X. Electronic Contents of the Registration Application Data for Classes II and III Import Medical Devices

IMPORTED PRODUCTS, CLASS II\III DOSSIER

Notes:
For application of import products, the applicant checks whether to submit original text data in non-Chinese language. If the language of the submission data by the applicant is Chinese, please check “No”, and the upload channel for the titles at all levels is only Chinese Data. If the language of the submission data by the applicant is non-Chinese, please check “Yes”, and the upload channel for the titles at all levels displays as Chinese Data and Original Language Data.

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
Chapter 1 —— Regional Management Information					
CH1.01	Explanation Letter for the Application	NR		NR	NR
CH1.02	Contents of the Application Data	R	The contents of the application data should be submitted, including sequence number of the contents, titles o the contents, applicable situations, name of the uploaded documents, and pages of the uploaded documents. For applicable situations, it should indicate whether the CR contents are applicable.	R	R
CH1.03	List of Terms and Abbreviations	CR		CR	CR
CH1.04	Application form	R	Upload the application form document with the data check code. Upload the Application Form for Priority Evaluation and Approval of Medical Devices (if available).	R	CR
CH1.05	List of the	CR		CR	CR

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
	medical devices				
CH1.06	Quality Management System, Comprehensive Quality System, or Other Certification Documents	R	An overseas applicant should submit certification documents complying with the requirements of the quality management system for medical devices in the country (region) of the registration place or production address, or passing certification by other quality management system. For application registration of domestic medical devices in accordance with the Approval of the Innovative Medical Devices by the Special Review and Approval Procedure/the Special Review and Approval Procedure for Innovative Medical Devices, the applicant should submit the notification letter for application of the innovative medical devices by special review and approval; if the samples are manufactured by another entrusted enterprise, the production license of the entrusted enterprise and the entrusting agreement should be provided. The production range of the production license should cover the category of the applied product.	R	R
CH1.07	Free Sale Certificate/Marketing Certification Documents	R	An overseas applicant should submit: 1. Certification documents to allow the product for marketing sale, issued by the competent authorities for medical devices in the country (region) of the registration place or production address. 2. If the product is not managed as medical device in the country (region) of the registration place or production address, the applicant should provide relevant certification documents, including the certification documents allowing the product for marketing sale in the country (region) of the registration place or production address.	R	R
CH1.08	User fees	NR		NR	NR
CH1.09	Contact situations prior to application,	CR	For example: Communication Meeting Minutes for Innovative Medical Devices.	CR	CR

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
	and prior communication records with the regulatory agency				
CH1.10	List to be reviewed	NR		NR	NR
CH1.11	Conformity statement/certification/declaration	There is no content under the title at the level.		There is no content under the title at the level.	
CH1.11.1	Declaration of Performance Indices and Recommended Standards	R	Declare that the product complies with the current national standard and industrial standards, and provide a list of the standards to be complied.	R	R
CH1.11.2	Environmental evaluation	NR		NR	NR
CH1.11.3	Certificate for Clinical Trial	NR		NR	NR
CH1.11.4	Declaration for applicable scope containing Rx or OTC description	NR		NR	NR
CH1.11.5	Truthful and accurate statement	R	For import products, the applicant and the agent should issue a self-assurance declaration for authenticity of the submitted data, respectively.	R	R
CH1.11.6	Summary and qualifications of Class III medical devices by the United States FDA	NR		NR	NR
CH1.11.7	Declaration of	R	The applicant declares that the product complies	R	R

