

## ***Medical Device Guide***

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#### ***1. The Structure and Definition of the Medical Devices Industry in China:***

China has adopted the medical device definition from European Union 93/42/EEC instruction. Medical device indicates instruments, equipments, utensils, materials or other goods, including required software, used separately or assembled for human beings. The effects on the body surface and inside of human beings are not achieved by pharmacology, immunology or metabolism measures. However, these measures might be concerned with or assistant with the effects. The use of medical device aims to achieve following objectives:

- 1) To prevent, diagnose, treat, ward and relieve diseases;
- 2) to diagnose, treat, ward, relieve and compensate on damage or deformity;
- 3) to research, replace and adjust the anatomy or physiological processes,
- 4) to control gestation.

Medical device standards are normative documents, established in accordance with the standard technology requirements needed, aiming for medical device, raw materials, finished products, design and production, using process, packaging and delivery etc. all aspects. It is the basis of supervision and management of medical device. Meanwhile, it is a significant technology basis for researching, producing, employing, circulating, supervising, managing and certificating on medical device.

## **2. Classification of Medical Device Standards:**

### **In accordance with the scope of standards:**

According to <People's Republic of China Standardisation Law> and <Standard Management of Medical Devices> ([link to 'related laws'- 'management method of industrial standard'](#)), the medical device standards are classified as national standards (GB), industry standards (YY) and registration product standards (YZB).

National standards are established and applied for regulating technology requirements nationwide. Industry standards are established for certain industry which has no national standards but needs standard technology requirements within the industry.

By September 2008, there are 168 national standards for medical devices and 555 industry standards. Regarding to medical device industry, national standards mainly include safety standards, basic standards, terms standards and high-risk product standards, such as IEC 60601 series and ISO10993 series, the international standards have all been transferred to China national standards. For instance, high-risk product standards, such as heart pacemaker standards, have been established as national standards as well. Industry standards are mainly product standards and technique standards for conformity assessment of products.

Registration product standard is a copy of technical documents, presented when applying for medical device product registration, which states the quality and technical requirements for declared products. Registration product standard is an important document for risk control during the registration and examination of medical devices. It can be national standards, industry standards and enterprise standards. Registration product standards refer to enterprises' technical secret in that government would neither open the information to public nor do statistical analysis for relevant information.

### **In accordance with the attribute of standards:**

China medical devices standards are assorted to compulsory standards and recommended standards, which differs from international standards. The difference on standard code between compulsory standards and recommended standards is that whether there is a "/T" following GB or YY. Compulsory standards have the attribute of law and must be implemented.

Recommended standards are similar to international standards and are not compulsorily carried out.

At present, there are 84 compulsory medical devices national standards, among which 57 adopted international standards; there are 284 compulsory industry standards with 111 adopted international standards.

### **3. *The relationship between medical devices standards and rule of law:***

Medical devices standards are specific reflection and carrier for rule of law. The tenet and root of <Supervision and Management of Medical Devices> ([link to 'related laws'- Supervision and Management](#)) is to assure the safety and effectiveness of medical devices and to guarantee human healthy and being safety. Medical devices standards are specific technical requirements for assuring product safety and effectiveness but not all requirements. Medical devices required registration system upon product manufacture in China. The compulsory standards, seen as rule of law, must be implemented when declare for medical devices registration. The recommended standards should be carried out as well in accordance with <Supervision and Management of Medical Devices> if the standards relate to products safety and effectiveness.

### **4. *Medical Devices Standards in Line with International Standards***

It is always an important principle for carrying out standardisation works that to positively adopt international standards and keep improving the adoption rate of medical devices international standards. Especially after China officially entries WTO/TBT, more emphasis has been paid to international standardisation works, encouragement and support were given to Standardisation Technical Committees for further involvement into international standardisation campaigns and also strived for taking part in or be in charge of establishment, edition and amendment of international standards. The above efforts provide a solid foundation to adopt international standards. In the meantime, it was clearly requested by 'Outline of the Eleventh Five-Year Plan' that to make every effort to attain 100% adoption rate for international standards whenever suitable and actualize domestic standards in line with international standards.

According to regulations in <The management measures of adopting International Standards> issued by National Standardisation Technical Committees, the levels of international standards that have been adopted into Chinese standards are divided into identical adoption and

modified adoption. Identical adoption standards are of same technical content and text structure with international standards, or of same technical content with international standards but existed few editing modifications. Modified adoption indicates existence of technical variations compared with international standards and clearly notes the differences along with their reasons. Editing modifications are allowed. Modified adoption does not include standards that only keep few or unimportant terms of international standards. For modified adoption, the text structure of Chinese standards should be in line with the text structure of international standards. The text structure can only be changed if the changes will not influence the content of international standards.

