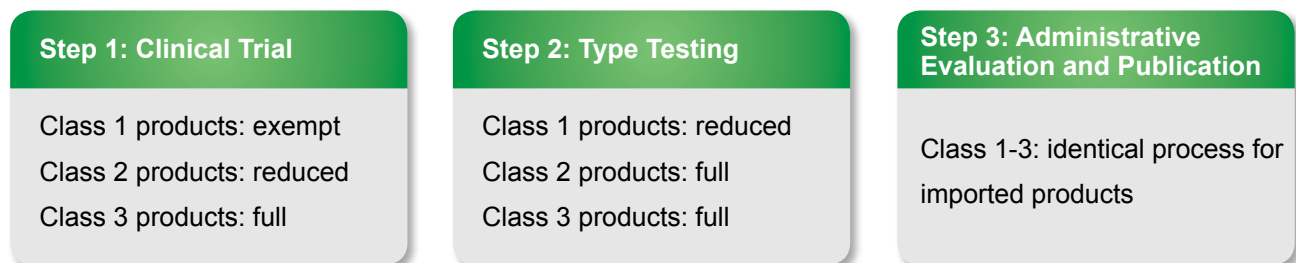


Approbation of Medical Devices in China



Registration, evaluation, and approval of medical devices imported into China are conducted by the *State Food and Drug Administration of China* (SFDA). According to SFDA regulations medical devices fall into three categories, quite similar to the classification system used in Europe. SFDA maintains a list of medical devices and their classification, which is not always identical to European practice.

The approbation procedure includes the following three steps:



Step 1: The clinical trial has to be undertaken in cooperation with a hospital in China and must be based on the intended use of the product in China. When selecting a potential cooperative partner for the clinical trial, it is important to consider future marketing approaches.

Note: Class 2 products can be exempt from clinical trial if one of the following applies:




- *Implantable devices, radio-emission sources, ultrasonic lasers, microwave devices; if approved by the regulatory authority in country of origin*
- *Manufacturer has record for 4 years marketing of medical devices in China, a certified quality system covering the device, and approval by regulatory authority in country of origin*
- *Product is built according to applicable Chinese standard and used for diagnosis or clinical chemistry only*

Step 2: The type testing is straightforward, takes approximately 6 weeks, and requires samples to be sent to China. All samples of medical devices – except consumables – will be returned to applicants. The Chinese definition of “medical devices” includes the software used for its proper application; the testing process may include testing of the software and related security aspects.

Note: Type tests undertaken outside of China are in general accepted for class 1 products, might be partially accepted for class 2 products, and are not accepted for class 3 products

Step 3: The last step is the formal application for SFDA registration: The procedure starts with a check of completeness and consistency of documentation by the “*Administrative Reception Service*” of SFDA. The ensuing technical review is performed by the “*Center for Technical Evaluation*” of SFDA. The final evaluation and decision is made by the “*Medical Device Department*” of SFDA. A notification of approval is sent to the applicant by the “*Administrative Reception Service*” of SFDA; the approval is valid for 4 years.

Additional Comments to the Approbation Procedure in China:

-  In its regulations, SFDA require a total duration of 90 working days to complete its regulatory review. It is important to note that this indication in duration is not binding and covers step 3 of the procedure only. It is frequently reported that **the full procedure may last anything from 6 to 12 months.**
-  Some medical devices might **require CCC certification** on top of registration with SFDA; according to the current CCC catalogue those devices are as follows: medical diagnostic X-ray equipment, haemodialysis equipment, hollow fiber dialyzers, extracorporeal blood circuits for blood purification equipment, artificial heart-lung machines, electrocardiographs, and implantable cardiac pacemakers.
-  The procedure requires that the applying company provides information on previous registrations in developed economies such as the European Union, United States and Japan. The complexity of the approbation procedure in China depends considerably on the **duration of the availability of the product in these markets** prior to the application with SFDA.

Note on the Standard: GB 9706.1-2007

*GB 9706.1-2007 is the Chinese endorsement of the second edition of **EN/IEC 60601-1**, which is the global reference standard for safety of electro-technical medical devices. GB 9706.1-2007 lays the ground for registering electro-technical medical devices in China. In addition, product-specific standards built upon EN/IEC 60601-1 and/or GB 9706.1-2007 have to be taken into account when assessing compliance of medical devices with China regulations.*

***The third edition of EN/IEC 60601-1 has not yet been adopted in China and cannot be used as reference for registration purposes in China.** Since the underlying concepts of the third edition of the standard are quite different from the second edition, it is generally not possible to obtain successful registration in China with products developed and documented according to the third edition of EN/IEC 60601-1. Whilst China embraced the concept of risk management for medical devices by adopting the standard ISO 14971 (in China: YY/T 0316), this does not yet apply for the approbation procedure.*

***It is of utmost importance that the producer / importer is aware of the applicable standards in China and that the product is built and documented according to GB 9706.1-2007 and all related product-specific standards in China,** which may differ considerably from the respective international standards. Currently there is no clear timetable for the adoption of the third edition of EN/IEC 60601-1 in China, thus related changes of the approbation procedure in China cannot be expected anytime soon.*

We are glad to hear from you and provide you with an initial plan of action and quotation:

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