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
	Conformity		with the administrative Measures for Registration of Medical Devices and the relevant laws & regulations, and declares that the product complies with the requirements of the relevant classes in the Principles for Classification of Medical Devices.		
CH1.12	Authorization Letter of the Master Documents	CR		CR	CR
CH1.13	Letter of Authorization of Agent	R	An overseas applicant shall submit the Letter of Authorization for its designated agent in mainland China, the Letter of Commitment by the agent, and a copy of the Business License or the Organization Registration Certificate of the agent.	R	R
CH1.14	Other Regional Management Information	CR	The enterprise of the product for priority application may upload the relevant reasons and bases (if applicable) for priority evaluation & approval.	CR	CR
Chapter 2 —— Summary Data					
CH2.1	Contents of the chapters and the sections	CR	The contents of the application data submitted include sequence number of the contents, titles o the contents, applicable situations, name of the uploaded documents, and pages of the uploaded documents. For applicable situations, it should indicate whether the CR contents are applicable.	CR	CR
CH2.2	Summary of the application	R	Describe the determination basis of the management category, classification code and name of the applied product.	R	R
CH2.3	Summary and Certificates for application prior to marketing	NR		NR	NR
CH2.4	Device description	There is no content under the title at the level, while the data are submitted under the title at the lower level.		There is no content under the title at the level, while the data are submitted under	

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
				the title at the lower level.	
CH2.4.1	Comprehensive description of the medical device and operating principles	R	1. For the products with various models and specifications, the differences between the models and specifications should be defined clearly. Comparison table and graphs and diagrams with illustrative text should be adopted to describe the structure and composition (or configuration), function, product features, operation mode, and performance indices of various models and specifications, etc. 2. Passive Medical Devices Describe the working principle, mechanism of action (if applicable), structure and composition (including the associated accessories), main raw materials and the characteristics of the product which are different from other similar products and the graphic explanations should be provided if necessary. 3. Active Medical Devices Describe the working principle, mechanism of action (if applicable), structure and composition (including the associated accessories), main functions and the component parts (the critical components and software) and the characteristics of the product which are different from other similar products and graphic explanations should be provided if necessary.	R	R
CH2.4.2	Description of the package of the medical device	R	Package description. The information of the package of the related product as well as the package situations of the accessories sold with this product. The initial package information suitable for the sterilization method should be explained for the sterile medical devices.	R	R
CH2.4.3	Research and development course of the medical device	R	The information of the similar products (marketed both at home and abroad) or the products of the previous generation (if there is) should be provided when the products refer to the similar products or the	R	R

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
			products of the previous generation and the research and development background and objective of the product applied for registration should be illustrated. For similar products, the reasons for selecting them as R&D reference should be explained.		
CH2.4.4	Reference and comparison with similar medical devices, or medical devices of the previous several generations (marketed in domestic and foreign markets)	R	Tabulate to illustrate comparatively differences and similarities between the product and the reference products (similar products or the products of the previous generation) in terms of working principle, structure and composition, manufactured materials, performance indexes, mode of action (e.g., implant, intervene) and the intended use.	R	R
CH2.4.5	Substantial equivalence discussion	NR		NR	NR
CH2.5	Applicable scope and/or intended uses and contraindications	There is no content under the title at the level, while the data are submitted under the title at the lower level.		There is no content under the title at the level, while the data are submitted under the title at the lower level.	
CH2.5.1	Intended uses; purpose of use; intended users; and applicable scope	R	1.Intended Use: It should be determined that the treatment and diagnosis provided by the product comply with the objectives defined in the Article 76 of Regulations for the Supervision and Administration of Medical Devices and the applicable medical stages (such as monitoring and rehabilitation after treatment) should be described. The target user and the skills/knowledge/training	R	R

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
			needed for operation of the product should be determined. It should be explained that whether the product is for single use or reuse. The medical devices intended to be combined with it should be explained. 2. Applicable population: Information of the target patient population (such as adults, children or neonates), information about the patient selection criteria and the parameters which should be monitored and the factors which should be considered in the use process.		
CH2.5.2	Intended operational environment/installation requirements	R	Expected operating environment: Places where the product intends to be used such as the medical institutions, laboratory, ambulance, and family, etc., and the environmental conditions which may affect the safety and efficacy (e.g., temperature, humidity, power, pressure, moving, etc).	R	R
CH2.5.3	Pediatric Use	CR		CR	CR
CH2.5.4	Use contraindications	R	Contraindications: If applicable, some inapplicable diseases, conditions or specific populations (e.g. children, elderly, pregnant women and lactating women and patients with hepatic and renal insufficiency) of the medical device should be explained clearly.	R	R
CH2.6	Global marketing course	There is no content under the title at the level.		There is no content under the title at the level.	
CH2.6.1	Marketing situations	CR		CR	CR
CH2.6.2	Adverse events and recall	CR		CR	CR
CH2.6.3	Sale, adverse events, and recall rate	CR		CR	CR
CH2.6.4	Evaluation/inspection report	NR		NR	NR
CH2.7	Summary of	CR	Other contents to be described. For the approved	CR	CR

