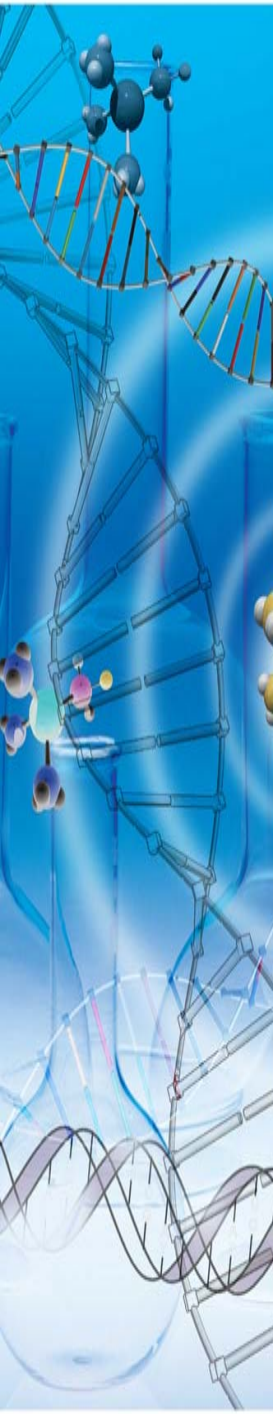

SFDA IVD Regulation and Registration in China

Jan.06, 2009

Jyton Enterprises Group

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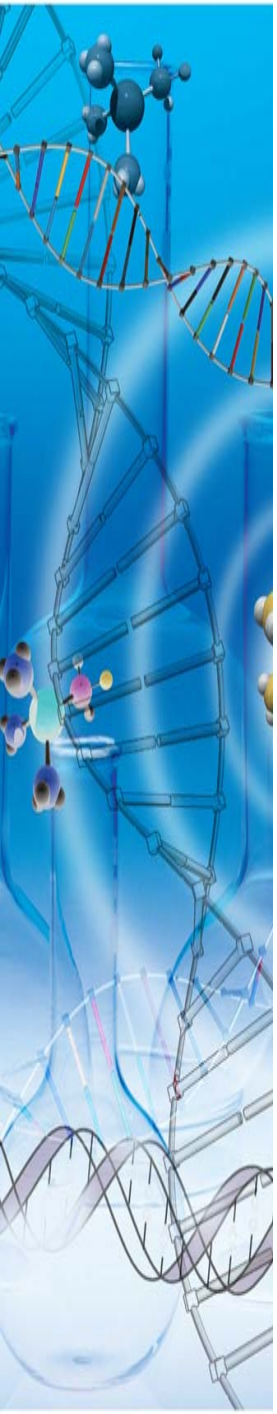

Topics

1. Company Overview
2. IVD Regulation
3. IVD Registration
4. Q & A

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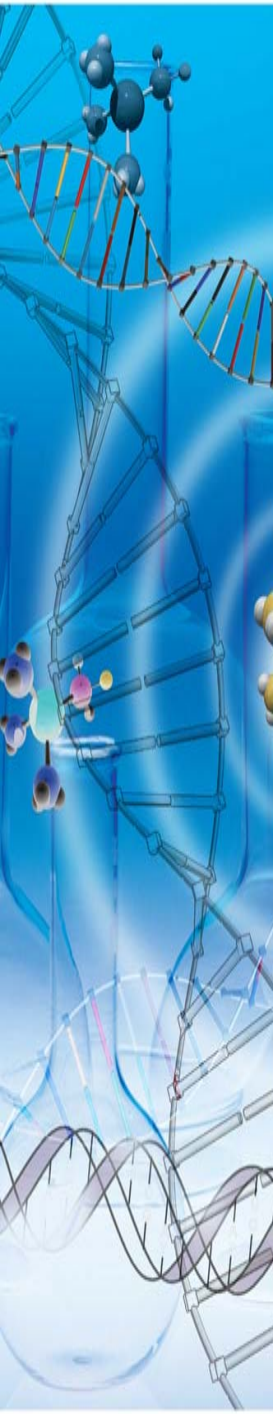

Company Overview

- Established in 1995, Jyton Enterprise provides high quality services to healthcare companies seeking to place their products on the global market.
- Headquarters in China with branches in US, EU, and Japan.
- 158 global employees in 6 offices
- Revenue $8M in 2008
- Core business is regulatory affairs consulting

