Appendix 1

Registration Certificate for Medical Device of People's Republic of China

(Format)

Registration Certificate No:

Name of Applicant	
Address of Applicant	
Manufacturing Address	
Agent Name	(For Imported Medical Device)
Address of Agent	(For Imported Medical Device)
Product Name	
Model /Specification	
Structure and Composition	
Intended Use	
Appendix	Product Technical Requirement
Other contents	
Remark	

Approved by (Department): Date of Approval: YYYY/MM/DD

Date of Expiry: YYYY/MM/DD

(Seal of Evaluation and Approval Department)

Appendix 2

Permission of change to registration for medical device of People's Republic of China

(Format)

Registration No.：

Product Name	
Change Contents	“*** (original registration content or item)" is changed to*** (changed content).
Remark	The permit is used in conjunction with the registration certificate “ ”

Approved by (Department): Date of Approval: YYYY/MM/DD

(Seal of Evaluation and Approval Department)

Appendix 3

CFDA Approval for Medical Device Clinical Trial

(Format)

Approval No.:

Name of Applicant	
Address of Applicant	
Name of Medical Device	
Model and Specification of Medical Device	
Structure and Composition of Medical Device	
Evaluation and Approval Comments	
Send to	
Copy to	
Remark	

Approved by (Department): Date of Approval: YYYY/MM/DD

(Seal of Evaluation and Approval Department)

Appendix 4

Requirements and Instructions for Medical Device Registration Application

level I headlines of application dossier	level II headlines of application dossier
1. Application form	
2. Supporting documents	
3. List of basic requirements for safety and effectiveness of medical device	
4. Summary	4.1 Overview 4.2 Product description 4.3 Model and specification 4.4 Packing instructions 4.5 Applicable scope and contraindications 4.6 Referenced clinical data of products of same kind or its predecessors (if any) 4.7 Other contents to be specified
5. Research Information	5.1 Product performance study 5.2 Evaluation study on biocompatibility 5.3 Biological safety study 5.4 Sterilization / disinfection process study 5.5 Study on shelf life and packaging 5.6 Animal study 5.7 Software study 5.8 Others
6. Manufacturing information	6.1 Information description of the manufacturing process of non-active/active products 6.2 Manufacturing site
7. Clinical evaluation material	
8. Risk analysis material of	

products	
9. Product technical requirement	
10.Product Type-testing report	10.1 Type-testing report 10.2 pre-assessment advice on Product technical requirement
11. Samples of instruction for use and label	11.1 Instruction for use 11.2 Label samples of minimum sales unit
12. Conformity statement	

The application dossier shall have an index which covers all level I and level II headlines, and separately compile page number for the corresponding information to each level II headline.

I. Application form

II. Supporting documents

(I) Domestic applicant shall provide:

1. Copies of business license and organization code certificate

2. When applying for registration of domestic medical devices according to Special Procedure of Approval and Evaluation for Innovative Medical Devices, applicant shall provide a notice of application for reviewing “Special procedure of approval and evaluation for innovative medical devices”, and if the sample products are produced by entrusted manufacturers, manufacturing license of the entrusted manufacturer and consignment agreement shall be provided. The scope of manufacturing license shall cover the category of the submitted products.

(II) Imported Medical Device applicant shall provide:

(1) Supporting documents of marketing authorization or certificate of the product issued by authority of the country (or region) where the applicant’s headquarter or manufacturing site is located, and the authorization/qualification documents of the enterprise.

(2) If the product is not managed as a medical device by authority of the country (or region) where the Imported medical device applicant is located, applicant shall provide relevant supporting documents, including supporting documents of marketing authorization and quantification certificate of manufacturer issued by authority of the country (or region) where the registration office or manufacturing site is located.

(3) Power of attorney of the foreign applicant for designating agent in China, copies of the letter of commitment and business license or copy of organization registration certificate of agent.

III. List of basic requirements for safety and effectiveness of medical device

The list is a document describing that the product complies with methods used in all applicable requirements of the List for Basic Requirements for Safety and Effectiveness of Medical Device (see Appendix 8) and proving its conformity. The reasons shall be given for all inapplicable requirements in the List for Basic Requirements for Safety and Effectiveness of Medical Device.

For documents included in application dossier, their specific locations in the dossier shall be provided; for those not included in application dossier, the name of documentary evidence and its document number in QMS shall be noted.

