

Medical Devices Classification

The State shall classify medical devices and administer them based on this 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.

The classification catalogue for medical devices shall be stipulated, adjusted and promulgated by the drug regulatory authority under the State Council, in accordance with classification principles after consulting with health authority under the State Council.

Initial registration for Medical Device

A. The Direction for the Application Form of Registration

1. All the contents filled in shall be in both Chinese and English ;
2. Upon the application, the form shall be printed ;
3. All the items must be completely filled in, and as for the vacant items, “/” shall be used to show inapplicability ;
4. The Name of Devices and Model, Name and Address of Manufacturer must be unanimously the same as the contents carried in the documents approved by the government of the Country (Region) of Origin, and must be consistent with the contents concerned carried in the test reports, operation manual of the product, and so on;
5. Any enterprise shall not set up the format for the Application Form for Registration without authorization.

B. About the Application Documents

1. The certificate of the legal production qualification of the Manufacturer.
 - 1) The certificate issued by the government agency of the Country (Region)of Origin to authorize the Manufacturer to engage in the production and distribution of medical devices(equivalent to the business certificate or manufacturing enterprise license).

- 2) The certificates may be submitted in the form of the copy thereof, subject to the seal by the original issuing agency or the notarization by the local notarization agency.
2. The qualification certificate of the applicant
 - 1) Business certificate of the Applicant ;
 - 2) The certificate of commission given by the Manufacturer to the agent for registration
3. The certificate recognized or approved by the government of the Country (Region) of Origin to authorize the products as medical devices to enter into the market of the country.
 - 1) The certificate recognized or approved by the government of the Country (Region) of Origin to authorize the products as medical devices to enter into the market of the country.
 - (1) In case of any special authorization documents specified by the government of Country (Region) of Origin for medical devices to be put into the market of the Country (Region) of Origin, such formal authorization documents as 510 K or PMA of the U.S. FDA, and the CE certificate of the EU shall be submitted.
 - (2) In case of one of the following circumstances:
 - a. That no special authorization documents are required to handle by the government of the Country of Origin ;
 - b. That in case of any change to the Products on the basis of the Products specified in the original special authorization documents, due to the difference in the partition of registration elements, no re-application is required by the government of the Country of Origin, the enterprise shall give a statement, and provide the following certificates:
 - ①The free sale certificate issued by the government; or
 - ②the certificate to the foreign government; and
 - ③the enterprise self-guarantee declaration in conformance with the provisions concerned of local regulations
 - 2) In case of no document issued by the government of Country of Origin to authorize the medical devices to be put into market
 - (1) If the products shall be regulated as medical devices in the Country of Origin, but they have not been authorized by the government of Country of Origin to be put into market, the Standards of the Products to be Registered authorized by the competent department shall be submitted; in case of Products of Class II or Class III, the full-performance test report, Clinical Trial Reports, risk analysis reports

within the territory of China and other documents necessary for the registration of import products shall be submitted, subject to which, the application may be accepted and after the acceptance, the on-site inspection of the production quality system will be arranged.

- (2) If the products shall be regulated as medical devices in the Country of Origin , but need not be authorized by the government of Country of Origin to put in the market because they are produced specifically for China , the first paragraph of this Article shall be applied.
 - (3) If the products fail to be regulated as medical devices in the Country of Origin but the Products are defined as medical devices in China in accordance with the definition of medical devices, the first paragraph of this Article shall be applied.
- 3) The certificates may be submitted in the form of the copy thereof, subject to the seal by the original issuing agency or the notarization by the local notarization agency.
4. The Standards of the Products to be Registered shall apply the Provisions for the Management of the Medical Devices Standards
- 1) The methods for the implementation of “Only the Original of the Standards Sealed or Signed by the Legal Representative may be submitted”:
 - (1) Standards of the Products to be Registered may be sealed through the following three methods:
 - a. to be sealed by the Manufacturer;
 - b. to be sealed by the office or representative office of the Manufacturer in China ;
 - c. to be sealed by the unit in charge of the conclusion, arrangement, drafting of the Standards of the Products to be Registered commissioned by the Manufacturer. And in the certificate of commission, it shall be clearly indicated that “the ××× Unit is commissioned to be responsible for the completion of the Standards of the Products to be Registered in China, and the Manufacturer shall be responsible for the quality of the Products” .
 - (2) the Definition of the Legal Representative : in accordance with the international practices, " the signature and seal of the Legal Representative” of the Manufacturer abroad may be signed and sealed by the senior official in charge of the corresponding business activities.