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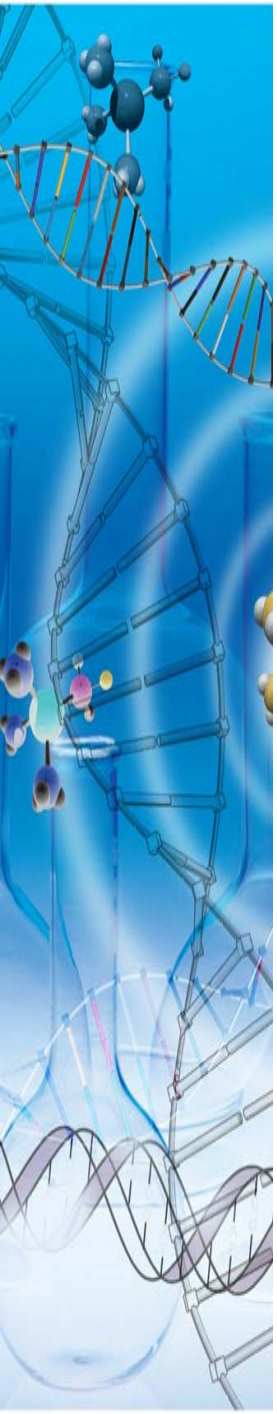

One-stop-shop Services Package China, EU & US

- Market research
- Distributor search
- Regulatory affairs consulting for Medical Device, Pharmaceutical, Health Food and Cosmetics) and clinical trial management
- Legal Agent and After Sales Agent in China
- Government relationship
- China employee recruitment
- Advertisement
- Meetings and seminars
- Medical translation

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Key Regulations for IVD Product Registration

- Management Method of IVD Products Registration (Interim) *(Directive [2007] No. 229, Effective Date: Jun. 1, 2007)*
- Guidance on clinical trials for IVD products *(Effective Date: Jun. 1, 2007)*
- Guidance on insert composition for IVD products *(Effective Date: Jun. 1, 2007)*

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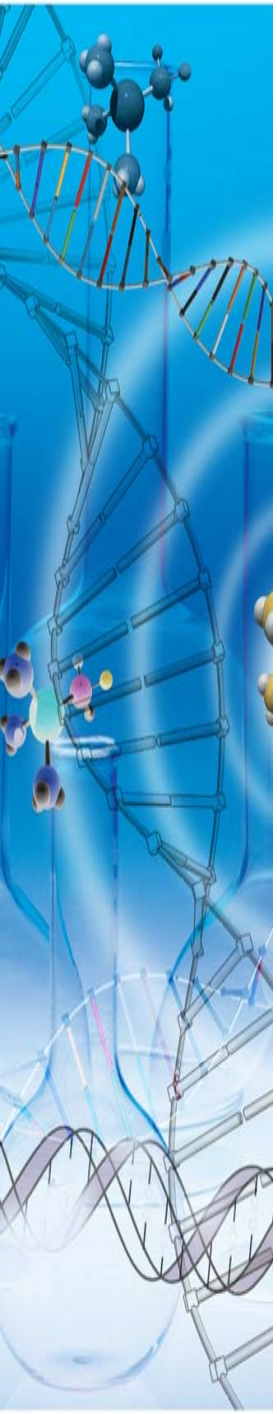

IVD Product Definition

The IVD Product mentioned in Management Method of IVD Products Registration (Interim) refers to the in-vitro diagnosis reagents administered as medical devices, including:

> "The reagents, reagent cartridges, calibrators, quality controls, etc. for in-vitro inspection of human body specimen (various body fluids, cells, tissue specimen, etc.) in the course of disease prevention, diagnosis, treatment monitoring, prognosis observation, health status evaluation and inherited disease prediction, which can be used independently or in combination with instruments, devices, equipment or systems."

IVDs used in blood screening and radionuclide IVDs are NOT included.

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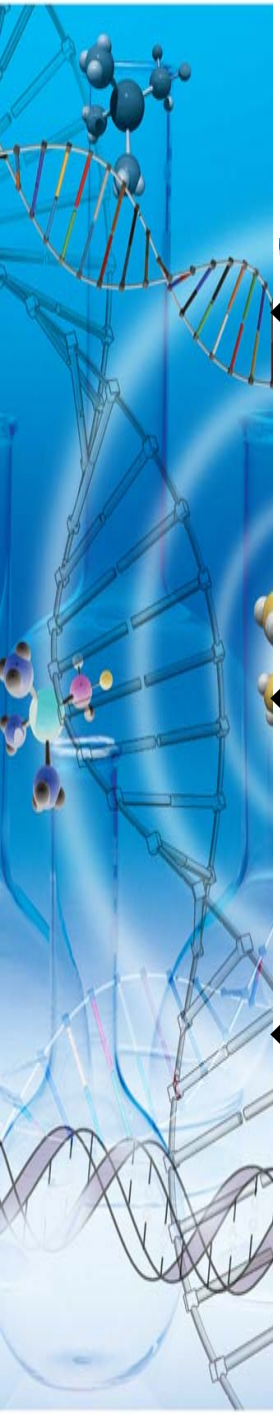

