

An overview of Regulation for Medical Devices in China (1/2)



Regulation and Registration of medical devices in China

In China, activities related to medical devices, including their manufacturing, marketing, distribution, and sale, are mainly regulated by the Regulations on Supervision and Administration of Medical Devices, most recently amended in May 2017. The **National Medical Products Administration (NMPA)** is the governmental authority principally responsible for the supervision and administration of medical devices.

English version of their website: <http://english.nmpa.gov.cn/>

Other Chinese Regulatory Authorities

- ❑ China Food & Drug Administration (CFDA): responsible for medical devices, drugs, and healthcare services.
- ❑ Center for Medical Device Evaluation (CMDE): responsible for conducting the dossier review during the medical device registration process.
- ❑ General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ): conducts mandatory safety registration, certification, and inspection for certain devices.

Classification

Similar to the United States, a three-class classification system, from Class I (lowest risk) to Class III (highest risk). Local testing and clinical trials are generally required for Class II and Class III devices.

Some imported devices may need to register with a higher level government authority than domestic devices.

To determine the classification of a medical device, a manufacturer refers to

- the Medical Device Classification Catalogue
- the classification notices by NMPA and
- the Rules for Medical Device Classification

Devices not specifically covered by the Medical Device Classification Catalogue or other relevant regulatory documents/guidance should be treated as Class III, or the manufacturer can submit an application to seek classification determination opinion from NMPA.

Regulatory Pathways

Regulations make a distinction between “domestic” and “imported” devices

Domestic devices

- ❑ Class I devices only require record-filing in the local NMPA branch
- ❑ Class II and Class III devices require a registration application.
 - Class II application is reviewed and approved on a local level, i.e. by the local NMPA branch
 - Class III application are reviewed by NMPA centrally.

Imported devices

- ❑ Class I devices: record-filing requirement
 - ❑ Class II and Class III devices: registration/approval requirement
- } All reviewed by NMPA centrally

Latest Updates

- ❑ A Unique Device Identification (UDI) Database is currently under creation intended to record the expiry and production dates of medical devices, device models and the alphanumeric UDI code of each device.
- ❑ The Chinese Clinical Trial Management System has been updated to facilitate the review of clinical data conducted outside of China.
- ❑ According to the 2018 draft amendment, foreign manufacturers will be allowed to import innovative devices (as per the Chinese definition) without providing market entry approval certificates from the country the device was manufactured in.

An overview of regulation of medical devices in China (2/2)



Central-level NMPA registration process

- ☐ Appointment of a local Regulatory Agent.
- ☐ Proof of approval of the medical device in the country of origin prior to registration in Chinese Authorities.
- ☐ Sample testing of the device from a NMPA-authorized testing center to obtain a valid testing report (only valid for one year). For Class I applications self-test reporting is usually sufficient.
- ☐ Preparation of a China Clinical Evaluation*.

Class I devices may not be required to provide clinical data based on the overall level of available evidence on safety and performance. Typically, clinical trials are required for Class II and Class III medical devices, unless they are falling into the currently-applicable NMPA exemptions.

Notes :

- a) manufacturers/potential importers should know that acceptance of data coming from clinical trials conducted outside of China are subject to approval.
- b) conducting clinical trials on high-risk devices in China is restricted and require NMPA approval
- ☐ Preparation of 'Product Technical Requirement' document (PTR) and submission of an application dossier for a preliminary technical review by CFDA.
- ☐ Upon potential revision and final draft acceptance, further review of the PTR by CMDE.
- ☐ CFDA final review and registration approval.

Of note:

- ☐ All manufacturers must provide evidence of compliance with China-specific GMP requirements as per Announcement No. 64/2014.
- ☐ Dossiers and all included documentation must be submitted in simplified Chinese.
- ☐ Certificates are valid for 5 years. A renewal application should be submitted 6 months prior to the expiration date to the same department where the original registration submission took place.

*China Clinical Evaluation

Only exempted devices per Announcements No. 94/2018 & No. 91/2019 are allowed to submit a simplified CER. All other devices should submit a full China Clinical Evaluation, which differs from EU CERs and requires the comparison of the device in scope with an equivalent device already approved in China, if applicable.

Equivalence must be proven in terms of:

- ☐ intended use
- ☐ the device's basic principles of operation
- ☐ manufacturing details
- ☐ production processes
- ☐ performance requirements
- ☐ clinical safety aspects
- ☐ alignment with national technical standards

A China Clinical Evaluation report should cover the following items:

- ☐ Intended use
- ☐ Labeling statements on contraindications, precautions, warnings and use specifications
- ☐ Basic principle of operation
- ☐ Device components
- ☐ Related production technology
- ☐ Manufacturing materials
- ☐ Safety evaluation
- ☐ National technical standards
- ☐ Verification & validation with respect to sterilization and packaging
- ☐ Labels and Instruction of Use