



# China Services



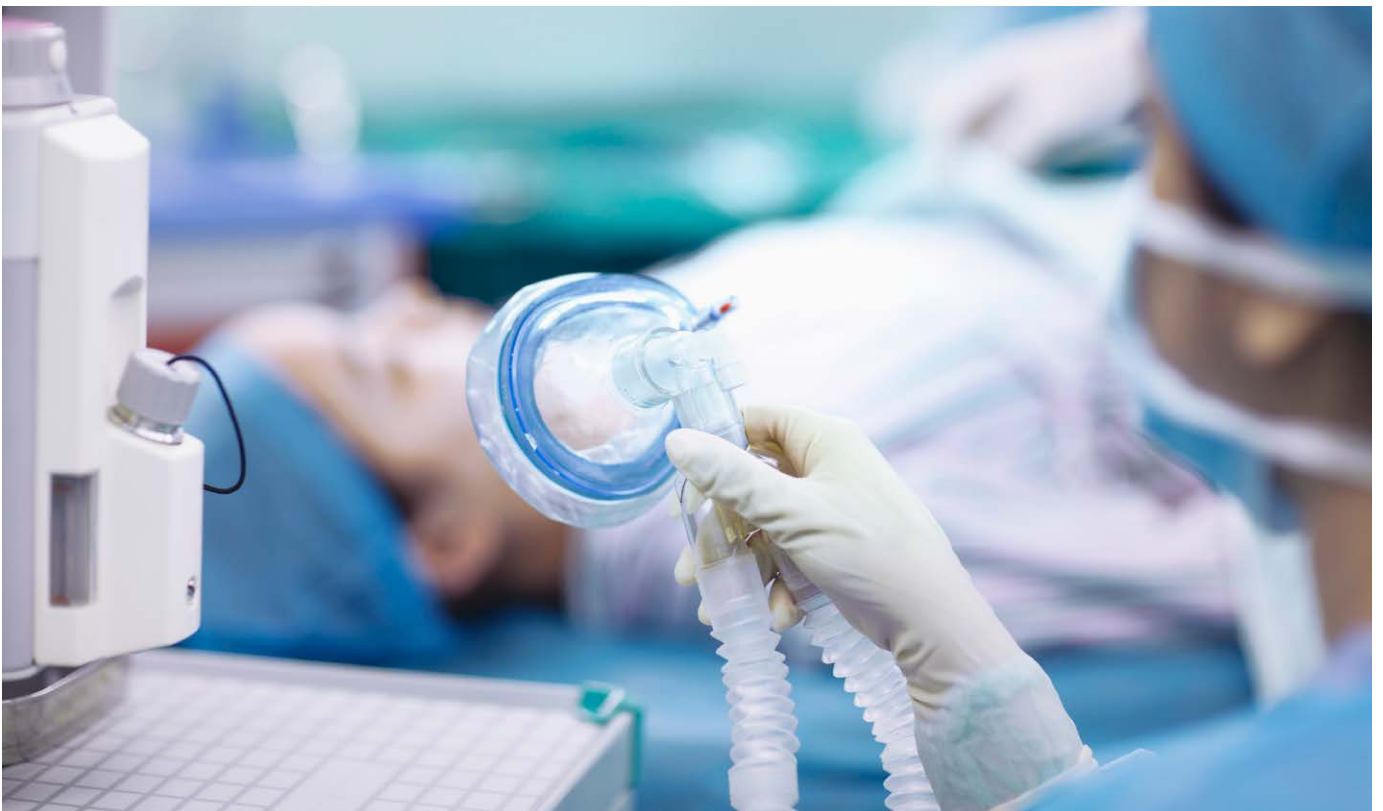
# Introduction

The medical device market in China is highly significant for international manufacturers due to its rapid growth and immense potential. With one of the world's largest populations and a rapidly aging demographic, there is a rising demand for advanced healthcare solutions, making China a crucial market for medical devices.

For higher-risk Class II and Class III devices—particularly those incorporating **new or innovative technologies**—the approval process becomes far more complex. It may involve extensive clinical trials, in-depth technical reviews, and rigorous documentation to demonstrate the device's safety, effectiveness, and compliance with Chinese standards. Class III devices, which pose the highest potential risk, often require the most comprehensive evaluations.