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
	other applications		parts or the associated accessories should be provided, copies of the approval number and approval document should be provide, explanation should be provided for the product intended to be used in the combination with other medical devices or universal products. The physical and electric connection modes between each combined medical devices in the system should be explained.		
Chapter 3 —— Nonclinical study Data					
CH3.1	Contents of the chapters and the sections	CR	The contents of the application data submitted include sequence number of the contents, titles o the contents, applicable situations, name of the uploaded documents, and pages of the uploaded documents. For applicable situations, it should indicate whether the CR contents are applicable.	CR	CR
CH3.2	Risk Management	R	Product Risk Analysis Data The product risk analysis data is the data formed by the records of the risk management process and the evaluation results of the product. The traceability of each of the following process should be provided for each judged hazard: (1) Risk analysis: Including the applicative scope of the medical device, judgment of the characteristics related to safety, judgment for hazards, and estimated risk of each hazardous situation. (2) Risk evaluation: For each judged hazardous situation, evaluate and decide whether the risk has to be reduced. (3) Implementation of the risk control measures and validation results, cite the testing and evaluation reports if necessary, such as medical electrical safety and biological assessments. (4) Acceptability judgment of the any one or more residual risks.	R	R
CH3.3	List of the basic requirements	R	List of the Basic Requirements for Safety and Efficacy of Medical Devices Describe the methods adopted that the product	R	R

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
	(EP) for safety and efficacy		complies with all the requirements in the *List of the Basic Requirements for Safety and Efficacy of Medical Devices*, and the documents to prove its conformity. For the inapplicable requirements in the List of the Basic Requirements for Safety and Efficacy of Medical Devices, the reasons should be explained. For the documents included in the product registration application data, the specific position of it in the application data should be explained. For the documents which are not included in the product registration application data, the document name of the evidence and its number in the quality management system should be indicated for reference.		
CH3.4	Standards	There is no content under the title at the level, while the data are submitted under the title at the lower level.		There is no content under the title at the level, while the data are submitted under the title at the lower level.	
CH3.4.1	List of the standards (technical requirements for products)	R	Product Technical Requirements The technical requirements of medical devices should be formulated in accordance with the provisions in the *Compilation Guidelines for Technical Requirements of Medical Devices.*	R	R
CH3.4.2	Conformity declaration and/or certification	R	Product Registration Test Report Provide the registration test report and pre-evaluation comments issued by the medical device testing institution with the qualifications of testing institution of medical device.	R	CR
CH3.5	Nonclinical Study	There is no content under the title at the level, while the data are submitted under the title at the lower level.		There is no content under the title at the level, while the data are submitted under	

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
				the title at the lower level.	
CH3.5.01	Physical and mechanical performance	CR	Based on the application product, provide applicable product performance study data under the titles at the level and at the lower level. The study data for product performance, and the study and compilation explanations for the product technical requirements should be provided, including the functional and safety indexes, and determination bases for other indexes related to quality control, and the adopted standards or methods as well as reasons and theoretical basis for adoption.	CR	CR
CH3.5.01.1	[Study description, study no., and start date]	CR		CR	CR
CH3.5.01.1.1	Summary	CR		CR	CR
CH3.5.01.1.2	Complete report	CR		CR	CR
CH3.5.01.1.3	Statistical data	CR		CR	CR
CH3.5.02	Chemical/material characterization	CR	Based on the application product, provide applicable product performance study data under the titles at the level and at the lower level. The study data for product performance, and the study and compilation explanations for the product technical requirements should be provided, including the functional and safety indexes, and determination bases for other indexes related to quality control, and the adopted standards or methods as well as reasons and theoretical basis for adoption.	CR	CR
CH3.5.02.1	[Study description, study no., and start date]	CR		CR	CR
CH3.5.02.1.1	Summary	CR		CR	CR
CH3.5.02.1.2	Complete report	CR		CR	CR

