



Medical device regulations in China

Meeting National Medical Products Administration requirements

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Getting to market in China

Medical devices that are commercially distributed in China are regulated under the **Regulation on Supervision and Administration of Medical Devices**. The regulation, which was published in 2014 and revised in 2017, 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 also increased significantly due to the **implementation of registration fees**. While many manufacturers may find it challenging to access the Chinese market 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), which 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 Chinese legislation governing medical devices is the Regulations on the Supervision and Administration of Medical Devices (State Order No. 650), implemented in June 2014 and updated in 2017. Supplemental rules and guidelines have additionally been released to support this regulation.

Medical device manufacturers must register their devices prior to commercialization in China. Different levels of control apply to medical devices of different classes. 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 full registration, including in-country testing, formal technical review, and possible clinical trials prior to 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 prior to expiration. Where 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 US manufacturer must have listing, clearance, or approval from the US 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.

Manufacturers must also appoint an 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 in China.



Class I applicants must prepare a full submission dossier for what is 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 (reports conducted outside of China are acceptable for Class I), 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
- Foreign and local 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 how US FDA Product Codes are 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 based on testing data already completed by the manufacturer for international approvals, applicable Chinese national and industrial standards, and the performance characteristics of the product itself. The Technical Requirement essentially outlines the specific criteria the product should meet in order 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 to the requirements set forth in the product Technical Requirement document. For Class I devices, foreign reports will suffice. For Class II and III devices, the reports must be issued by NMPA authorized test labs.

There are currently 22 centers 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. Manufacturers have two options when conducting the in-country testing process, “registration testing” or “commission testing”. Test reports from either process can be used for NMPA registration.

There are no fees for “registration testing”, however the queue timeline is long and unpredictable, generally at least eight months or more. Additionally, many NMPA test centers will not accept new “registration testing” orders from foreign manufacturers. The fees for “commission testing” generally range from US\$5,000 – US\$20,000 per device family, but the overall timelines are shorter. Upon initiation of the “commission testing” process, the test center will provide a testing schedule clearly detailing the testing timeline. The total timeframe for “commission testing” is estimated at six months, although some products take longer.

The product Technical Requirement, 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 trial exemption lists. Manufacturers should have already identified a suitable clinical strategy before beginning the in-country testing process, as clinical trials must start within one (1) year after the China test report is issued.

The manufacturer must provide 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. 25](#)).
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 efficacy 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 Chinese market. Authorization from the predicate device's manufacturer needs to be obtained if any 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, in order to establish substantial equivalence, details on the manufacturing process, material specifications, clinical data, literature, and more on the predicate device are required.

Further, manufacturers need to obtain authorization letters in order 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 efficacy 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 product Technical Requirement, 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 broad 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 Good Manufacturing Practices, may also be requested during the review stage. In Emergo's experience, it is rare for the NMPA to request a QMS inspection for foreign manufacturers. However, the NMPA reserves the right to request an inspection at any time.
- 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 differ depending on the type of change. Modifications may require updates to the Technical Requirement 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. NMPA review timeline for change notifications is estimated at two months. For extensions and registration modifications, the review timelines are the same as for the initial registration.

NMPA official review timelines

| Review Stage | Import Class II / III* | | | | Import Class I* | |
|---------------------------|---------------------------------|---------------------------------|---------------------------|---------------------------------|-----------------|--------------|
| | 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) | - | - |
| 2nd 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 of significant clinical value. In order 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 40 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 + Conclusion

Challenges to registering medical devices in China 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, Chinese regulators have expanded their list of devices exempt from clinical trial 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 helps medical device companies with regulatory compliance and market access in China and markets worldwide. Here's how we can help:

- China Agent representation
- 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 authors

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