Medical device registration

Medical devices need pre-market approval

All medical devices entering the Chinese market are required to obtain pre-market approval from the Chinese State Food and Drug Administration (SFDA). The approval is known as the *medical device registration*.

The rules for medical device registration are governed by 2 main regulations, namely the "r*egulations for the supervision and administration of medical devices*" (2000), and the "*measures for the administration of medical device registration*" (2004). Both regulations describe the legal requirements for obtaining medical device registration in China. The SFDA has undertaken revisions of the administrative measures and changes are expected in the latter half of 2011.

The Chinese classification system for medical devices is similar to the European system, however differences do exist and applicants are advised to carefully consult the classification list published by the SFDA. In China, medical device classification lays the foundation of the registration requirements and procedures. All class III and imported devices are managed directly by the central SFDA.

In addition to the medical device registration, 8 types of medical devices are required to obtain China Compulsory Certification (CCC) before entering China. The CCC mark is managed by the Chinese quality and quarantine authorities (AQSIQ) and the application process is additional to medical device registration. Read more about CCC registration here.

Products requiring CCC registration, in addition to medical device registration			
Electrocardiographs	Haemodialysis equipment	Extracorporeal blood circuit for blood purification equipment/blood purifying device	Hollow fibre dialyzers
Implantable cardiac pacemakers	Medical X-ray diagnostic equipment	Rubber condoms	Artificial heart lung machines

A medical device manufacturer can apply for the CCC certification and medical device registration at the same time. In this case it is important to choose a designated laboratory that is authorised to carry out both tests. This will allow the type test to be conducted both on the basis of registered standard and general CCC compliance.

How to determine classification of a medical device?

In China, medical devices are classified into 3 classes, namely Class I, II & III. The classification system is based on the risk of using the device and can be summarised in the following categories:

Class I	Medical devices for which safety can be ensured through routine administration;
Class II	Medical devices for which further control is required to ensure their safety of use;
Class III	Medical devices that are implanted into the human body, or used for life support, or pose potential risk to the human body and thus require strict safety surveillance.

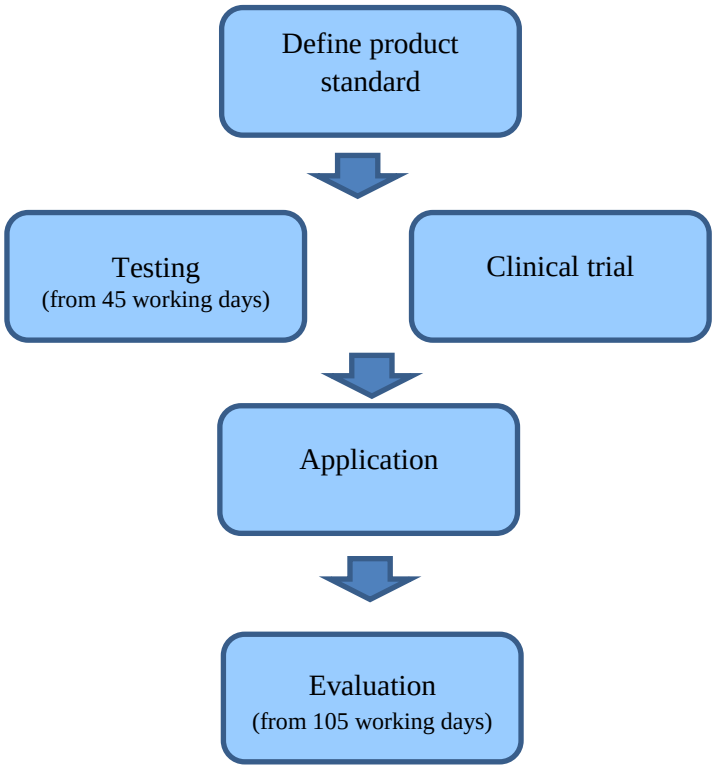
For registration, applicants can identify their medical device from the list provided on the SFDA's website (only available in Chinese) or consult the reference list provided in annex 1 of this guideline. There are currently 44 categories and the SFDA continues to update the list.

If the device cannot be identified through the official list, the manufacturer will need to submit an application to the SFDA for class designation of the product, based on the level of safety, structural characteristics and use of the device. In this case, the applicant should make a detailed introduction of the device, its functions, structural characteristics and classification status in the manufacturer's home country. This process takes 20 working days or more depending on the characteristics of the device and if the device is already approved in other countries.