IVD Product Classification

- Class III IVD Products :
  - IVD related to the inspection of antigen, antibody and nucleic acid, etc. for pathogen; blood group and tissue typing; human genes; inherited diseases; narcotic, psychotropic and toxic drugs for medical use; targets sites of curative drugs; tumor markers and allergies.
- Class I IVD Products:
  - Microorganism culture medium (not used for microorganism identification and medicine sensitivity experiment);
  - Products for specimen treatment, e.g. hemolytic agents, diluents, staining solutions, etc.
- Class II IVD Products: <u>The rest IVD products are classified as Class II</u>

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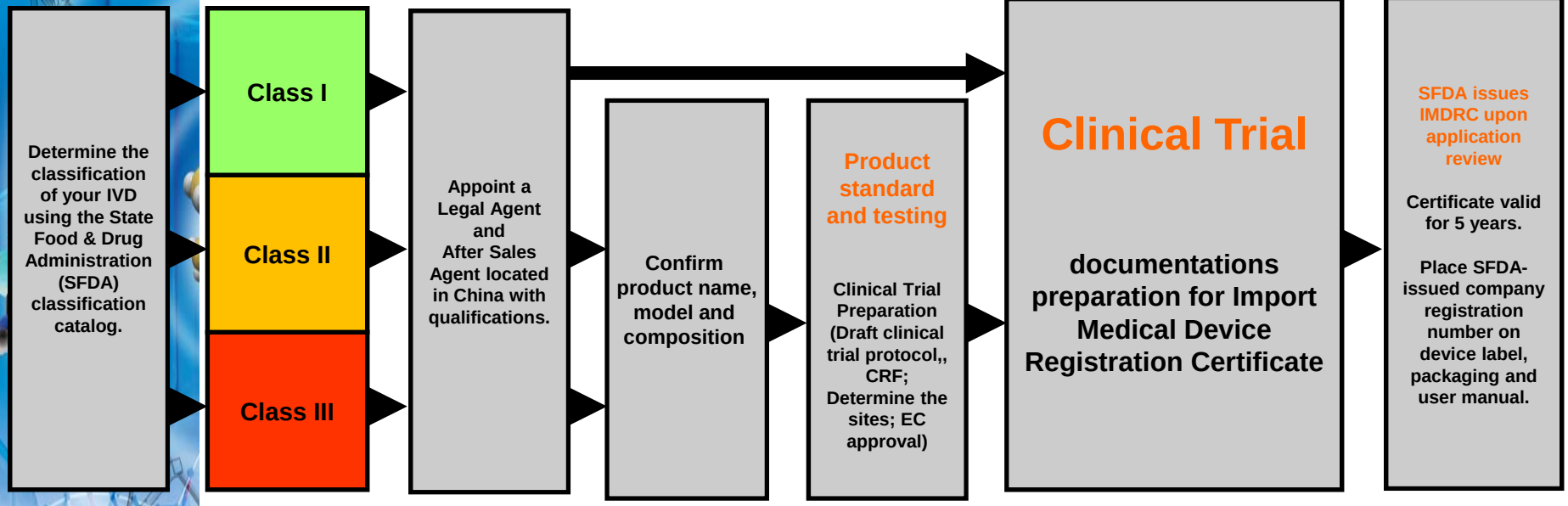
IVD Registration Process



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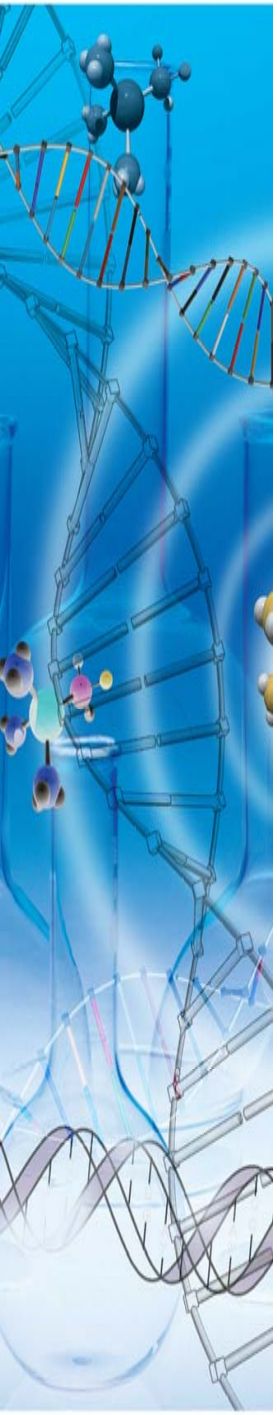