- 2) The Standards of the Products to be Registered reviewed, codified, and recorded by SDA Standard and Technical Committee ;
- 3) As for the Products with national standard and industrial standards, the manufacturer shall, with the implementation of the standards mentioned above, based on its own specialties, supplement and add corresponding requirements, formulate the Standards of the Products to be Registered , and assure the safety and effectiveness of the operation of the Products ; if the enterprise thinks that no requirements on safety need to be added, and that the direct adoption of national standard and industrial standards as the manufacturer Standards of the Products to be Registered is sufficient for the assurance of the safety and effectiveness of the products, the manufacturer shall submit a statement justifying that without any increase and improvement in the standard index on the basis of national standard and industrial standards, the safety and effectiveness of the products for application can be assured, declaring to bear the quality liabilities after the launching of the products and carrying the model, specification of the Products. As for the products with ISO or IEC standards, the manufacturer shall convert the standards to the Standards for the Products to be Registered.

5. Operation Manual of the Products

- 1) The methods for the implementation of “Only the Original of the Operation Manual Sealed or Signed by the Legal Representative may be submitted”:
 - (1) The Operation Manual of the Products of Class II or Class III shall be sealed by the Manufacturer ; the Operation manual of the Products of Class I shall not be sealed.
 - (2) The Definition of the Legal Representative : in accordance with the international practices, " the signature and seal of the Legal Representative” of the Manufacturer abroad may be signed and sealed by the person in charge of the corresponding business activities.

- 2) Implementation of the “Administrative Provisions on the Operation Manual of Medical Devices” .

The operation manual of medical devices shall implement the national standards provided in “Operation Manual for Industrial Products--General provisions”. In accordance with the specialty of the medical devices , the following contents shall be included:

- (1) Name of Product, Name, Address, Postal Code and Tel. of the Manufacturer ;
- (2) Registration number of the products;
- (3) Applied product standards ;

- (4) The main structure, performance, specification of the Products ; the usage, scope of application, contraindication , precautions, cautions and suggestions of the Products;
- (5) Interpretation of the figures, logos, abbreviations, etc. of the labels and marks ;
- (6) Illustration and graphic expression of the Installation and Operation;
- (7) The Maintenance methods, special storage methods and length of life of the Products ;
- (8) other necessary contents specified in the Product Standards.

6. The Type test Report presented by the medical devices quality test agency recognized by the State Drug Administration within the recent one year (Applied to the Products of Class II and Class III)

1) About Test-after-Registration of import products

The following import products may apply to Test-after-Registration :

- (1) X-Ray Computerized Topography(C T) ;
- (2) Positron Emission Computerized Topography (PET) ;
- (3) Single Photon Emission Computerized Topography (SPECT) ;
- (4) Extraneous Shock Wave Crusher ;
- (5) Color Ultrasonic Diagnostic Scanner ;
- (6) Large Laser Therapy Apparatus ;
- (7) Large X-Ray Diagnostic Equipment ;
- (8) Automatic Biochemical Analyzer ;
- (9) Cobalt 60 Therapy Unit ;
- (10) Gamma Knife ;
- (11) Medico- electronic Linear Accelerator ;
- (12) Simulated Positioner ;
- (13) Magnetic Resonance Imaging System

To apply Test-after-Registration of import products , the Manufacturer shall submit an application for the Test and that the Products shall commit to complete the Test at first, as the product gets into the Chinese market. If the product fails to pass the following test, the registration certificate shall be cancelled by the original issuing agency.

