



Re-Registration of Imported Products (Medical Devices)

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. The Application Form may be downloaded from SDA website.

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".