CHINA MEDICAL DEVICES REGISTRATION

China Food and Drug Administration (hereafter referred to as CFDA) is a department directly under the State Council which supervises the food safety, health care products and cosmetics and takes charge of the drug administration. It is responsible for administrative and technical supervision on the R&D, production, distribution and use of drugs (including traditional Chinese medicine, traditional Chinese medicine decoction pieces, drugs made from chemical raw materials and preparations, antibiotics, biochemical drugs, biological products, diagnostic drugs, radioactive drugs, stupefacient, toxic drugs, psychotropic drugs, medical apparatus, hygienic materials, medical packing materials, etc.); comprehensive supervision, organization and coordination of safety management of food, health care products and cosmetics as well as investigation and treatment of major accidents according to law; examination and approval of health care products. The registration of medical devices is mandatory.

See more detailed information on www.cnda.cfda.gov.cn

All medical devices sold and used in China should apply for registration in accordance with the Administrative Measures for Medical Device Registration issued by CFDA. Medical devices that are not approved for registration must not be sold or used.

CFDA registers and manages the medical devices by classification:

- Class I Medical Devices are those for which safety and effectiveness can be ensured through routine administration
- Class II Medical Devices are those for which further control is required to ensure their safety and effectiveness

- Class III Medical Devices are those which are implanted into the human body, or used for life support or sustenance, or pose potential risk to the human body and thus must be strictly controlled in respect to safety and effectiveness

CFDA reviews the overseas medical devices and issues the registration certificates after approval. Registration of medical devices from Taiwan, Hong Kong and Macao, unless otherwise specified in Administrative Measures for Medical Device Registration, follows the instructions for overseas medical devices.

Relevant domestic websites to medical device information:

- China Medical Device Information Network www.cmdi.gov.cn
- China Medical Device Information Network is an official website authorized by CDFA. It releases official policies, laws and regulations and announcements for medical device manufacturers and other legal documents regarding registration of food and drug. The registration status can also be checked on Chinese version website.

Approval basis

Regulation on the Supervision and Administration of Medical Devices - came into force since April 1, 2000.

In order to standardize the registration and filing management of medical devices and ensure their safety and effectiveness, the Administrative Measures for Medical Device Registration was approved at CFDA administration affairs conference on June 27, 2014. On July 30, 2014, CFDA Order No. 4 announced that the Measures would come into effect on October 1, 2014.

Validity period of the certificate

Registration certificate of medical devices is valid for 4 years.

Registration procedures of medical devices

Any new medical device shall go through two steps to finish the registration in CFDA:

- Detection
- Registration

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Step 1: Detection

A) Apply for registration of product standard (for simplified Chinese version only)

Medical devices applied for registration shall have applicable product standards based on national standards, industrial standards, or specifically-formulated standards, but the newly formulated standards for registered product must not be lower than national or industrial standards. The applicant shall compile and submit the applicable standards for registered products in accordance with the CFDA's management requirements on medical devices. CFDA will accept and consider the qualified product standards. The successfully registered product standards will serve as the basis of local type test and assessment in future.

B) Review of product standards

CFDA will review the submitted product standards. The considered period prescribed by CFDA is 2 months. If the product standard fails the review, the applicant shall modify it according to real condition and resubmit.

C) Application for local type test (within China)

The applicant can apply to a CFDA-certified test lab (according to the types of lab product designated to test) within China for type test after the applicable product standard being registered successfully. In accordance with the product standard approved, the designated local test lab will give specific requirements for the test sample, e.g. how many samples need to be sent to the lab, whether it needs to test the corresponding parts and accessories, etc.

D) Type test in local lab

The samples shall be sent to designated local test lab for type test, and the completion time of test and test report specified by CFDA is 45 working days.

E) Clinical trials (if applicable)

Medical devices complying with applicable product standards through test can be used in clinical trials or applications for registration. The agency which applies for registration of the medical device shall be responsible for initiating, implementing, organizing, financing and monitoring clinical trials. The test period is subject to the product category, product complexity, and the integrity of submissions. After the clinical trial of the medical device is completed, the medical institution which undertakes the clinical trial will produce a clinical trial report in accordance with the requirements and form specified of the clinical trial plan of the medical device.