IV. Summary

(I) Overview

Describe the management category, criteria for determining the classification code and device name of the product

(II) Product description

1. Non-active medical devices

Describe the product's operation principle, mechanism of operation (if applicable), structure & composition (including supporting accessories), main raw materials and different features with other products of same kind; and graphic or charts with explanation shall be provided as necessary.

2. Active medical devices

Describe the product's operation principle, mechanism of operation (if applicable), structure & composition (including supporting accessories), main function and functions of componential parts (critical components and software) and different features with other products of same kind; and graphic or charts with explanation shall be provided as necessary.

(III) Model and specification

For the products with various models and specifications, a detailed list shall be made for differences between each model and specification from the perspective of structure or composition (or configuration), function, product feature, operating mode, performance indices and others. Comparison table, graphic or charts with explanation shall be used to summarize the difference.

4. Packing instruction

Product packaging information and packing instruction of accessories sold together with such products; for sterilized device, original packaging information corresponding to sterilization method shall be indicated.

(V) **Intended use and contraindication**

(1) Intended use: Specify the treatment and diagnosis provided by the product meet the purpose defined in Article 76 of the Regulations for the Supervision and Administration of Medical Devices, and describe the applicable treatment periods of the

product (e.g., post-treatment monitoring, rehabilitation, etc.); define the target users and the skills/knowledge/trainings required by users to operate such products; Explain the operation pattern: single use or reusable; specify medical devices intended to be used in combination with the product.

(2) Intended service environment: intended use place of such products, including hospital, medical/clinical laboratory, ambulance and home, and ambient conditions that may affect its safety and/or performance (for instance, temperature, humidity, power, pressure and movement);

(3) Target population: Targeted patients information (such as adults, children or neonates), the standards information for patients to select and relevant parameters shall be monitored during use;

(4) Contraindication: if applicable, the medical device shall specify the diseases or conditions (e.g., children, elderly people, pregnant and breast-feeding women, and patients with hepatic and renal insufficiency) that they cannot be used.

(VI) The reference information of domestic and Imported medical device products of same kind(if any) or its predecessor shall be given as well as the purpose of interpretation the goal of product research and development. For products of same kind, the reason for choosing them as the research & development shall be provided as reference.

Comparisons of the product and reference (product of same kind or its predecessors) shall be given from their similarities and differences in a list in terms of operation principles, structure & composition, manufacturing materials, performance indices, operating mode (e.g. implantation, intervention), and applicable scope.

(VII) Other contents to be specified. With regard to components or

accessories approved by relevant departments, approval number and copy of approval document shall be provided; products that are intended to be used in conjunction with other medical devices or universal adaptable products to work together for the desired function shall be indicated; the physical, electrical connection type between components of combination medical devices in the system shall be indicated.

V. Research Information

Provide the applicable research materials for the submitted product.

(I) Product performance study

The information shall cover research information for performance study, technical requirements study and its compiling instructions, including performance and safety indices (e.g. electric safety, electromagnetic compatibility, and radiation safety), determination basis for other QC-relevant indices, adopted standards or methods and the theoretical basis and reasons for their being adopted.

(II) Biocompatibility evaluation study

The biocompatibility evaluation shall be made on the materials that are in direct/indirect contact with the patients and users in the final product.

The information on biocompatibility evaluation shall include:

1. Basis and method of biocompatibility evaluation.

2. Description of materials used in the product and their characteristics when in contact with human body.

3. Reasons and arguments for implementation or exemption of biological test.

4. Evaluation on the available data or test results.

3. Information on bio-safety research

For the products with biological safety risks containing allogeneic materials, materials of animal origin, or biologically active substances, the biological safety research information concerning relevant materials, and biologically active substances shall be given, including the description of processing, preservation, testing and treatment process of the tissue, cell and materials acquisition. Moreover, it is needed to demonstrate source (including screening details of donors) and describe the verification testing on the methods removing or inactivating virus, other pathogens and immunogenic substances during the manufacturing process. The brief summary for process assessment shall be provided.

(IV) Information on disinfection/ sterilization process validation

1. Sterilization by manufacturer: Specify sterilization process (methods and parameters) and sterility assurance level (SAL), and provide the sterility validation report.

2. Sterilization by end user: Recommend sterilization process (methods and parameters) specified and provide the evidence. For products that can tolerate sterilization at least twice, supporting materials of product’s resistance to recommended sterilization methods shall be provided.