IVD Registration Process

Normal Timeline:

1)	**Sample testing**	**2-3 months**
2)	**Clinical trial**	**based on protocol**
3)	**CMDE review**	**60 working days**
4)	**SFDA final approval**	**30 working days**

Total about: 18 months

Note: Sample testing and clinical trials for Class I IVD product is not required.

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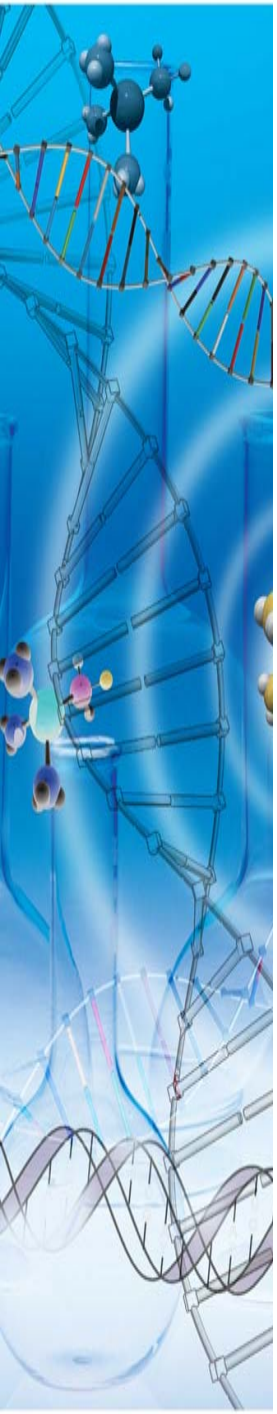

Registration Requirements List

- SFDA registration application form (Item 1)
- Legal Certification (Item 2)
- Research Summary (Item 3)
- Product Insert (Item 4)
- Product quality specification (Item 5)
- Testing report (Item 6)
- Research information of key raw materials (Item 7)
- Research information on manufacturing process or reaction system (Item 8)

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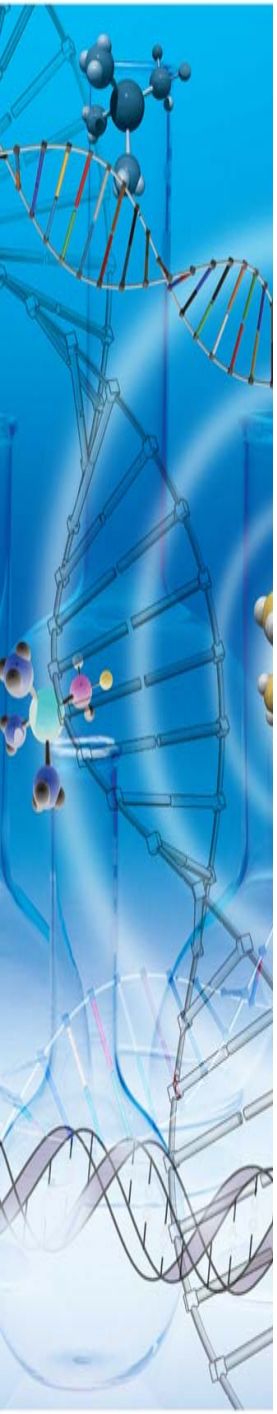

Registration Requirements List

- Analytical performance evaluation data (Item 9)
- Reference value (reference range) determination data (Item 10)
- Stability data (Item 11)
- Clinical research data (Item 12)
- Production records and QC release report (Item 13)
- Product package and label artwork (Item 14)
- Quality management system inspection report (Item 15)

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Legal Documents (Item 2)

- Requirements for legal documents are the same as Medical Device
  - Legal Production Qualification
  - Authorization of Registration in China
  - Marketing Approval from foreign government
  - Quality Management System certification
  - Quality Guarantee Letter
  - Authorization Letter to a Chinese Agent
  - Self-guarantee Declaration Letter