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
CH3.5.02.1.3	Statistical data	CR		CR	CR
CH3.5.03	Electric system: Safety, mechanical, and environmental protection, and electromagnetic compatibility	CR	Based on the application product, provide applicable product performance study data under the titles at the level and at the lower level. The study data for product performance, and the study and compilation explanations for the product technical requirements should be provided, including the functional and safety indexes, and determination bases for other indexes related to quality control, and the adopted standards or methods as well as reasons and theoretical basis for adoption.	CR	CR
CH3.5.03.1	[Study description, study no., and start date]	CR		CR	CR
CH3.5.03.1.1	Summary	CR		CR	CR
CH3.5.03.1.2	Complete report	CR		CR	CR
CH3.5.03.1.3	Statistical data	CR		CR	CR
CH3.5.04	Radiation Safety	CR	Based on the application product, provide applicable product performance study data under the titles at the level and at the lower level. The study data for product performance, and the study and compilation explanations for the product technical requirements should be provided, including the functional and safety indexes, and determination bases for other indexes related to quality control, and the adopted standards or methods as well as reasons and theoretical basis for adoption.	CR	CR
CH3.5.04.1	[Study description, study no., and start date]	CR		CR	CR
CH3.5.04.1.1	Summary	CR		CR	CR
CH3.5.04.1.2	Complete report	CR		CR	CR
CH3.5.04.1.3	Statistical data	CR		CR	CR

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
CH3.5.05	Independent software/software components	CR	Based on the application product, provide applicable product performance study data under the titles at the level and at the lower level. For the product incorporating software, a separated description document of the medical device software should be provided. The contents includes the basic information, realization process and core algorithm and the level of detail depends on the safety level and complexity level of the software. Meanwhile, the statement on the naming rule of the software version should be issued to determine all the fields and the definition of the fields of the software version and determine the full version of the software and the identification version used for release of the software.	CR	CR
CH3.5.05.01	Description of independent software/software components	CR		CR	CR
CH3.5.05.02	Hazard Analysis	CR		CR	CR
CH3.5.05.03	Specifications for software requirements	CR		CR	CR
CH3.5.05.04	System structure diagram	CR		CR	CR
CH3.5.05.05	Software Design Specification	CR		CR	CR
CH3.5.05.06	Traceability analysis	CR		CR	CR
CH3.5.05.07	Process description of the service cycle of the software	CR		CR	CR

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
CH3.5.05.08	Software verification and qualification	CR		CR	CR
CH3.5.05.08.1	[Study description, study no., and start date]	CR		CR	CR
CH3.5.05.08.1.1	Summary	CR		CR	CR
CH3.5.05.08.1.2	Complete report	CR		CR	CR
CH3.5.05.08.1.3	Statistical data	CR		CR	CR
CH3.5.05.09	Version update history	CR		CR	CR
CH3.5.05.10	Residual defects (errors and failures)	CR		CR	CR
CH3.5.05.11	Network security	CR		CR	CR
CH3.5.05.12	Interoperability	CR		CR	CR
CH3.5.06	Biocompatibility and toxicological evaluation	CR	Based on the application product, provide applicable biocompatibility evaluation study data under the titles at the level and at the lower level. Biocompatibility Evaluation Studies The biocompatibility of the materials if the finished products which directly or indirectly contact with the patients and users should be evaluated. The study data of biocompatbility evaluation should also include: 1. Basis and methods for biocompatbility evaluation. 2. Description of the materials used in the product and the nature of contact to human body. 3. Reasons and arguments for the implementation or exemption of biological tests. 4. Evaluation of the existing data or test results.	CR	CR
CH3.5.06.1	[Study	CR		CR	CR