3. Residual toxicity: Where sterile device is provided and methods used for sterilization may generate residue easily, the adopted residue and treatment methods shall be determined and supporting materials shall be offered.

4. End user’s disinfection: it is required to specify the recommended cleaning/sterilization process (methods and parameters) and provide the evidence.

(V) Confirmation of shelf life and packaging of products

1. Confirmation of shelf life: Shall provide the report and protocol of shelf life verification.

2. For medical devices with limited re-use times, provide the validation data of use times

3. Packaging and packaging integrity: maintain packaging integrity of device within the declared shelf life under the packaging and distribution environment

(VII) Software study

For products containing software, the independent descriptive document of medical device software shall be provided. The document shall include basic information, realization process and core algorithm, the details depend on the security level and sophisticated degree of software. Provide a statement about software version naming rules, specify all fields and their meanings of software version, and determine the complete version of software and its identification version used for release.

(VIII) Other information

Other research information or literature provided the safety or effectiveness of the product.

VI. Manufacturing Information

(I) Non-Active medical device

The manufacturing process shall be clearly indicated and the key technology and special process shall be given as well as explanation of its in-process control point. The use of various processing agent and control over impurities (such as residual monomers, residues of small molecules, etc.) during the manufacturing shall be clearly indicated. Furthermore, the basis for

determining the processing technologies affecting the product performance, and related research information or literature shall be available.

(II) Active medical devices

The descriptive information on the manufacturing process of the product shall be contained, for which, the form of flow chart can be used for giving an overview of its in-process control points.

Note: For some active medical devices (for example: cardiac pacemakers and leads), the description on manufacturing process information regulated in article VI.1 shall be taken.

(III) Manufacturing site

If a product is manufactured at multiple research and manufacturing sites, the actual situations of each research and manufacture site shall be given.

VII. Clinical evaluation material

Submit the clinical evaluation material according to the relevant provisions; imported medical device shall provide clinical evaluation material used in their market application with foreign medical device authorities.

VIII. Risk analysis material of products

The risk analysis material of products is formed by recording the risk management process and evaluation results of products. The traceability of each of following processes assessed as harmful shall be provided:

(I) Risk analysis: Include the assessment of applicable scope and safety-related characteristics of the medical device, the harm assessment, and the risk evaluation of each harmful situation.

(II) Risk evaluation: Evaluate and decide whether or not to reduce

the risks for each assessed harmful situation.

(III) Validation reports of risk control measures and its implementation (e.g., medical electric safety, biological evaluation, etc.)

(IV) Evaluate the acceptability of one or more residual risks.

IX. Product Technical Requirement

The product technical requirement for medical device shall be compiled according to the provisions of the Compiling Guidelines of Product Technical Requirement for Medical Device. The Product technical requirement is submitted in duplicate with statement of identity of the two copies.

X. Product Type-Testing Report

Such report and pre-assessment advice shall be issued by medical device testing institutions recognized by the CFDA.

XI. Instruction for use of the product, designed package and label samples of minimum sales unit

Comply with the relevant regulatory requirements.

XII. Conformity statement

(I) The applicant declares that the product complies with the relevant requirements of the Provisions for Medical Device Registration and the relevant regulations; declares that the product complies with the classification requirements of the Medical Device Classification Rules; declares that the product complies with the current national standards, industrial standards, and provides an up-to-standard list

(II) Self-assurance statement for the authenticity of materials submitted (for domestic products, the statement is issued by the applicant; for imported products, by the applicant and the agent).

Appendix 5

Requirement and Instruction for Application Documents of Registration Extension

I. Application form

II. Supporting documents

The domestic applicant shall provide the copies of business license (in duplicate) and organization code certificate ; the Imported medical device applicant shall provide the power of attorney for designating the agent in China, the agent's letter of commitment, and one copy of business license (in duplicate) or institution registration certificate.

Note: It is not necessary to provide marketing certification issued by the authority of the country (or region) where the applicant's registration address or manufacturing address is located when applying for registration extension of imported medical devices.

III. Registration applicant's statement that no changes are made to the product

The applicant shall provide the statement that no changes are made to the product.

IV. Copy of the original Registration Certificate for Medical Device and its appendixes; copy of previous change documents of Registration Certificate for Medical Device.