In addition to regulatory requirements, manufacturers must also understand **localization challenges**, such as adapting product labels, ensuring compliance with Chinese technical standards, and addressing language requirements for instructions and packaging. The entire approval process can be time-consuming and resource-intensive, potentially taking months or even years, depending on the complexity of the device and the level of risk involved.

**The Technical Documentation for EU and US is not sufficient for China submission!**



# How does NSF support the manufacturers?

From product development, market entry to post-market surveillance and renewal/change process – Our native-speaking consultants support you throughout the entire lifecycle of your medical device.

On all important milestones of a China Registration, we also offer a **one-day training** in which you can ask our experts questions and we provide comprehensive insights for your China registration, including renewal and change registration.





## 1. Design a China Registration Strategy

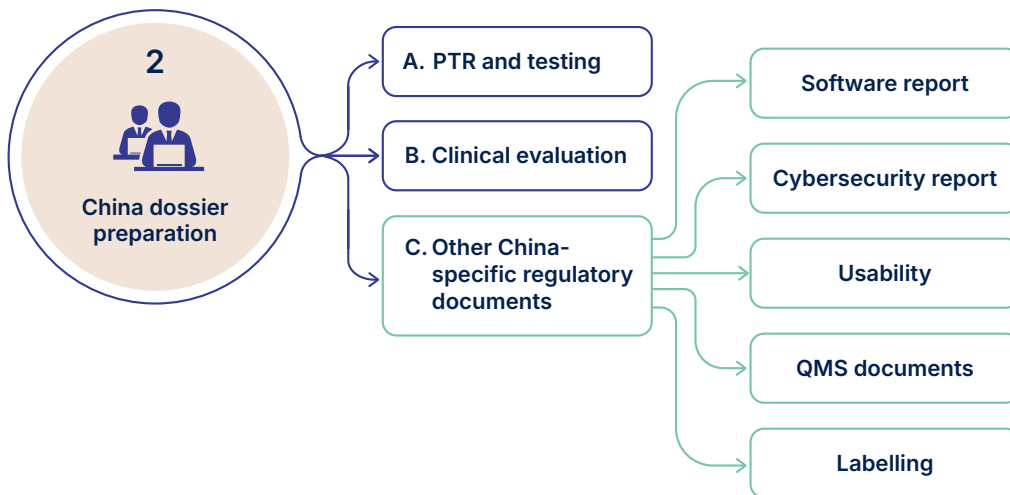
The most important task for a China registration is effective planning. If the China registration is planned in a well-structured manner, **the time-to-market can be shortened and costs reduced.**

Thanks to our many years of experience, we can provide the best possible support for efficient planning for your medical device.

NSF helps manufacturers in:

- accurately determining the **classification** of the medical device in line with China's National Medical Products Administration (NMPA) regulations and define the appropriate clinical pathway for registration.
- identifying applicable **Chinese Standards (GB, YY) and CMDE-Guidance** related to the safety, performance, and functionality of the medical device.





## 2. China Dossier Preparation (Technical Documentation China Submission)

NSF assists manufacturers in preparing registration documents in compliance with eRPS requirements, including China-specific documents such as:

### A. PTR – Product Technical Requirement

preparation of the PTR Template Draft together with the manufacturer by according to CMDE Guidance and Chinese Standards.

Review and implementation of applicable guidelines and standards issued by the Center for Medical Device Evaluation (CMDE). Performing a thorough gap/need analysis to ensure compliance with all regulatory requirements and identifying areas needing improvement.

The requirements of the PTR often have to be **tested in China** – and there are additional or different technical requirements in China.

We can prepare you optimally for testing in China and support communication with the test laboratories, saving you valuable time.

### B. China Clinical Evaluation (China CER)

With years of experience in writing China CERs, we provide professional support for manufacturers in compiling a complete Clinical Evaluation Report that reviews clinical data and demonstrates the safety and effectiveness of the device in accordance with Chinese clinical evaluation guidelines.

**eRPS (electronic Regulated Product Submission) is a digital platform used by the Center for Medical Device Evaluation (CDME) to manage the regulatory approval process for medical devices.**

### C. Other China Specific Regulatory Documentation

We help medical device manufacturers understand and navigate Chinese regulatory requirements by highlighting key differences from EU and US regulations. Our service includes providing China specific templates that align with NMPA expectations, ensuring a structured and efficient documentation process. We customize these templates to fit the specific needs of each manufacturer, facilitating a compliant market entry into China.