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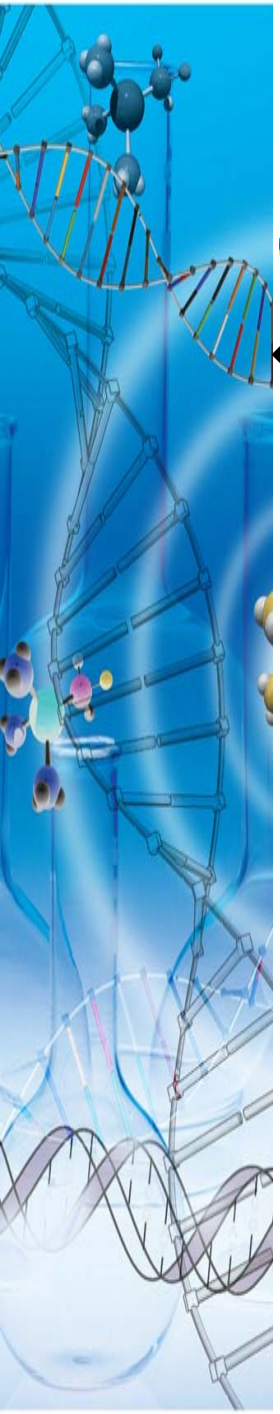

Research Summary (Item 3)

- Research summary shall include:
  - Intended use
  - Product description
  - Biological safety evaluation information
  - Summary of key research and evaluation results
  - Global registration status overview
  - Others if necessary

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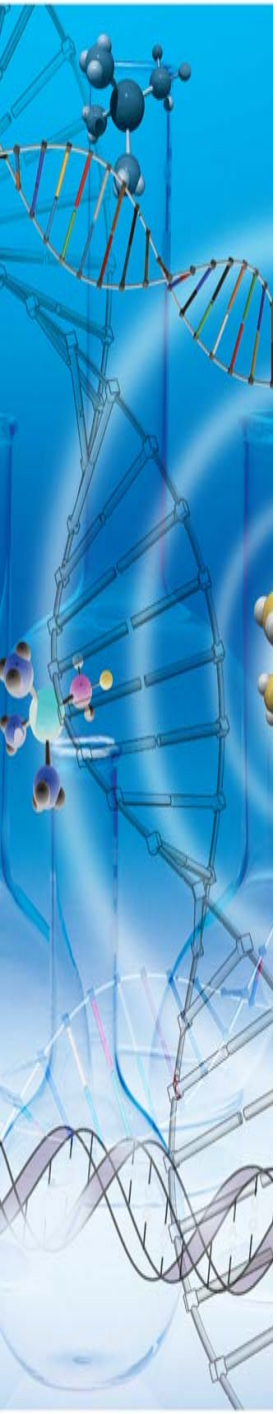

Analytical Performance Evaluation (Item 9)

- The performance evaluation shall include:
  - Sensitivity
  - Specificity
  - Diagnostic range
  - Accuracy
  - Deviation

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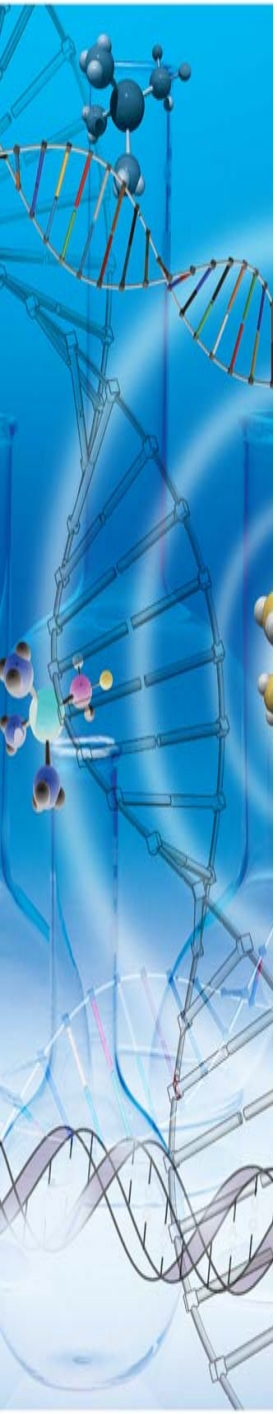

Sample Testing (Item 6)

- Sample testing is required for Class II and III IVD registration.
- For Class II IVD products, testing is required for one batch sample.
- For Class III IVD products, testing is required for 3 consecutive batches.
- Testing should be conducted at SFDA certified testing centers.