V. Product analysis report within valid period of registration certificate:

(1) Clinical application of the product, user complaints and

measures taken accordingly;

(2) Summary report of analysis and evaluation for the medical device adverse events (AE), the report shall list suspected post-market medical device AE and instruct every processing solution taken by the manufacturer accordingly. The aforesaid AEs shall be analyzed and made assessment, and clarify the reasons for the occurrence of adverse events and described its impact on safety and effectiveness.

(3) Describe market situation of products in all different countries and regions.

(4) Information on the supervision and random inspection for the product (if any).

(5) The reason, process and handling results for the recall shall be specified if recall occurs.

(6) In case any work specified in the Registration Certificate for Medical Device requires completing, the applicant shall provide relevant summary reports and appropriate information.

VI. Product type-testing report

If the mandatory standards of medical devices have been revised, the product testing report proving that the product can meet the new requirements shall be provided. The product testing report may be a self-inspection report, entrusted testing report or testing report complying with the provisions of the notice for implementing mandatory standards. Here, the entrusted testing report shall be issued by the medical device testing centers recognized by CFDA

VII. Conformity statement

(I) Applicant declares that the product complies with the requirements of the Provisions for Medical Device Registration and the relevant regulations; declares that the product complies with

the existing national standards and industrial standards, and provides a list of complied standards.

(II) Self-assurance statement for the authenticity of materials submitted (for domestic products the statement is issued by applicant and for imported products by applicant and agent respectively).

VIII. Others

If any changes are made to product technical requirement within valid period of original medical device registration certificate, Product technical requirement modified according to the registration change document shall be submitted in duplicate.

Appendix 6

Requirement and Instruction for Application Documents of Change Registration

Requirements and instructions of application documents of Change of Admistrative Matters

I. Application form

II. Supporting documents

(I) Domestic applicant shall provide:

1. One copy of business license (in duplicate).

2. One copy of organization code certificate.

(II) Imported medical device applicant shall provide:

1. Provide relevant supporting documents for marketing approval and qualification certificate issued by the medical device authority of the country (or region) where the Imported medical device applicant's registration address or manufacturing address is located when they are needed in changing items; provide explanation if changes can be made to items without approval from the medical device authority of the country (or region) where the Imported medical device applicant's registration address or manufacturing address is located.

2. Power of Attorney for the Imported medical device applicant designating the agent in China, the agent's Letter of Commitment, and one copy of business license (in duplicate) or institution registration certificate.

III. Change statement provided by the applicant

IV. Copies of original medical device registration certificate and its appendixes, and copies of previous medical device registration change documents

V. Requirements for change application

(I) Change of applicant's name:

Enterprise name change approval notice (domestic applicant) and/or list of change details and supporting documents

(II) Change of applicant's residence:

List details of the change and supporting documents.

(III) Change of domestic medical device manufacturing address:

Provide the manufacturing license changed accordingly.

(IV) Change of agent:

1. The applicant issues the statement for agent change.

2. The applicant issues the power of attorney for designating the new agent, and the new agent issues the letter of commitment.

3. One copy of the agent's business license (in duplicate) or institution registration certificate after change.

(V) Change of agent's residence:

Provide one copy of business license (in duplicate) or organization code certificate before and after change.

VI. Conformity statement

(I) Applicant declares that the product complies with the requirements of the Provisions for Medical Device Registration and the relevant regulations; declares that the product complies with the existing national standards and industrial standards, and provides a list of complied standards.

(II) Self-assurance statement for the authenticity of materials submitted (for domestic products the statement is issued by applicant and for imported products by applicant and agent respectively).

Requirements and instructions of application documents of Change of Approval Matters

I. Application form

II. Supporting documents

(I) Domestic applicant shall provide:

1. One copy of business license (in duplicate).

2. One copy of organization code certificate.

(II) Imported medical device applicant shall provide:

1. Relevant documents if the new market clearance or new enterprise qualification certificate issued by the medical device authority of the country (or region) where the imported medical device applicant’s registration address or manufacturing address is located is required for change items; or description if the change items need not to be approved by the medical device authority of the country (or region) where the Imported medical device applicant’s registration address or manufacturing address is located.

2. Power of Attorney for the Imported medical device applicant designating the agent in China, the agent’s Letter of Commitment, and one copy of business license (in duplicate) or institution registration certificate.

III. Change statement issued by applicant

IV. Copies of original medical device registration certificate and its appendixes, and copies of previous medical device registration change documents

V. Requirements for application documents of changed items

Selectively submit the following documents according to the specific changes:

(I) Comparative table and description of product name change.

