



CHINA MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering China



START HERE: WHAT IS THE PRODUCT IN CHINA?



1 Confirm China regulatory identity

Confirm intended use, user, technology, anatomical contact, whether the device is sterile, implantable, invasive, active, software-driven, measuring, or subject to special technical standards; determine whether the product is domestic or imported.



General medical device



Sterile / implantable / invasive



Software / active / special

2 Choose the regulatory route

CLASS I



Low risk

Filing route

Generally lower-risk devices; filing rather than full registration.

CLASS II



Moderate risk

Registration route

Moderate-risk devices require NMPA registration.

CLASS III



High risk

Registration route

Higher-risk devices require the strongest evidence and registration review.

Device attributes such as sterility, implantability, invasiveness, active energy, software, duration of contact, and novelty can materially change classification and route.

3 Build the China market-access infrastructure



NMPA / CMDE framework

Use the *Regulations on Supervision and Administration of Medical Devices* plus classification rules and registration / filing provisions.



China legal agent

Imported devices appoint a legal agent in China to handle registration coordination and post-market communications.



Product technical requirements & testing

Prepare product technical requirements and the required testing / self-testing package for the route.



Chinese labeling / launch readiness

Build Chinese labeling, IFU, symbols, and commercialization materials consistent with the approved dossier.

4 Build the evidence stack



Administrative

Device description, intended use, classification rationale, route documents.



Quality / QMS

Manufacturing and quality-system readiness, supplier controls, sample readiness.



Testing / type testing

Bench, safety, EMC, software verification, biocompatibility, sterilization, packaging, shelf life, and performance testing as applicable.



Clinical evaluation

Clinical evaluation report and, when needed, clinical evidence or clinical trial support.



Labeling & IFU

Chinese labeling and instructions for use aligned to the filing / registration content.



RA TRAP TO AVOID

Do not begin with "How long is China?" Begin with product identity, imported vs domestic status, classification, testing strategy, clinical evaluation strategy, and legal-agent readiness.



STRATEGIC INSIGHT

In China, product attributes such as sterility, implantability, active technology, software, and special standards often drive the classification and evidence path; plan early.



CHINA MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

From classification to commercialization — with the decision points a newer RA professional should watch

A Program flow



B What gets heavier as the class rises?

Factor	CLASS I	CLASS II	CLASS III
Pathway intensity	Light / filing oriented ● ● ● ● ●	Moderate ● ● ● ● ●	Highest ● ● ● ● ●
Testing burden	Low ● ● ● ● ●	Moderate ● ● ● ● ●	Very high ● ● ● ● ●
Clinical evidence	Usually not required ● ● ● ● ●	May be required ● ● ● ● ●	Usually required ● ● ● ● ●
QMS scrutiny	Basic ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●
Post-market control	Lower ● ● ● ● ●	Moderate ● ● ● ● ●	Highest ● ● ● ● ●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on product complexity, evidence quality, application completeness, testing outcomes, and regulator workload.



i Planning ranges are Hopestone estimates, not NMPA promises.

⌚ Actual timing varies with classification, testing, clinical route, dossier quality, translation, and review questions.

D Labeling & language essentials

Chinese-language labeling / IFU
Chinese text is required; the Chinese version governs.

Product labeling
Name, model/ specification, registrant / legal agent, registration or filing number, warnings, storage and other required items.

Instructions for use
Installation, operation, contraindications / precautions, maintenance, reusable-device reprocessing where applicable.

Claims control
Labeling and promotional claims must align with the approved intended use and dossier.

Product identifier / traceability
Prepare UDI / traceability documentation where applicable and maintain records.



PRIMARY RESOURCES USED FOR THIS TRAINING AID

- Regulations on Supervision and Administration of Medical Devices (NMPA)
- Provisions for Medical Device Registration and Filing (NMPA)
- Rules for Classification of Medical Devices (NMPA)
- Provisions for Instructions and Labels of Medical Devices (NMPA)
- NMPA: <https://www.nmpa.gov.cn>
- CMDE: <https://www.cmde.org.cn>



IMPORTANT

Product-specific China requirements, standards, testing, and current regulator expectations govern. Confirm the current route before execution.



CHINA MEDICAL DEVICE: EXECUTION DETAILS & HIGH-RISK DECISION POINTS



Use this page to identify the issues most likely to change route, evidence burden, or launch timing.

E Country-specific decision points

Sterile claims



Sterile devices usually trigger higher control expectations, validated sterilization evidence, packaging and shelf-life support, and may shift classification or evidence needs versus a non-sterile version.

Implantable / invasive use



Implantability, invasiveness, anatomical site, and duration of contact can move a device into a higher-risk class and increase non-clinical and clinical expectations.

Active / electrical / software



Active energy, electrical safety, EMC, cybersecurity, and software lifecycle documentation can become critical dossier elements; standalone software and connected functions must be analyzed carefully.

Special standards / type testing



Applicable Chinese standards and product technical requirements drive the registration testing package; special standards may materially affect test scope, samples, and timing.

Clinical evaluation route



Determine early whether the product can rely on a clinical evaluation report or exemption logic, or whether stronger clinical evidence or clinical-trial support may be needed.

Imported vs domestic setup



Imported devices need China legal-agent coordination and China-ready dossier alignment; domestic vs imported setup affects responsibilities, document flow, and post-market execution.

F Execution checklist

- ☐ 1. Intended use, users, and claims are frozen enough to classify reliably.
- ☐ 2. Classification rationale captures sterility, invasiveness, implantability, software, and active-energy features.
- ☐ 3. Imported-versus-domestic route and legal-agent responsibilities are confirmed.
- ☐ 4. Product technical requirements and applicable Chinese standards are mapped.
- ☐ 5. Testing, sample, and QMS readiness are aligned to the proposed route.
- ☐ 6. Clinical evaluation strategy is documented and evidence gaps are understood.
- ☐ 7. Chinese labeling, IFU, symbols, and commercialization language are dossier-aligned.
- ☐ 8. Registration maintenance, change control, vigilance, and UDI / traceability planning are assigned.

G High-impact practical notes



Renewal / change control

Approved registrations must be maintained and certain changes require formal change handling before implementation.



Post-market vigilance

MAHs and agents must support adverse-event monitoring, re-evaluation, and corrective actions.



UDI / traceability

Prepare UDI and traceability data where applicable and integrate into the China launch plan.



USE THE TIMELINES AS PLANNING RANGES, NOT REGULATORY PROMISES

Actual duration depends on classification, testing scope, clinical route, standards, translation, dossier completeness, review questions, and manufacturing readiness. Build the China critical path before committing launch dates.



Accuracy review basis: current official NMPA / CMDE source framework accessed August 2026. Verify product-specific requirements at execution.