China’s requirements are particularly high in these areas:

- [Software Report](#)
- [Cybersecurity Report](#)
- [Usability Report](#)
- [QMS Documents](#)
- [Labeling](#)

**PTR (Product technical requirements) is a core part of the Chinese medical device registration dossier – Registration testing should be conducted according to the PTR.**



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Deficiency letter &  
supplementary

### 3. Deficiency Letter and Supplementary Support

NSF assists manufacturers in analyzing questions raised in deficiency letters and developing effective response strategies.

NSF can support the communication between the manufacturer and the NMPA during the supplementary process for a better understanding of the requests.

**A Deficiency Letter** is an official notification from NMPA for additional information or clarifications during the medical device registration review.

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Post-Market  
Surveillance

### 4. Post-Market Surveillance (PMS) Strategy

There are additional country-specific requirements in China for post-market surveillance. We offer the following services for your medical device:

#### Compilation of Periodic Risk Evaluation Report (PRER)

After market approval NSF helps compiling and submitting the Periodic Risk Evaluation Reports in compliance with China's post-market surveillance requirements. These reports should assess the ongoing safety and performance of the device in the market and highlight any emerging risks.

#### Adverse Event reporting and recall

We also assist manufacturers in the Adverse Event (AE) reporting process in China, as well as handling international reporting requirements. NSF also supports recall processes if necessary, ensuring swift and compliant action to address product safety issues, minimize market disruption, and maintain regulatory adherence.

#### Annual Self-Inspection Report Support

NSF supports registrants and filers in preparing and submitting their Annual Quality Management System Self-Inspection Report in compliance with NMPA regulations to ensure timely, accurate submissions and maintain full regulatory compliance.





## 5. Change Management

Manufacturers must monitor any changes in the medical device's design, manufacturing process, or intended use that may require filing or change registration under NMPA regulations.

### Tracking Regulatory Changes

NSF helps assessing whether changes are classified as minor adjustments or substantial modifications that justify regulatory approval.

### Change Filing and Registration Support

NSF provides comprehensive support to manufacturers in navigating the change registration process. This includes compiling and submitting relevant documentation, coordinating with regulatory authorities, and ensuring all modifications align with Chinese regulatory standards.

### Risk Assessment and Compliance Guidance

By conducting detailed impact analyses to assess how product changes might affect compliance with local standards, NSF can offer strategic advice to ensure manufacturers stay aligned with NMPA expectations and avoid delays in the approval process.



## 6. Renewal Management

Renewal management is just as important as the registration. If this is not carried out on time, the medical device must be registered again, which costs a lot of resources.

We help you to organize your renewal management efficiently.

### Certificate Expiry Tracking

NSF helps maintaining a proactive system to track the validity periods of regulatory certificates, ensuring that the manufacturer is aware of upcoming expiration dates well in advance.

### Preparation and Submission of Renewal Applications

NSF works closely with manufacturers to prepare all required documents for the renewal of product registrations. Submit renewal applications in a timely manner to avoid lapses in certification and ensure uninterrupted market access.

### Regulatory Liaison

NSF can also liaise between the manufacturer and the NMPA throughout the renewal process, addressing any requests for additional information and ensuring smooth communication with authorities to facilitate the renewal approval.

The **Renewal** of medical device registration for Class II/III in China must be done every **5 years**.

# Why use NSF services?

NSF provides comprehensive guidance on NMPA registration, offers regulatory consulting, NMPA registration training and comprehensive support in quality assurance to ensure regulatory compliance throughout the entire product life cycle in China, helping manufacturers overcome these barriers and successfully enter the Chinese market.

- Over 25 years of expertise in the medical device industry
- Multilingual team of international experts based in Hamburg, Germany
- Integrated approach combining regulatory, technical, and clinical expertise
- Extensive hands-on experience and in-depth knowledge of China's regulatory requirements
- Comprehensive support services for the entire approval process, including registration strategic planning, gap analysis, document compilation, QMS audit according to Chinese GMP and communication with regulatory authorities