(II) Comparative table and description of changes in product technical requirement.

(III) Comparative table and description of model and specification changes.

(IV) Comparative table and description of structure and composition changes.

(V) Comparative table and description of changes in the applicable scope of products.

(VI) Comparative table and description of manufacturing address change of imported medical devices.

(VII) Comparative table and description of changes in “Other contents” in the registration certificate.

(VIII) Description about other changes.

VI. Safety risk management report related with product changes

VII. Materials about the effects of changes on the safety and effectiveness of the product

Analyze and describe the effects of changes on the safety and effectiveness of the product, provide the relevant research materials, and provide the clinical evaluation material for changed intended use.

VIII. Type-testing report for changes in product technical requirement

IX. Conformity statement

(I) Applicant declares that the product complies with the requirements of the Provisions for Medical Device Registration and the relevant regulations; declares that the product complies with the existing national standards and industrial standards, and provides a list of complied standards.

(II) Self-assurance statement for the authenticity of materials submitted (for domestic products the statement is issued by applicant and for imported products by applicant and agent respectively).

Appendix 7

Requirements and Instructions for the Documents Required for Medical Device Clinical Trial Approval

I. Application form

II. Supporting documents

(I) Domestic applicant shall provide:

1. One copy of business license (in duplicate).

2. One copy of Organization Code Certificate.

(II) Imported medical device applicant shall provide:

1. Supporting documents for marketing approval and qualification certificate issued by the medical device authority of the country (or region) where the Imported medical device applicant's registration address or manufacturing address is located.

2. Power of Attorney for the agent designated by Imported medical device applicant, Letter of Commitment from the agent, and one copy of Business License (in duplicate) or Institution Registration Certificate (in duplicate).

III. Description of investigational product

The description shall cover the design principle, work principle, product characteristics, structure & composition and schematic diagram, manufacturing materials, packaging materials, model & specification and classification basis, main manufacturing technologies, delivery state, mechanism of action, and intended use of the investigational medical device.

IV. Preclinical study material

Generally, the preclinical study material shall include:

(I) Pre-clinical study data of the investigational medical device obtained by applicant (e.g. laboratory studies and animal tests)

(II) Publications and critical reviews concerning the safety and effectiveness of the investigational medical device.

(III) Research & development, marketing and clinical application data of domestic and Imported medical device products of same kind and data of comparison between the investigational medical device and the domestic and Imported medical device marketed products of same kind in aspects of work principle, structure & composition, manufacturing materials, technical parameters and intended use.

(IV) Information of adverse events concerning the investigational medical device.

(V) Benefit-risk analysis report of the clinical trial.

(VI) Other study data required.

V. Product technical requirement

VI. Type-testing Report for registration and pre-assessment advice issued by the medical device testing centers

VII. Samples of product IFU and label

VIII. Clinical trial protocol

The clinical trial protocol shall meet the relevant requirements of the Good Clinical Practice for Medical Device formulated by CFDA, and the analysis materials proving the scientificity and rationality of the protocol shall be provided.

IX. A written approval of clinical trial issued by the Ethics Committee

The written approvals of clinical trial issued by the ethics committees of all the clinical trial institutions shall be provided.

X. Conformity statement

(I) The applicant declares that the product complies with the requirements of the Provisions for Medical Device Registration and relevant regulations.

(II) The applicant declares that the materials submitted are authentic and true.

Appendix 8

List of Basic Requirements for Safety and Effectiveness of Medical Device

Article No.	Requirements	Applicable	Method for proving the conformity	documents for providing objective evidences for conformity
A	**General Principle**			
A1	Design and manufacture of medical device shall ensure that such medical device will be used by intended users (if applicable) with certain technical knowledge, experience, educational background, training experience and medical or hardware conditions, based on intended use method prescribed by manufacturer under the intended conditions and usage without causing damage to medical environment, patients' safety or safety and health of users and other people. During the use process, potential risks may be acceptable when compared with benefits of patients and advanced methods of protecting health and safety shall be in place.			
A2	The design and manufacture of the medical device shall follow the safety principles and take into account existing technical capacity. If adopt risk control, it shall ensure that the residual risk of each hazard is acceptable. Manufacturer shall adopt the following principles in order to: (1) Identify known or predictable hazard and assess the risks caused by intended use and predictable improper use (2) Eliminate risks as much as possible during the design and manufacture process			