2) About the Scope of Acceptance for Examination of the Examination Center

The test on placing the Products under the competent unit shall be determined in accordance with the "government certified Scope of Acceptance for Examination of the Examination Center". The enterprise may at its option select one among the qualified examination centers. In case of any ambiguity on the catalog of the Scope of Acceptance for Examination of the

Examination Center, a written report shall be submitted to the office of acceptance, and the office will deliver the case to the competent department to designate one center for test.

- 3) Under the following Circumstances, no test is required :
 - (1) Among the laboratory equipment, the electrophoresis apparatus 、 centrifuge 、 Ultra Low temperature refrigerator 、 paraffin slicing machine 、 paraffin embedding machine, cell centrifuge smearing machine, and full automatic dying machine no clinical trial reports and Product Type Test Reports issued by the medical devices quality test agency and recognized by the State Drug Administration are required to be provided .
 - (2) The Products of Class I in accordance with catalog of classification of the medical devices Products of China.

- 4) As for the medical devices in conformance with both of the following conditions the application for exemption from test may be made :
 - (1) The domestic enterprise has received the authentication certificate of GB/T19001+YY/T0287 or GB/T19002+YY/T0288 issued by the quality system authentication agency recognized by the State Drug Administration, and the quality system concerned has covered the Products for application.
The Products abroad has received the authorization of launching from the competent department of the Country of Origin, and the certificate is still valid, and the enterprise has been authenticated in accordance with the ISO 9000 Serial Standards (or equivalent).
 - (2) the difference between the structure and performance of the Products for application and those of the registered products of a kind is insignificant in terms of safety and effectiveness.
 - (3) the Products for application are not implantable device.
 - (4) no radioactive sources exist in the Products for application.
 - (5) In case of any malfunction , no grave injury accidents such as death of and body injury of the user or operator will be caused.

7. The clinical trial report of medical devices, the methods on the provisions of the report should be applied in accordance with the “Provisions for the ‘Subitem of Clinical Reports’ for the Registration of Medical Devices”. The clinical trial shall be implemented in accordance with the “Provisions for the Clinical Trial Management of Medical Devices”.
 - 1) Prior to the promulgation of the new Clinical Trial Management Methods, the quantity and trial period of the Clinical Trial shall be implemented in accordance with the “Interim Provisions for the Clinical Verifications of Medical Devices” issued by the State Drug

Administration in 1997. If in accordance with the requirements for sub-item concerned, the provisions for Clinical Reports are not necessary, the enterprise may make a statement upon the application.

2) Clinical Reports of Import Products in the Country of Origin may be provided through the following two methods :

(1) in case that clinical reports are required to submit upon the authorization of launching by the Country of Origin, the clinical reports upon the authorization of launching by the Country of Origin shall be provided ;

(2) in case that no clinical reports are required to submit upon the authorization of launching by the Country of Origin, the Manufacturer shall make a statement that no clinical reports are required to submit upon the authorization of launching by the Country of Origin , and guarantee the authenticity thereof. In the event, the enterprise may submit the Clinical Trial Reports and documents after the launching of the Products.

3) Under the following Circumstances, no clinical reports are required.

(1) In accordance with the clear division of work in the State Drug Administration, Among the IVD reagent approved and registered by Department of Medical Devices , in case of those for the diagnosis of hepatitis and AIDS, the Clinical Trials shall be carried out in designated medical institutions (quantity and statistical methods undetermined); as for other types of IVD reagent, generally no Clinical Reports are required to be provided.

(2) As for condom Products, no Clinical Reports are required to be provided.