How to apply for medical device registration?

The application procedure and timeframe for medical device registration can be simplified in the following graph:

Flow chart and timeframe of the medical device registration process



The SFDA advice on its website is that the application procedure can take 105 working days, however this is not including the time period for testing or conducting a clinical trial. Overall, the process can be divided into 5 steps:

1. **Appointing an agent** – applicant must be a legal Chinese entity;
2. **Standards and testing** - compliance testing at a designated laboratory in China;
3. **Clinical trial** – depending on approval and classification a clinical trial may be required;
4. **Application** – application and supporting documentation;
5. **Evaluation** – the Centre for Medical Device Evaluation (CDME) conducts a technical evaluation of information provided and issues registration.

1. Appointing an agent

According to the provisions of medical device registration, application for medical device registration can only be carried out by a Chinese legal entity. Overseas manufacturers of medical devices without legal representation in China are thus required to apply for product registration through agent services. When using agent services, the manufacturer is required to issue a letter of authorisation stipulating the relationship between the agent and the manufacturer.

The agent will play an important part in the application process and careful consideration should be given when selecting agents. The important selection criteria can be the agent's experience in dealing with regulatory affairs, experience in compilation and modification of the registered product standard, etc.

2. Standards and testing

Medical devices will be covered by Chinese national standards (GB standards), professional/sectorial standards (YY standards) stipulated by the SFDA, or both.

National **GB standards** are often harmonised with relevant international standards, however deviations do occur. The Standardisation Administration of China (SAC) provides a **national standards enquiry** service searchable by standard number, title, ICS code, etc.

Professional/**sectorial YY standards** are managed directly by the SFDA and can be searched on the SFDA website (although only available in Chinese).

In addition, The **EU-China Standardisation Information Platform** provides a useful search tool covering both national GB standards and professional YY standards for the medical devices industry.

Innovative or new products not yet covered by existing standards can submit manufacturing standards for registration, also known as registered product standards. Registered product standards should, as a minimum, meet the general safety and quality requirements of Chinese GB and professional standards. Reference to ISO or other official standards can also be provided.

For medical devices covered by Chinese GB or professional standards, but where deviations exist due to functionalities of the specific device, the manufacturer can make additions and add corresponding requirements to the standard relevant to the device.

If the device directly adopts Chinese GB and/or professional standards, the manufacturer is required to submit a statement confirming that the applicable Chinese standards are adopted without modifications.

Conformity testing is carried out by a designated Chinese laboratory. Therefore, once the standards covering the device have been determined, the device can be submitted for pre-approval type test at the designated laboratory. The type test will be conducted against the identified standard(s) verifying that the device fulfils all requirements.

The manufacturer is free to select the designated laboratory among a list provided by the SFDA. All designated laboratories are located in China.

All medical device applications should contain the designated laboratory testing reports except for Class 1 medical devices.

The sampling of the product will be determined by the applicable standard, both with regards to sampling size and testing of parts and components.

As stated in previous regulations, the type test was originally required to be completed within 45 working days – not including CCC testing. This regulation has since been revoked, so the timeframe can only be used as a reference, as testing will now depend on the workload of the testing laboratory.

The testing laboratory will liaise directly with the manufacturer/agent regarding required documentation, samples and work process.

When the testing is completed and applicable fees have been paid, the test laboratory will issue a test report (valid for 6 months) to be submitted as part of the medical device registration.

Exemptions
Type testing can be avoided if the imported medical device meets the following conditions:

- The medical device has already received market approval by the competent authority in the country of origin;
- The manufacturer holds a valid ISO 9000 (or equivalent) certificate;
- No significant differences exist between the device for application and the device registered in terms of structure, performance and safety.

3. Clinical trial

Class II and III medical devices require clinical data and the clinical trials may need to be conducted in China depending on a number of factors. The following conditions determine if the product needs clinical trial conducted in China or not:

Require Chinese clinical trial

- Class II & III devices that have not received market approval by the regulatory authority in the country of origin are required to undergo clinical trials in China.