	(3) Take full protective measures (such as alarm) to minimize residual risks (4) Notify residual risks.			
A3	Medical device shall achieve its expected performance and meet the requirements of applicable scope under the use conditions specified.			
A4	Degree of degradation of features and property of medical device will not affect its safety within the life cycle under the normal usage and maintenance conditions			
A5	Design, manufacture and packaging of medical device shall ensure that transportation or storage conditions specified in its instruction for use (such as change of temperature and humidity) will not have adverse impacts on product features and performance.			
A6	All risks and unintended effects shall be minimized and acceptable to ensure the benefits outweigh the risks in normal use.			
B	**Basic Principles of Safety Performance of Medical Device**			
B1	Chemical, physical and biological properties			
B1.1	Product materials shall meet the requirements given in Section A, in particular: (1) The selection of materials shall pay particular attention to their toxicity and inflammability (if applicable). (2) Compatibility of materials with biological tissue, cell and body fluid shall be taken into consideration based on intended use. (3) The selection of materials shall consider hardness, wear resistance and fatigue strength and other properties (if applicable).			
B1.2	Medical device shall be designed, manufactured and packed to minimize the risks brought by			

	pollutants and residue to the personnels engaged in transportation, storage and use as well as patients. In particular, attention shall be paid to duration and frequency of contact with exposed human tissue.			
B1.3	Medical device shall be well designed and manufactured to guarantee usage safety when product comes into contact with other materials, substances and gas during normal use or conventional procedures. Where medical device is used for drug administration, such products shall be well designed and manufactured complying with relevant regulations and limitations concerning pharmaceutical management without changing the product performance complying with its intended use.			
B1.4	Medical device shall be designed and manufactured to minimize the risks caused by substances filtered out or leaked, and particular attention shall be paid to carcinogenicity, teratogenicity and reproductive toxicity.			
B1.5	Medical device design and manufacture should consider the features of products and its service environment during the intended use of products to minimizing the risks caused by substance going into or out of the products accidentally.			
B2	**Infection and Microbial Contamination**			
B2.1	Medical device shall be designed and manufactured to minimize the risk of infecting patients, users and other people. Design shall meet the following requirements: (1) Easy to operate (2) Minimize the leakage of micro-organism from the device and/or exposure of micro-organism during operation			

	(3) Prevent the microbial contamination of human on devices and samples.			
B2.2	The medical device with microbiological requirements shall comply with the microbiological requirements before use.			
B2.3	The sterile medical device shall comply with the sterility requirements before use.			
B2.4	Sterile medical device or medical device with microbiological requirements shall be processed, manufactured or sterilized with validated methods.			
B2.5	Sterile medical device shall be manufactured under the corresponding controlled state (such as environment with corresponding purification degree).			
B2.6	Package of non-sterile medical device shall preserve the product integrity and cleanliness. For products requiring sterilization before use, its package shall minimize the risks of microbial contamination and suit relevant sterilization methods provided by manufacturer.			
B2.7	Where same or similar medical device may be sold as sterile or non-sterile phases, package or label of such products shall differentiate the difference			
B3	**Drug-device Combination Product**			
B3.1	Validate the safety, quality and performance of the drug and the drug-device combination product.			
B4	**Biogenic Medical Device**			
B4.1	For medical device containing animal origin tissue, cell and other substances, such animal origin tissue, cell and substances shall conform to related laws and regulations in China and comply with its intended use. Animal origin materials shall be well preserved for future reference.			

	Processing, preservation, testing and treatment process of animal tissue, cell and other substances shall provide optimal safety protection for patients, users and other people (if applicable). In particular, validated removal or inactivation methods shall be used to deal with virus and other infection agents.			
B4.2	For medical device containing human tissue, cell and other substances, proper source or donors shall be selected for reducing the risk of infection. Processing, preservation, testing and treatment process of human tissue, cell and other substances shall provide optimal safety protection for patients, users and other people (if applicable). In particular, validated removal or inactivation methods shall be used to deal with virus and other infection agents.			
B4.3	For medical device containing micro-organism cell and other substances, processing, preservation, testing and treatment process of cell and other substances shall provide optimal safety protection for patients, users and other people (if applicable). In particular, validated removal or inactivation methods shall be used to deal with virus and other infection agents.			
B5	**Environmental Characteristics**			
B5.1	Where medical device is intended to be used in conjunction with other medical device or equipment, the overall safety of the system after the combined application shall be guaranteed without impairing the performance of device or equipment. Any restrictions on combined application shall be specified in the label and (or) instruction for use. The connection system that shall be operated by the user,			