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Clinical Trial (Item 12)

- Clinical research data conducted in foreign countries are required for submission.
- Clinical trial conducted in China is required for

  Class II & III IVD products:

Required	Hospitals	Cases
Class III IVD	≥ 3	1,000
Class II IVD	≥ 2	200

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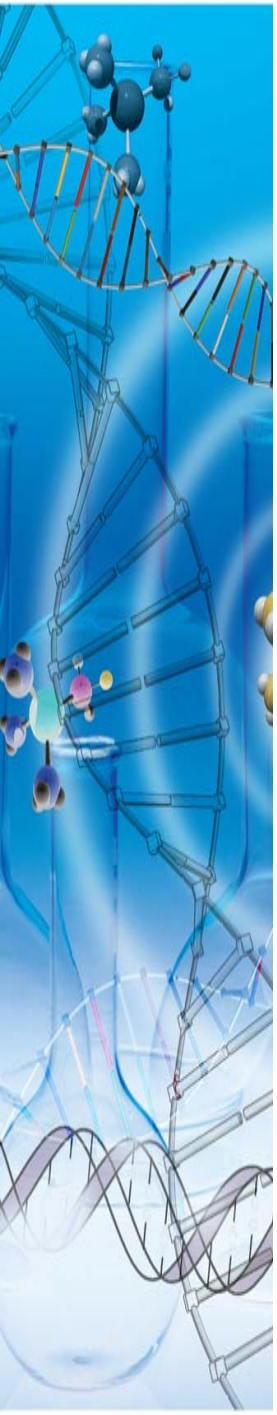

中华人民共和国

PEOPLE'S REPUBLIC OF CHINA

医疗器械注册证

REGISTRATION CERTIFICATE FOR MEDICAL DEVICE

注册号：国食药监械(进)字 2005 第 3572845 号

REG. NO: SFDA(I) 20053572845

你单位生产的 ，经审查，符合医疗器械产品市场准入规定，准许注册。自批准之日起有效期四年。

特此证明。

This is to certify that the medical product manufactured by your company has been inspected by our office and is permitted to register on the Chinese market. This registration certificate is valid for four years from the date of issue.

国家食品药品监督管理局

State Food and Drug Administration

2005 年 10 月 9 日

进口医疗器械注册专用章

附 件：医疗器械产品注册登记表

ATTACHMENT: MEDICAL DEVICE REGISTRATION RECORD

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医疗器械产品注册登记表
MEDICAL DEVICE REGISTRATION RECORD

注册号：国食药监械（进）字 2005 第 3572845 号
REG. NO.: SFDA（1）20053572845

生产者名称 MANUFACTURER	
生产者地址 MANUFACTURER'S ADDRESS	
生产场所地址 ADDRESS OF MANUFACTURING SITE	
产品名称 NAME OF DEVICE	
规格型号 MODEL	
产品标准 PRODUCT STANDARD（S）	
产品性能结构及组成 PERFORMANCE, STRUCTURE AND COMPONENTS OF THE PRODUCT	
产品适用范围 INDICATIONS	
注册代理 REGISTRATION AGENT	
售后服务机构 SERVICE AGENT(S)	
备注 NOTES	二〇〇五年十月九日

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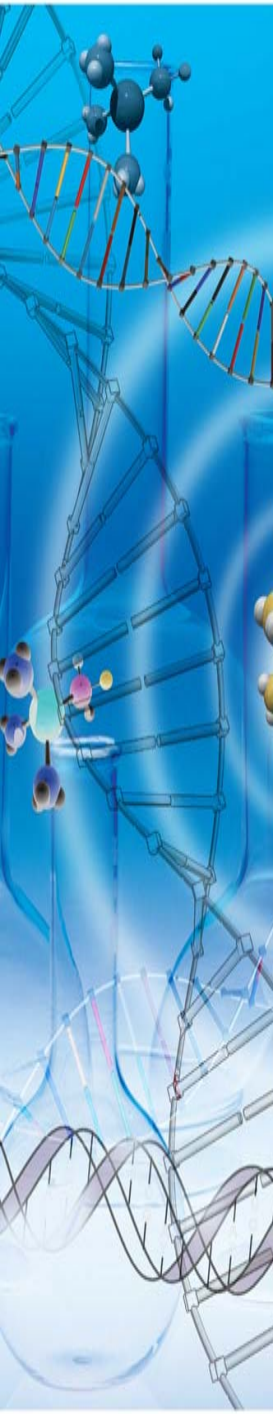

Q&A

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