(3) Among the laboratory equipment, the electrophoresis apparatus , centrifuge , Ultra Low temperature refrigerator , paraffin slicing machine , paraffin embedding machine, cell centrifuge smearing machine, and full automatic dying machine no clinical trial reports and Product Type Test Reports issued by the medical devices quality test agency and recognized by the State Drug Administration are required to be provided.

(4) The Products of Class I in accordance with the catalog of classification of the medical devices Products of China.

8. The Product Quality Guaranty presented by the Manufacturer, to promise that the quality of the products registered and sold in China are unanimously the same as that of the identical products put into market in the Country (Region) of Origin.

9. The certificate of commission for the After-Sale Service Agency designated in China, the letter of commitment and business certificate of the commissioned agency.

- 1) Certificate of commission of After-Sale Services
 - (1) Presented by the Manufacturer;
 - (2) The name of the Products shall be indicated clearly in the certificate of commission;
 - (3) In case of multilevel commissioning, the consignor at every level shall provide the certified documents of the Manufacturer.
- 2) The letter of commitment
 - (1) The contents promised in the letter of commitment shall be consistent with the matters consigned in the certificate of commission;
 - (2) The letter of commitment shall also contain :
 - a. Liabilities for reporting the Product quality accidents ;
 - b. Liabilities for actively contacting with the State competent department in charge of the registration of medical devices ;
- 3) The qualification certificate of after-sale service units
Business certificate(the scope of business shall contain corresponding technical service items)or the registration certificate of the representative agency in China of the manufacture.

10. The Self-Guarantee Declaration on the authenticity of the materials submitted.

" The Self-Guarantee Declaration on the authenticity of the materials submitted " shall be presented by the manufacturer.

- 1) Presented by the manufacturer or the office thereof in China ;
- 2) A list of the materials submitted ;
- 3) Commitment on the Liabilities.

Renewal Registration for Medical Device

1. The Direction for the Application Form for Registration
 - 1) All the contents shall be in both Chinese and English ;
 - 2) All the contents must be printed ;
 - 3) All the items must be completely filled in, and as for the vacant items, “/” shall be used to show inapplicability ;

- 4) The Name of Devices and Model, Name and Address of Manufacture must be unanimously the same as the contents carried in the documents approved by the government of the Country (Region) of Origin, and must be consistent with the contents concerned carried in the test reports, operation instructions of the product, and so on;
 - 5) Any enterprise shall not set up the format for the Application Form for Registration without authorization.
2. As for the medical devices products manufactured by enterprises abroad, they shall be re-registered 6 months prior to the date of expiry of the registration certificates. Upon the application for re-registration, the following materials shall be submitted:
- 1) The qualification certificate of the Applicant.
 - 2) Copy of the original registration certificate.
 - 3) The certificate recognized by the government of the Country (Region) of Origin to authorize the products as medical devices to enter into the market of the country.
 - 4) Technical Standards of Products: Requirements of Safety and Technical Performance of Products, and the corresponding experimental measures (the standards of the products to be registered).
 - 5) Operation manual of Products.
 - 6) Type test Reports issued by the Medical Devices Quality Detection Agency authorized by the State Drug Administration within the recent one year(applied to Products of Class II and Class III).
 - 7) Product Quality Follow-up Reports.
The Product Quality Follow-UP Reports presented by the Manufacturer or after-sale service agency after the application in the medical units of China.
 - 8) The Product Quality Guaranty presented by the Manufacturer, to guarantee that the quality of the products registered and sold in China are unanimously the same as that of the identical products put into market in the Country (Region) of Origin.
 - 9) The certificate of commission for the After-Sale Service Agency designated in China, the letter of commitment and business certificate of the commissioned agency.
 - 10) The Self-Guarantee Declaration on the authenticity of the materials submitted.

Note: The requirements for the documents listed in Items (1), (3), (4), (5), (6), (8), (9), (10) shall be consistent with those carried in "the Initial Registration of Import Products".