	such as liquid, gas delivery, or mechanical coupling shall be designed and structured to minimize the risks caused by improper connection.			
B5.2 B5.2.1	Medical device shall be well designed and manufactured for eliminating and reducing the following risks as much as possible: Risk of causing injury to patients, users or other people because of physical or ergonomics effectiveness reasons;			
B5.2.2	Risks of improper operation caused by ergonomics, human factors and operating environmental factors;			
B5.2.3	Reasonably foreseeable external factors or environment conditions related risks, such as magnetic field, external electromagnetic effects, electrostatic discharge, radiation from diagnosis and treatment, pressure, humidity, temperature and pressure and changes of accelerated speed			
B5.2.4	Risks caused by the product when contacting with materials, liquid and gases during normal operation and use;			
B5.2.5	Risks caused by compatibility of software and operating environment;			
B5.2.6	Risk of accident entry of substances;			
B5.2.7	Risk of mutual interference for products that are used in conjunction with other medical devices in the clinical diagnosis and treatment;			
B5.2.8	Risks of medical device that can't be maintained or calibrated (such as implantable devices) because of materials ageing, reduced measurement or control accuracy.			
B5.3	Medical device shall be designed and manufactured to minimize the risks of combustion and explosion under the state of normal use or			

	single failure, especially medical device exposed to combustible or inflammable substances or used in conjunction with combustible or inflammable substances during the process of intended use.			
B5.4	The medical device shall be adjusted, calibrated and maintained to ensure the design and manufacture can guarantee the safe operation of corresponding processes.			
B5.5	The medical device shall be designed and manufactured to facilitate the safe disposal of wastes.			
B6	**Medical Device with Diagnostic or Measuring Function**			
B6.1	The medical device with diagnostic or measuring function shall be designed and manufactured to take full account of its accuracy, precision and stability. Manufacturer shall specify the limiting value about accuracy.			
B6.2	Given the intended use of medical device, scope of any measurement, monitoring or display value shall be designed based on the principle of ergonomics.			
B6.3	The measured values shall be in metric units commonly used in China and can be understood by users.			
B7	**Radiation Protection**			
B7.1	General requirements: The medical device shall be designed, manufactured and packed to minimize the radiation to patients, users and others while not affecting the therapeutic and diagnostic functions.			
B7.2	Expected radiation: medical device use radiation for therapy and diagnostics purpose shall have controllable radiation dose. And the medical device shall be designed and manufactured to ensure the repeatability and			

	errors of relevant adjustable parameters are within the allowable range. If the radiation expected of the device is potentially harmful, the device shall be equipped with appropriate sound and light alarm for the radiation.			
B7.3	Non-expected radiation: medical device shall be designed and manufactured to minimize the exposure of patients, users and other people to non-expected, spurious or scattered radiation.			
B7.4	Ionizing radiation: for medical device that is expected to emit ionizing radiation, its design and manufacturing shall ensure that measurement, geometric distribution and energy distribution (or quality) of radiation emitted is controllable. Medical device emitting ionizing radiation (intended for radiology diagnosis) shall be designed and manufactured to reach the clinical image quality required and minimize absorbed dose of radiation received by patients and users. Medical device producing ionizing radiation (intended for radiologic treatment) shall be designed and manufactured to realize the reliable monitoring and control over the beam dose, beam type, energy, and energy distribution (when applicable).			
B8	**Medical Device with Software or Stand-alone Medical Software**			
B8.1	Medical device integrating electronic programmable system (including software) or stand-alone medical device software shall be designed to guarantee repeatability, reliability and performance. In case of single failure, proper measures shall be applied to remove and reduce risks as much as possible.			
B8.2	For medical device integrating software or stand-alone medical			