The level codes for the international standards that have been adopted into Chinese standards are:

IDT: Identical adoption

MOD: Modified adoption

The Chinese standards, established in accordance with international standards, should indicate on the cover page and state in the preface clearly about the international standards' serial number, name and level code. Any Chinese standards adopted or quoted from international standards, should indicate the serial number and level code of international standards clearly in the 'normative quoted document' chapter. Names of international standards should be provided when the names of standards are different.

The specific indicating methods for the level of international standards that have been adopted into Chinese standards should comply with <Guideline for Standardisation, Part 2: Principle of Using International Standards> (GB/T20000.2).

For Chinese standards, which adopted from international standards, should explain or indicate technical differences and editing modifications. The specific explanation or indicating methods should comply with <Guideline for Standardisation, Part 2: Principle of Using International Standards> (GB/T20000.2).

The indicating methods of Chinese standards which are adopted from international standards are as follows:

- 1) Chinese standards, adopted from international standards as Identical adoptions, use double code to demonstrate, for example:  
GB xxxxx – xxxx / ISO xxxxx : xxxx.
- 2) Chinese standards, adopted from international standards as modified adoptions, will only use Chinese standards code.

The relationship between Chinese standards and international standards besides identical adoptions and modified adoptions, also include non-equivalent. Non-equivalent does not belong to adoption of international standards, but only indicating the corresponding relationship between Chinese standards and relevant international standards.

Non-equivalent means that the technical content and text structure are different from relevant international standards. The differences have not been pointed out clearly. Non-equivalent also include standards that only keep few or unimportant terms of international standards.

The code for non-equivalent is NEQ.

Therefore, for Chinese standards, adopted from international standards as modified adoptions, all modifications about technical index or terms should be noted in preface, text and Annex.

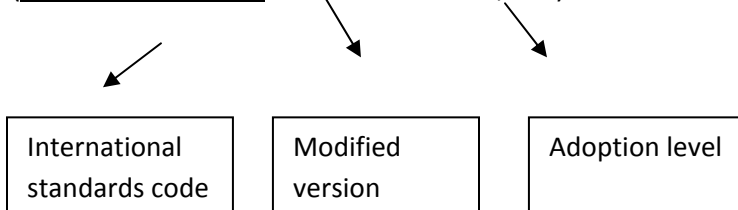
As to medical devices standards, its adoption rate of international standards increases year by year. According to the statistic, currently the adoption rate of international standards for medical devices is about 75%, which including 74% identical adoption (IDT).

Chinese standards adopted from international standards mainly include IEC60601 series standards and ISO 10993 series. Since the industry standards are mainly product standards, some standards are based on the level of China medical devices industry, the adoption rate is lower than that of national standards. At present the adoption rate of international standards for industry standards is about 35%, which includes 50% identical adoption (IDT).

For example:

GB9706.1-2007 Medical Electrical Equipment Part 1: General Safety Requirements

(IEC 60601-1:1988+A1:1991+A2:1995, IDT)



At the meantime of adopting IEC and ISO standards established by International Standardisation Organisation, China positively adopts European standards (EN), American standards (ASTM) and Japanese standards, etc. However, the adoption of these foreign advanced standards would not be treated as adopting international standards. Therefore, no indications would be shown on the cover page but would be referred in standards' preface.

## **5. Standards Information resources**

### ***Medical Devices Standards Catalogue:***

National medical devices standards can be found at National Standardisation Technical Committees's website [www.sac.gov.cn](http://www.sac.gov.cn). Industry standards can be found at State food and Drug Administration website [www.sfda.gov.cn](http://www.sfda.gov.cn) and Centre for Medical Device Evaluation [www.cmde.org.cn](http://www.cmde.org.cn).

### ***Medical Devices Standards content:***

To purchase printed standards: Standards Press of China (state standards/industry standards)

To get free access to compulsory state standards: National Standardisation Technical Committees's website [www.sac.gov.cn](http://www.sac.gov.cn). No compulsory industry standards for free access online available.

### ***Medical Devices Standards planning project:***

State standards can be found at National Standardisation Technical Committees's website [www.sac.gov.cn](http://www.sac.gov.cn). New projects are published to known. Industry standards can be found at State food and Drug Administration website [www.sfda.gov.cn](http://www.sfda.gov.cn). Industry standards are released as industry standards project notice.

### ***Medical Devices Standardisation Technical Committee:***

Major scope of business and abroad counterparts' condition and contacts can be seen in Annex. All standards indicate responsible unit in standards preface and this unit will explain the content of the standards. Therefore, the responsible unit can be found in Annex and contacted for communicating technical content of standards. If anyone who wishes to take part in establishment, edition and amendment of the standards, they can follow the above procedure to find out responsible unit and express their willingness.