Do not require Chinese clinical trial

- Class I devices;
- Class II devices conforming to Chinese national and professional standards, and used for diagnostics or clinical chemistry;
- Class II & III devices that have received market approval in the country of origin, when they meet the following criteria;
- If it is not a Class III product and in the groups of implantable devices or radio-emission resource, ultrasonic laser, microwave type of device.

Some Class III medical devices will need to go through an expert panel review in order to determine if the device needs clinical trial in China or not. This is particularly the case for *implantable devices* and devices with *radio-emission resources, ultrasonic lasers, and microwave* functions.

The timeframe for concluding clinical trials in China will depend on the complexity of the product and the availability of patients for the trial.

The clinical trial should be carried out at two hospitals in China. The SFDA has published a list on its website of designated clinical institutions where trials can be carried out. These hospitals are also capable of conducting clinical studies for drugs as well.

There are no approval procedures for conducting clinical trial studies in China but the manufacturer/agent is required to notify the local regulatory authority about the on-going clinical study.

4. Application

It is a pre-requirement for submitting the medical device application that the device has a valid test report and clinical trial report as described above. Once the manufacturer has obtained this documentation, the application can be submitted to the SFDA.

It is important that consistency is kept throughout the application – names should be matching with business registrations, product codes, etc. Any inconsistency will result in a delay in the application process. The application should be submitted in Chinese.

In summary, the application should contain the following documentation:

	Documentation
1	**Application form** for the medical device to be registered.
2	**Legal qualification certification** of the manufacturer that confirms the authorisation to engage in the production and distribution of medical devices. The copy should be notarised by local competent authorities.
3	Copy of the **business licence** of the applicant, either the manufacturer's representative office or an agent. If the applicant is an agent, an **authorisation letter** must be presented clearly stating the relationship with the agent and that the manufacturer takes responsibility for the product.
4	Documents proving that the device has received **market approval in the country of origin** (or other regions) or has been accepted by the competent medical device authorities overseas in another way. If the documentation is provided in copy it should receive the seal from the original regulatory authority or be notarised by competent local authorities.
5	Applying product standards (provided in two copies) - the standard document - the description of development of standards (applicable to registered product standard/manufacturing standard) - If the device adopts GB or professional standards: a. Declaration of conformity by the manufacturer; b. Statement of commitment accepting responsibility for product quality by the manufacturer; c. Description of the model and specifications of product with a seal of the manufacturer; d. The registered product standards should be signed by the manufacturer or by the competent institution responsible for drafting the standards. In the authorisation letter from the competent institution, the manufacturer shall take full responsibility for quality and safety.

6	**Operations manual** of the device – operational manual for Class II & III should be sealed by the manufacturer. The operational manual needs to follow the requirements set out in the "*administrative provisions on the operation manual of medical devices*".
7	Medical Device **test report** issued by a designated testing laboratory for Class II & III medical devices. The report should be submitted within 6 months after issuing with a registration application that needs a clinical study, and within 12 months for the registration application with no clinical study.
8	Medical device **clinical trial report –** including the contract for the clinical study, protocol followed in the study and the final report (when applicable). If a foreign clinical trial report is submitted in accordance to the registration requirements, it must contain the signatures of responsible inspectors and the seal of the hospital or health institution.
9	**Product quality guarantee** confirming that the quality of the product exported to China will have the same quality as the one in the country of origin.
10	Authorisation letter to the delegated agent in China, together with supporting documentation provided by the agent.
11	Letter of authorisation to the designated company/institution responsible for **after sales service.**
12	**Self-declaration** of **the authenticity and truthfulness of the documentation submitted** by the manufacturer/agent – listing all documentation submitted and taking legal liabilities for the product.

5. Evaluation

The centre responsible for receiving applications within the SFDA will examine the application and its supporting documentation and will decide if the application is accepted or not for filing. This process normally takes around 5 working days.

Once the Centre for Medical Device Evaluation (CDME) receives the application, a technical evaluation will begin, taking 60 working days or more depending on the sophistication of the device.

The technical evaluation involves several layers of systematic examination focusing on the safety and effectiveness of the medical device. The evaluation is carried out by CMDE internal reviewers and can involve external expertise.

At the end of the technical evaluation, CDME will issue an evaluation report passing its judgment on the device. The evaluation report is submitted to the SFDA for final approval. According to related regulations, SFDA may send an inspection/auditing group to Class III manufacturers abroad to check their quality assurance system based on Chinese national standards GB/T 19001-ISO 9001, 19002-ISO9002 and other relevant medical device standards and registered product standards.