	device software, its software must be confirmed according to the most advanced technology level (It is needed to consider R&D cycle, risk management, verification and validation).			
B9	**Active Medical Device and Device Connecting with Active Element**			
B9.1	For the active medical device of a single fault, measures shall be taken to eliminate or reduce risks as much as possible.			
B9.2	Where patient safety is guaranteed by medical device with internal power supply, such medical device shall have the function of inspecting power supply status.			
B9.3	Where patient safety is guaranteed by medical device with external power supply, such medical device shall have the alarm system for indicating power failure			
B9.4	Medical device intended for monitoring one or more clinical parameters of patients shall be equipped with proper alarm system for giving warning to users when life health of patients is seriously deteriorated or patients are in danger.			
B9.5	The design and manufacturing of medical devices shall contain the methods to reduce electromagnetic interference.			
B9.6	Medical device shall be designed and manufactured to minimize the risk of electromagnetic interference as such interference may affect the operation of the device and other devices under the normal sevice environment.			
B9.7	When installation and maintenance is carried out based on requirements of manufacturer, medical device shall be designed and manufactured to minimize the risk of accidental electric shock of patients, users and other people under the states of normal use or			

	single failure.			
B10	**Mechanical Risk Protection**			
B10.1	Medical device shall be designed and manufactured to protect patients and users against mechanical risks caused by mobile resistance, unstable components and moving parts.			
B10.2	Except that vibration is specific performance of medical device, medical device shall be designed and manufactured to minimize the risks caused by product vibration. If feasible, proper measures shall be applied to limit or restrict vibration (especially vibration source).			
B10.3	Except that noise is the specific performance of medical device, medical device shall be designed and manufactured to minimize the risks caused by product noise. If feasible, proper measures shall be applied to limit or restrict noise (especially noise source)			
B10.4	The terminals and connectors for connecting electricity or gas or providing hydraulic pressure and pneumatic pressure operated by the user shall be designed and constructed to minimize the operation risk.			
B10.5	If the some part of the medical device has to be connected or reconnected before or in use, the medical device shall be designed and manufactured to minimize the risk of connection errors.			
B10.6	The accessible medical device parts and its surrounding areas (excluding the parts or areas providing heat or reaching the given temperatures) shall not reach dangerous temperature in normal use.			
B11	**Protection of Risks for medical device that Provide Energy or Substance to the Patients**			
B11.1	Medical device providing substance or energy to patients shall be designed and constructed to accurately set and maintain the			

	output, in order to ensure the safety of patients and users.			
B11.2	If insufficient output may lead to risks, medical device shall have methods to prevent and/or indicate “insufficient output”. Such products shall have proper prevention methods to prevent energy or substances reaching hazard level from being output accidentally.			
B11.3	Medical device shall be clearly labeled with the functions of controls and indices. If device operation may indicate the use instructions, operating state or adjustment parameters of system, such information shall be easy to understand			
B12	**Protection to Non-professional User against Application Risks**			
B12.1	Medical device shall be designed and manufactured and take the technology known by non-professional users and service environment into account, sufficient instructions shall be provided to facilitate understanding and use.			
B12.2	The medical device shall be designed and manufactured to minimize the risks of operational errors and misunderstanding of non-professional users.			
B12.3	Medical device shall try to have procedures that can be used by non-professional users to inspect whether product operates normally during use.			
B13	**Label and Instruction for Use**			
B13.1	Considering the training and knowledge received by users and for the purposes of making users obtain full information to identify manufacturer, safely use of the device and guarantee expected performance, such information shall be easy to understand.			
B14	**Clinical Evaluation**			
B14.1	Materials about clinical evaluation			

	of medical device shall be provided in accordance with existing laws and regulations in China.			
B14.2	Clinical trial shall be in strict compliance with Declaration of Helsinki. Approval of clinical trial shall conform to existing laws and regulations in China.			
Note	1 If applicable if in Column 3, indicate “Yes”. If not applicable, indicate “No” and state relevant reasons. 2. Fill in Column 4 methods proving that the medical device meets the basic requirements for safety and effectiveness. Methods for proving the conformity shall include (1) Recognized international, national and industry standards; (2) Comply with the relevant national standards, industrial standards, and international standards concerning medical devices. (3) Verification methods generally accepted in the industry; (4) Applicable verification methods of manufacturer; (5) Comparison with products of same kind already launched. (6) Clinical evaluation 3. The location and number of evidences provided for conformity shall be noted in the registration application materials. For documents included in product registration application materials, their locations shall be specified, for example, VIII. Registration inspection report (medical electric safety: prevention of mechanical risks); Section 4.2 of the instruction. For documents not included in the product registration application materials, their names and numbers in the quality control system documents shall be noted for inspection.			