

# Chinese Medical Device Registration Update

## – SFDA introduces 96 new Industrial Standards

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China has introduced [96 new Industrial Standards](#) in December 2010, to be implemented from 1st June, 2012. The seventh article in the [Provision on Medical Device Registration \(2004\)](#) (医疗器械注册管理办法) specifies that all medical device manufacturers are required to submit evidence of compliance to product standards that are equal or more stringent than their respective National or Industrial Standards for registration in China.

The competent body in China, the State Food and Drug Authority (SFDA), has its unique procedures and guidelines for registration of medical products. A Product Standard Dossier (产品标准) which is broadly equivalent to a Summary Technical File. The Dossier must include evidence of compliance with Chinese National Industrial Standards is mandatory and it is the manufacturer's assurance for each product's function and safety. Certification to International standards such as ISO and IEC are not automatically recognised by SFDA.

There are three levels of [standards](#) adopted by SFDA; the National Standards (国家标准), the Industrial Standards (行业标准) and the Enterprise Standards (企业标准). Only when there is no applicable National/Industrial standard should the manufacturer submit its own product standards as the Enterprise Standard for SFDA review. Though the high-level standards often overlap with the international standards, the more technical ones are typically heavily based on Chinese practises.

The 96 standards introduced incorporate 34 Mandatory Standards, covering a wide range of products, for example:

- Bioabsorbable sutures
- Blood pressure monitoring and electrocardiograph machine
- Haemodialysis equipment
- Optometry equipment
- Respiratory tract humidifiers
- Single use injection devices
- Steam sterilizers
- Ultrasound bone densitometers

The remaining 62 are *Recommended* Standards. These are written by a separate national standards body but some may in future be mandatorily adopted by the SFDA Centre for Medical Device Evaluation. These include:

- Broth and agar medium
- Chemiluminescence analysis for tumor marker, cancer antigen and carbohydrate antigen
- Clinical laboratory testing and in vitro diagnostic test systems
- Dental equipment
- Implants for surgery: Partial and total hip joint prostheses
- Medical grade polycarbonate and UHMWPE
- Medical grade silicone gel, elastomers and foams
- Sterilized packaging and re-sterilized devices
- X-ray imaging

Overseas manufacturers are required to have a Product Standard Dossier for each product. This must include:

1. Evidence of compliance with **all** relevant National and Industrial Standards; or
2. If no National/Industrial Standards is applicable,
  - a. an Enterprise Standard drafted and signed by the manufacturer or its Chinese representative; or
  - b. an Enterprise Standard drafted by a third party with manufacturer's commissioning letter detailing manufacturer is liable for product quality.
3. Manufacturer's Declaration of Conformity; and
4. Manufacturer's Declaration of Product Liability; and
5. Explanatory notes on product models and specifications.

Any existing ISO or IEC certification needs to correspond to an identical Chinese National/Industrial Standards to be recognised by SFDA. As the Product Standard Dossier is the foundation for the mandatory product Type Test (注册检测) in Class II and III medical devices registration, incomplete or deficient inclusion of National/Industrial Standards may result in an inappropriate Test Protocol which may not be noticed until SFDA review. At which stage, any such deficiency could cause rejection of Type Test results. The result would be lengthy registration delays and expensive test reruns.

***Need help with navigating SFDA registration and understanding the Technical Requirements for SFDA review?***

The chief of our Beijing office, Dr. Davey Han, has extensive experience working with SFDA. Dr Han's close working relationships at a senior level with the SFDA and deep knowledge of requirements facilitates active dialogue with the agency and a smooth regulatory review.

For specialist professional advice on SFDA registration and service tailored to your specific needs contact us at

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