center to facilitate the in-country testing process. All test information should be submitted to the test center in simplified Chinese. Furthermore, it’s typically valuable for manufacturers to send a technical engineer to the test center to observe the testing process and answer product-related questions.





Clinical requirements

The NMPA requires clinical data for all Class II and Class III devices, unless the device appears in one of the regulator's published clinical evaluation exemption lists.

The manufacturer must provide clinical data from either a clinical trial or scientific literature. The options are as follows:

1. Clinical data from a study conducted in China. The trial shall comply with China Good Clinical Practice (GCP) (NMPA Order No. 28).
2. Clinical data obtained from a foreign clinical trial. The trial shall comply with China GCPs. Additionally, the manufacturer must validate that the ethnic differences of the patient/subject population do not affect the safety and effectiveness of the device for use on the Chinese population. If the NMPA does not accept the validation of this data, a bridging study in China may also be required.
3. A Clinical Evaluation Report (CER) leveraging clinical data/literature of a predicate device already on the market in China. Authorization from the predicate device's manufacturer must be obtained if unpublished data is used.

While preparing a CER using a predicate device seems to be the easiest option, most manufacturers struggle to obtain sufficient information on the predicate device to establish equivalency. For example, to establish substantial equivalence, details on the manufacturing process, material specifications, clinical data, literature and more on the predicate device are required.

Further, manufacturers must obtain authorization letters to use unpublished and other comparison data from the predicate device's manufacturer. There is also a risk that the NMPA may not accept a CER to prove the safety and effectiveness of the device; thus, the regulator may request additional clinical trials during the application review.

To prepare for a clinical trial in China, manufacturers should involve a clinical research organization (CRO) to help determine the number of sites and patients and develop the clinical trial protocol. This protocol must be submitted with product information, the PTR, and its corresponding China test reports to obtain Ethics Committee approval. Manufacturers will then sign clinical trial contracts with selected hospitals and submit a record filing of the clinical trial to the local branch of the NMPA before initiating the clinical trial.

Submission process

Once all necessary documents are compiled, the dossier may be submitted to the NMPA for review.

The steps are:

- The application will first go through a completeness check. The NMPA requires payment of the registration fee upon acceptance of the application.
- The application will be transferred to the Center of Medical Device Evaluation (CMDE) for a detailed technical review.
- An on-site inspection of the manufacturing facility, to China's GMP, may also be requested during the review stage. In our experience at Emergo, it is rare for the NMPA to request a QMS inspection for foreign manufacturers. However, the NMPA reserves the right to request an inspection.
- During the technical review, the reviewer will usually request supplementary information, clarification, additional testing or even a clinical trial. The manufacturer will have only one chance to provide a satisfactory response, within a maximum timeframe of one year from the date of the reviewer's request.
- The reviewer may also request an Expert Panel Meeting for novel or high-risk medical devices. If required, this step will occur before the supplementary information request. The Expert Panel consists of clinical, statistical, and technical experts selected by the NMPA. A representative of the manufacturer is expected to deliver a presentation to introduce the device, as well as address any questions asked by the panel. Additional information may be requested based on the outcome of this meeting.
- Once the application passes the technical review, a final administrative review occurs before the approval certificate is issued



Registration certificates are valid for five years. Manufacturers can apply for extension (renewal) no later than six months prior to the certificate expiry date, under the condition that the product remains the same as the product currently approved. Extensions cannot include changes to the product or the addition of any new models.

If the device undergoes any change, manufacturers must notify the NMPA by submitting a change notification or a registration modification application. The application complexity will depend on the type of change. Modifications may require updates to the PTR or re-testing, depending on the changes made and/or if any applicable national

or industrial standards have been revised or released since the previous approval. For extensions and registration modifications, the review timelines are the same as for the initial registration.

NMPA official review timelines

Import Class II/III*					Import Class I*	
Review stage	Initial registration	Registration modification	Modification notification	Extension	Filing	Modification
Acceptance	8	8	8	8	<5	<5
Technical evaluation	60 (Class II) 90 (Class III)	60 (Class II) 90 (Class III)	-	60 (Class II) 90 (Class III)	-	-
Second technical evaluation	60	60	-	60	-	-
Administrative evaluation	20	-	-	-	-	-
Issue certificate	10	10	10	10	-	-
NMPA Fee (CNY)**	210,900-308,800	42,000-50,400	n/a	40,800	n/a	n/a

* Times are in business days.

** Fees listed in table are for imported devices; domestic manufacturer application fees are different.

“Green Channel” expedited registration

To encourage medical device research and innovation, the NMPA established a Green Channel expedited registration process for medical devices that are innovative and have significant clinical value. To be eligible for this process, manufacturers must hold intellectual property of the core technology in China.

The timeframe to obtain confirmation that the device qualifies for the Green Channel is 60 working days. If the product is deemed of significant clinical value and approved for this route, it will be labeled as an “innovative medical device” and will be eligible for the expedited registration review process. Green Channel registration applications are reviewed with higher priority than standard applications.



Summary and conclusion

Challenges to registering medical devices in China are common. They must be carefully considered by foreign manufacturers interested in this large market. For medium- and high-risk devices, the possibility that manufacturers may have to conduct clinical trials in China to meet NMPA requirements may prove daunting. However, the regulators have expanded the list of devices exempt from clinical evaluation requirements, and the Green Channel expedited pre-market review option may ease market entry for qualifying devices.

Given China's economic heft, increase in healthcare spending and demand for medical devices, some foreign manufacturers will find more advantages than disadvantages in undertaking an NMPA registration.

Learn more

Need help with NMPA compliance? Emergo by UL helps medical device companies with regulatory compliance and market access in China and other markets worldwide. Here's how we can help:

- Device classification and clinical requirements assessment
- NMPA registration and submissions

Learn more about how we can help you with China medical device compliance at [EmergobyUL.com](https://www.emergobyul.com).

About the author

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Janet Zhang is the consultant for NMPA registration, located in Emergo by UL's Beijing office. She has rich experience in NMPA registrations from Class I to Class III. She has worked on over 80 product types such as laser generators, ECG monitors, implants, balloon catheters, puncture instruments, surgical tools and more.