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
	description, study no., and start date]				
CH3.5.06.1.1	Summary	CR		CR	CR
CH3.5.06.1.2	Complete report	CR		CR	CR
CH3.5.06.1.3	Statistical data	CR		CR	CR
CH3.5.07	Non-material-mediated pyrogens	CR		CR	CR
CH3.5.07.1	[Study description, study no., and start date]	CR		CR	CR
CH3.5.07.1.1	Summary	CR		CR	CR
CH3.5.07.1.2	Complete report	CR		CR	CR
CH3.5.07.1.3	Statistical data	CR		CR	CR
CH3.5.08	Safety of biological origin (human/animal) materials	CR	Based on the application product, provide applicable biosafety study data under the titles at the level and at the lower level. Biosafety Studies For the products with biosafety risk which contain the allogeneic materials, materials of animal origin or bioactive substances, the biosafety study data of the related materials and the bioactive substances should be provided. Including that acquisition, processing, storage, test, and treatment processes of tissues, cells, and materials are described; the source (including screening details of the donors) is clarified, and the validation trials for removal or inactivation methods of viruses, other pathogens, and immunogenic substances during production are described; brief summary of process validation.	CR	CR
CH3.5.08.1	Certificate/certification	CR		CR	CR
CH3.5.08.2	[Study	CR		CR	CR

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
	description, study no., and start date]				
CH3.5.08.2.1	Summary	CR		CR	CR
CH3.5.08.2.2	Complete report	CR		CR	CR
CH3.5.08.2.3	Statistical data	CR		CR	CR
CH3.5.09	Sterilization confirmation	There is no content under the title at the level, while the data are submitted under the title at the lower level.		There is no content under the title at the level, while the data are submitted under the title at the lower level.	
CH3.5.09.1	Sterilization by the end user	CR	Based on the application product, provide applicable sterilization/disinfection process study data under the titles at the level and at the lower level. Sterilization by the end user: The determination bases for the recommended sterilization process (methods and parameters) and the recommended sterilization method should be defined. For the products which can tolerate the sterilization for twice or more times, the study data of related recommended sterilization method tolerance of the product should be provided.	CR	CR
CH3.5.09.1.1	[Study description, study no., and start date]	CR		CR	CR
CH3.5.09.1.1.1	Summary	CR		CR	CR
CH3.5.09.1.1.2	Complete report	CR		CR	CR
CH3.5.09.1.1.3	Statistical data	CR		CR	CR
CH3.5.09.2	Sterilization by the	CR	Based on the application product, provide applicable sterilization/disinfection process study data under the	CR	CR

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
	manufacturer		titles at the level and at the lower level. Sterilization by the manufacturer: The sterilization process (method and parameters) and sterility assurance level (SAL) should be defined and the sterilization qualification report should be provided.		
CH3.5.09.2.1	[Study description, study no., and start date]	CR		CR	CR
CH3.5.09.2.1.1	Summary	CR		CR	CR
CH3.5.09.2.1.2	Complete report	CR		CR	CR
CH3.5.09.2.1.3	Statistical data	CR		CR	CR
CH3.5.09.3	Residual toxicity	CR	Based on the application product, provide applicable sterilization/disinfection process study data under the titles at the level and at the lower level. Residual toxicity: If the method used for sterilization may cause residue, the residue information and the adopted treatment method should be defined and the study data should be provided.	CR	CR
CH3.5.09.3.1	[Study description, study no., and start date]	CR		CR	CR
CH3.5.09.3.1.1	Summary	CR		CR	CR
CH3.5.09.3.1.2	Complete report	CR		CR	CR
CH3.5.09.3.1.3	Statistical data	CR		CR	CR
CH3.5.09.4	Cleaning and disinfection qualification	CR	Based on the application product, provide applicable sterilization/disinfection process study data under the titles at the level and at the lower level. Disinfection by the end user: The determination bases for the recommended disinfection process	CR	CR