Step 2: Registration

A) Submissions for registration application

The applicant may conduct registration upon receipt of the test report and the clinical trial report (if applicable).

B) Document assessment

CFDA will first review the test report issued by the designated test lab and related application documents. This process generally requires 5 working days.

C) Technical review

The technical review requires 50 working days.

D) Administration review

The auditor will check the conformity of the application document, test report, and clinical report (applicable product). This process takes about 10 working days.

E) Verification and approval

Senior officials will carry out further inspection and final approval of the submissions. This process requires 20 working days.

F) Issuance of the certificate of registration

After all the inspections are passed, the medical device can be registered with the certificate. The issuing time usually requires 5 working days.

Submissions for registration of imported medical devices

Submissions for new registration application:

- Application form
- Supporting documents for legal production qualification of producers
- Qualification Certificate of Applicant
  a. Business license/registration certificate of the applicant agency, in which its business scope must be related to medical device
  b. The service life of the business license/registration certificate shall be within the term of validity
- Supporting documents which can certify the product is approved by the government of the country of origin (area) to export to its market as medical device
- Technical standards for products registered
- Type test report
- Clinical Study Report
- Product Instruction Manual
- Additional materials that may contribute to the review
- Product quality guarantee issued by producer
- Power of attorney, letter of commitment, business license/ registration certificate of service organization
- Self-assurance statement of authenticity of the submissions

Application submissions for re-registration

The certificate of registration is valid in four years. A re-registration shall be applied for 6 months before expiry.

- Application form (printed)
- Qualification Certificate of Applicant
- Copy of the original certificate of registration
- Supporting documents which can certify the product is approved by the government of the country of origin (area) to export to its market as medical device
- Technical standards for products registered
- Type test report
- Quality tracking report
- Product Instruction Manual
- Power of attorney, letter of commitment, business license/ registration certificate of service organization
- Product quality guarantee issued by producer
- Additional materials that may contribute to the review
- Self-assurance statement of authenticity of the submissions

Q&A

Q: All medical products require CFDA certification?

A: Yes, all medical products require CFDA certification.

Q: Is CFDA a certification system or only a registration system?

A: Actually, CFDA is a special registration system.

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Q: What are the Chinese standards required for CFDA certification/registration?
A: At the aspect of electrical, the Chinese standards for CFDA are GB 9706 series. But for CFDA registration, the requirement is not limited to the electrical performance. For the traditional product, CFDA have its mandatory or recommended standards. The applicant can choose to declare to conformity to them or draft the enterprise standard by itself; the enterprise standard should be stricter than the CFDA standard. But for the new developed or complicated medical device, the first step of CFDA registration is to register the product standard, which is drafted by the applicant and involve all of the aspects of the product.

Q: Are the CFDA standards similar to any IEC standards?
A: The electrical standards of CFDA are similar to IEC 601 series.

Q: We know that a local representative is required for CFDA. What will the duties be for this representative?
A: The most important role of the local representative is the after-sell service.

Q: Is it only the client/ local representative that can apply for CFDA or can it be done by a consultant?
A: There is no limit for the applicant. Both the client, its local representative or the consultant can apply for CFDA.

Q: What kind of test reports is required for CFDA (we know that clinic test report is required but are there other reports)?
A: The sample test report should be issued by the authorized domestic test lab and within a year.

Q: Can the CFDA be based on test reports from an accredited testing and certification body out of China?
A: Till now all of the accredited testing labs are domestic. There is no testing and certification body is accredited by CFDA.

Q: In a presentation we have about China for medical products it is mentioned the following:
- **Mandatory standard (GB, YY) , recommended standard (GB/T, YY/T)**
- **National standard (GB, GB/T) SDFA standard (YY, YY/T)**
- **Registered product standard (ZCB)**

what "YY", "T" and "ZCB" stands for?
A: "YY" stands for "Medical and medicine"
"T" stands for "recommended"
"ZCB" stands for "registration standard"

What Intertek can do

Intertek China provides comprehensive services for registration of medical device, including:
- Information consultation on medical device for CFDA registration
- Translation and preparation services of applicable product standards in accordance with customer's English materials
- Registration of product standards, coordination of local type tests and application for product registration as an agent on behalf of customers

FOR MORE INFORMATION

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