According to the medical device regulation, the medical device certificate is valid for 4 years. The renewal of the registration should be started 6 months prior to the expiry date.

Annex 1

Classification of medical devices by categories			
#	Category	Product example	Class
1	General operation instruments	Scalpel Stitch scissors	I I
2	Micro surgery instruments	Micro scissors Micro forceps	I I
3	Neurosurgery instruments	Dural knife Dural dissector	II II
4	Ophthalmologic instruments	Corneal scissors Corneal forceps	I I
5	Ear-nose-throat instruments	Ear probe Tonsil scissors	I I
6	Stomatological operation instruments	Gum scissors Pocket probe	I I
7	Thoracic-cardiovascular surgical instruments	Sternotome Cardiac surgical scissors	I I
8	Abdominal surgery instruments	Angular scissor Gallstone forceps	I I
9	Urinary and anal surgery instruments	Prostate scissors Anoscope	I I
10	Orthopedic instruments	Finger saw Periosteum elevator	I I
11	Gynecologic operation instruments	Disposable umbilical cord scissors Uterine scissors	II I
12	Family-planning operation instruments	Uterine curet Deferens separating forceps	I I
13	Injecting & punctuating instruments	Disposable sterilised syringe and rubber plug Disposable venous infusion needle	III III
14	Burn treatment (plastic surgery) instruments	Forceps for orthopaedic Eyelid forceps	I I
15	General diagnostic instruments	Electronic thermometer Spirometer	II II
16	Medical electronic devices and equipment	Implanted pacemaker Acoumeter	III II
17	Medical optical instruments and endoscopes	Anomaloscope Medical magnification	II I
18	Medical ultrasonic devices and relative equipment	Foetal monitor Ultrasonic stethoscope	II II
19	Medical laser devices and equipment	Ophthalmic laser scanner Nitrogen molecular treatment instrument	III III
20	Medical high-frequency devices and equipment	Micro-wave scalpel Micro-wave prostate treatment instrument	III III
21	Physical treatment and recovery equipment	Amblyopia therapy instrument Magnetic therapy instrument	II II
22	Chinese medicine instruments	Acupuncture needle Guasha board	II I
23	Medical magnetic resonance equipment	Superconductive magnetic resonance imaging system Magneto encephalograph System	III II

24	Medical X-ray equipment	X-ray contact treatment instrument CT scanner for whole body use	III III
25	Medical X-ray equipment accessories and parts	High pressure injector Medical X-ray film	II I
26	Medical high performance radiation equipment	Medical neutron therapy unit Medical proton therapy unit	III III
27	Medical nuclide equipment	Bone density scanner Radionuclide scanner	II III
28	Medical radiation protection tools & apparatus	Exposure suit Protective gloves	I I
29	Medical testing and analysis devices	Blood type analyser Electrolyte analyser	III II
30	Medical laboratory testing equipment	Acer hemastix Incubator	II II
31	External circulation & blood processing equipment	Artificial heart-lung machine Heat exchanger	III II
32	In-plant materials and artificial organs	Artificial heart Hearing aid	III II
33	Operation/emergency/diagnose/therapy room equipment	Synchronous life support machine Ejector jet pump	III II
34	Stomatological equipment	Electrical dental chair Dental operating-light	II I
35	Nursing equipment	Electrical wheel chair Ordinary hospital bed	II I
36	Disinfecting and sterilisation equipment	UV germicidal lamp Ultrasonic disinfection equipment	I II
37	Low temperature/cooling therapeutic equipment	Liquid nitrogen treatment instrument Ice bag	II I
38	Stomatological materials	Acrylic teeth Porcelain teeth	III II
39	Medical hygienic materials & dressings	Bio-protein jelly Collagen sponge	III III
40	Medical sutures and binding materials	Biogum Surgical catgut	III III
41	Medical macromolecule materials and products	Condoms Sterile medical gloves	II II
42	Software	Tongue image analysis Instrument Medical magnetic resonance imaging system	II III

* Source: SFDA & "Guide to medical device regulations and practices in the People's Republic of China" 2010, Department of Foreign Affairs and International Trade Canada

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