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
			(methods and parameters) and the recommended disinfection methods should be defined.		
CH3.5.09.4.1	[Study description, study no., and start date]	CR		CR	CR
CH3.5.09.4.1.1	Summary	CR		CR	CR
CH3.5.09.4.1.2	Complete report	CR		CR	CR
CH3.5.09.4.1.3	Statistical data	CR		CR	CR
CH3.5.09.5	Re-treatment of reusable devices	CR		CR	CR
CH3.5.09.5.1	[Study description, study no., and start date]	CR		CR	CR
CH3.5.09.5.1.1	Summary	CR		CR	CR
CH3.5.09.5.1.2	Complete report	CR		CR	CR
CH3.5.09.5.1.3	Statistical data	CR		CR	CR
CH3.5.10	Animal Testing	CR	Based on the application product, provide applicable study data of the preclinical animal trial under the titles at the level and at the lower level. The study data of preclinical animal trial include study purpose, results, and records of the animal trial.	CR	CR
CH3.5.10.1	[Study description, study no., and start date]	CR		CR	CR
CH3.5.10.1.1	Summary	CR		CR	CR
CH3.5.10.1.2	Complete	CR		CR	CR

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	report				
CH3.5.10.1.3	Statistical data	CR		CR	CR
CH3.5.11	Usability/human factors	CR		CR	CR
CH3.5.11.1	[Study description, study no., and start date]	CR		CR	CR
CH3.5.11.1.1	Summary	CR		CR	CR
CH3.5.11.1.2	Complete report	CR		CR	CR
CH3.5.11.1.3	Statistical data	CR		CR	CR
CH3.6	Nonclinical study literatures	NR		NR	NR
CH3.7	Shelf life and package validation	CR	Product validity period and packaging study	CR	CR
CH3.7.1	Product stability	CR	Determination of the validity life: If applicable, the validation report of the validity life of the product should be provided.	CR	CR
CH3.7.1.1	[Study description, study no., and start date]	CR		CR	CR
CH3.7.1.1.1	Summary	CR		CR	CR
CH3.7.1.1.2	Complete report	CR		CR	CR
CH3.7.1.1.3	Statistical data	CR		CR	CR
CH3.7.2	Package validation	CR	1. For the medical devices with limited times of reuse, the validation data of the times of use should be provided. 2. Package and integrity of the package: The evidence to keep the integrity of the package within the labelled shelf life and under the storage and transportation conditions.	CR	CR
CH3.7.2.1	[Study	CR		CR	CR

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
	description, study no., and start date]				
CH3.7.2.1.1	Summary	CR		CR	CR
CH3.7.2.1.2	Complete report	CR		CR	CR
CH3.7.2.1.3	Statistical data	CR		CR	CR
CH3.8	Other data	CR		CR	CR
CH3.8.1	[Study description, study no., and start date]	CR		CR	CR
CH3.8.1.1	Summary	CR		CR	CR
CH3.8.1.2	Complete report	CR		CR	CR
CH3.8.1.3	Statistical data	CR		CR	CR
Chapter 4 —— Clinical study Data					
CH4.1	Contents of the chapters and the sections	CR	The contents of the application data submitted include sequence number of the contents, titles o the contents, applicable situations, name of the uploaded documents, and pages of the uploaded documents. For applicable situations, it should indicate whether the CR contents are applicable.	CR	CR
CH4.2	Summary of clinical evidences	CR		CR	CR
CH4.2.1	Clinical evaluation data	CR	Clinical Evaluation Data The clinical evaluation data should be submitted according to the corresponding requirements. Clinical evaluation of products included in the Catalogue of Medical Devices Exempted from Clinical Trials, and analysis and evaluation for the data obtained from clinical trial or clinical use of the medical devices of the same type should comply with the requirements of the Technical Guideline for Clinical Evaluation of Medical Devices.	CR	CR
CH4.2.2	Data from	CR	Based on the application product, provide applicable	CR	CR

