Provisions for IFU and labeling of Medical device

Article 1

The Provisions are formulated in accordance with the *Regulations for the Supervision and Administration of Medical Devices* with a view to standardizing the IFU and labeling of medical device, and ensure the use safety of medical devices.

Article 2

All medical devices sold and used within the territory of the People's Republic of China shall comply with the Provisions to attach IFU and labeling.

Article 3

The “IFU of medical device” refers to the technical documents made by the registration applicant or the filing applicant to be provided with the product for users, it shall cover the basic safety and effectiveness information about the product and guide the correct installation, debugging, operation, use, repair and maintenance.

The “labeling of medical device” refers to the text, graphics or symbols attached on medical device itself or its packaging to be used for identifying products features, safety warnings and other information.

Article 4

The content of the IFU and labeling shall be scientific, true, complete, accurate and consistent with the product features.

The content of the IFU and labeling shall be consistent with the contents registered or filed

The content of the labeling shall be consistent with its IFU.

Article 5

The descriptions for disease names, professional terms, diagnostic and therapeutic processes and results in the IFU and labeling shall adopt the professional terms published or standardized nationally; metrological units shall meet the corresponding requirements in national standards.

Article 6

Symbols or marking colors in IFU and labeling of medical devices shall meet the corresponding requirements in national standards. If there is no relevant standard, the symbols and marking colors shall be described in IFU attached with the medical devices.

Article 7

IFU shall be attached in the minimum sales unit of medical device.

The medical device user shall use the medical device according to its IFU.

Article 8

The name of medical device product shall be generic name. Generic name should comply with the naming rules for medical devices formulated by CFDA. The name of Class II and Class III medical device products should be consistent with the name of the product in Registration Certificate for Medical Device.

Product name of medical devices shall be clearly marked in prominent position of the IFU and labeling.

Article 9

The IFU and labeling of medical device shall be in Chinese and the use of Chinese shall meet the national common language specification. Other languages may be attached the IFU and labeling of medical device, but Chinese statement shall prevail

Article 10

The IFU of medical devices shall meet the requirements of national standards or relevant industrial standards, and following information shall be included generally:

1) Product name, model and specification;

2) Name, resident, contacts and after-sale service institute of the registration applicant or the filing applicant; imported medical device shall also specify the name, resident, contacts of the agent;

3) Name, resident, manufacturing address, contacts, number of the Manufacture Certificate for Medical Device or the Filing Certificate for Manufacturing Class I Medical Device of the manufacturer; for commissioned manufacture, resident, manufacturing address, number of the Manufacture Certificate for Medical Device or the Filing Certificate for Manufacturing Class I Medical Device of the commissioned party shall also be included;

4) Number of the Registration Certificate for Medical Device or the Filing Certificate for Medical Device;

5) Number of product technical requirements;

6) Product performance, main structural composition or components, scope of application;

7) Contraindications, precautions, warnings and matters needing attention;

8) Instructions or graphics for installing and use; medical device used by individual