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
	Clinical trials		data of the clinical trial under the titles at the level and at the lower level.		
CH4.2.2.1	[Trial description, protocol no., and start date]	CR		CR	CR
CH4.2.2.1.1	Synopsis of the clinical trial	CR		CR	CR
CH4.2.2.1.2	Clinical Trial Report	CR		CR	CR
CH4.2.2.1.3	Clinical trial data	CR		CR	CR
CH4.2.3	Summary of clinical literatures, and other known rational information	CR		CR	CR
CH4.3	Relevant documents approved by the Ethics Committee	CR	Written opinions of the ethics committee to agree to carry out the clinical trial, and the template of the informed consent form (if applicable). Protocol of the clinical trial.	CR	CR
CH4.4	Location of the clinical trial, and the contact information of the Ethics Committee	NR		NR	NR
CH4.5	Other clinical evidences	CR	For import medical devices, it should also provide clinical evaluation data when foreign medical device regulatory authorities approve this product for marketing.	CR	CR
CH4.5.1	[Study introduction, study no., and start date]	CR		CR	CR

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
CH4.5.1.1	Summary	CR		CR	CR
CH4.5.1.2	Complete report	CR		CR	CR
CH4.5.1.3	Statistical data	CR		CR	CR
Chapter 5 —— Package Insert and Label					
CH5.01	Contents of the chapters and the sections	CR	The contents of the application data submitted include sequence number of the contents, titles o the contents, applicable situations, name of the uploaded documents, and pages of the uploaded documents. For applicable situations, it should indicate whether the CR contents are applicable.	CR	CR
CH5.02	Product/package label	R	The sample label of the minimum sales unit should comply with the requirements of the relevant laws and regulations.	R	R
CH5.03	Package description/instruction for use	R	The package insert of the product should comply with the requirements of relevant laws and regulations.	R	R
CH5.04	Electronic Instruction	NR		NR	NR
CH5.05	Doctor's Manual	CR		CR	CR
CH5.06	Patient information leaflet	CR		CR	CR
CH5.07	Technical instructions	CR		CR	CR
CH5.08	Patient file Label/card and implantation registry card	NR		NR	NR
CH5.09	Product Brochure	NR		NR	NR
CH5.10	Other package insert and label materials	CR		CR	CR
Chapter 6A —— Quality Management System Procedure					
CH6A.1	Summary	NR		NR	NR

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
	Letter of the Application				
CH6A.2	Contents of the chapters and the sections	CR	The contents of the application data submitted include sequence number of the contents, titles o the contents, applicable situations, name of the uploaded documents, and pages of the uploaded documents. For applicable situations, it should indicate whether the CR contents are applicable.	CR	CR
CH6A.3	Regulatory information	There is no content under the title at the level, while the data are submitted under the title at the lower level.		There is no content under the title at the level, while the data are submitted under the title at the lower level.	
CH6A.3.1	Product Description Information	R	Production and Manufacture Information 1. Passive Medical Devices The production and processing process of the product should be determined, the key process and special process should be indicated and the process control points should be explained. The use situations of various processing aids in the production process and control situations of the impurities (such as residual monomer, micromolecular residue) should be determined. 2. Active Medical Devices The production process of the product should be determined and the process control points may be explained in the form of flow chart.	R	R
CH6A.3.2	General Production Information	R	Manufacturing Sites If there are many development and manufacturing sites, the actual situations of each development and production site should be summarized.	R	R
CH6A.3.3	Required Tables	NR		NR	NR
CH6A.4	Quality Management	NR		NR	NR

RPS Table of Contents	Title	Applicability	Requirements for Documents	Applicable Situations of Chinese Data	Applicable Situations of Original Text Data
	System				
CH6A.5	Management Responsibility Procedure	NR		NR	NR
CH6A.6	Resources Management Procedure	NR		NR	NR
CH6A.7	Product Realization Procedure	NR		NR	NR
CH6A.7.1	Design and Development Procedure	NR		NR	NR
CH6A.7.2	Purchase Procedure	NR		NR	NR
CH6A.7.3	Control Procedure for Production and Services	NR		NR	NR
CH6A.7.4	Control Procedures for Monitoring and Measuring Devices	NR		NR	NR
CH6A.8	QMS Procedures for Measurement, Analysis, and Improvement	NR		NR	NR
CH6A.9	Other Quality System Procedures	NR		NR	NR
Chapter 6B —— Quality Management System Procedure of Application Medical Devices				**NR**	