Controlled State：

Distribution Number：

Quality Manual

Document Number：HD / QM - 2024

Version No. / Number of revisions：E/2

Release Date：2024-08-11

Implementation Date：2024-08-12

Changzhou Haida Medical Equipment Co.,Ltd

Organization：2024. 8. 11

Audit：2024. 8. 11

Approve：2024. 8. 12

Add:Sanhekou Industrial Park
Changzhou, Jiangsu ,P.R.China 213000
Tel:0086-519-83992059
E-mail: info@medicalstapler.com
Website: www.medicalstapler.com

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文 件 更 改 记 录

SN	Number	Page	chapter	State	Changed by	Reviewer	Approver	Change the content	Change date
1	20220221	ALL	ALL	E/0				Expand the scope of product certification	2022-2-21
2	20220221	ALL	ALL	E/0				Add MDR 120 (3) additional content	2022-2-21
3	20230520	ALL	ALL	E/1				Revise according to the newly released standards	2023-5-20
4	20240811	ALL	ALL	E/2				Update EN ISO 13485 standard requirements	2024-8-11

0. 1 Quality Manual Approval Statement

Quality Manual Approval Statement

Our company's E/2 version of the Quality Manual is based on GB/T 19001-2016 "Quality Management System Requirements", GB/T 42061-2022/ISO 13485:2016, EN ISO 13485:2016+AC:2018+A11:2021 "Medical Device Quality Management System Requirements for Regulatory Use", EU Medical Device Directive MDD 93/42/EEC+2007/47/EC Appendix II (excluding II.4), EU Medical Device Regulation EU 2017/745 (MDR) Article 120 (3), EU 2017/745 (MDR) Article 10 (9), as well as "Medical Device Production Quality Management Specification", "Medical Device Production Quality Management Specification Appendix Aseptic Medical Devices" and "Medical Device Production Quality Management Specification". Formulated in accordance with the requirements of the Appendix on Implantable Medical Devices and based on the actual situation of our company. The Quality Manual elaborates on the scope, quality policy, and quality objectives of our company's quality management system, specifies the responsibilities and authorities of each department, and establishes the description of the processes, sequence, and interactions between processes of our company's quality management system, as well as references to procedural documents. The Quality Manual is the basic regulation of our company's quality management, the guideline for the operation of the quality management system, and also the company's commitment to customers. The E/2 version of the Quality Manual will be officially implemented from August 12, 2024, and the original E/1 version of the Quality Manual will be invalidated at the same time.

All employees should carefully study the E/2 version of the Quality Manual, deeply understand its spirit, and strictly follow and implement it in their work.

General Manager：

Date： 2024.8.11

0. 2 Quality Policy Approval Staement

Quality Policy Approval Staement

Our company's quality policy is:
Excellent quality, compliance with regulations, customer satisfaction, and continuous improvement
Its meaning:
Excellent quality "refers to our company's adherence to technological progress, close tracking of the development trends of similar products both domestically and internationally, active adoption of new technologies, processes, and materials, acceleration of new product development, and efforts to make the technical performance and grade of our products reach the advanced level both domestically and internationally; At the same time, strengthen the risk management of the entire product implementation process, strictly control the quality of each link from design, procurement, production, sales, and service, and ensure the safety and reliability of product quality.
Compliance with regulations is the first element of an enterprise and a prerequisite for its establishment. Our company strictly abides by all applicable laws and regulations, including business regulations, quality regulations, medical device regulations, etc., and consciously engages in production and business activities within the framework of the law.
Customer satisfaction is the business philosophy and relentless pursuit of enterprises. Our company focuses on customers and provides them with safe and effective medical equipment products and excellent services in a long-term and stable manner to meet their needs and achieve customer satisfaction.
Continuous improvement "refers to the company continuously improving product quality through strict quality management and control, and utilizing quality policies, quality objectives, audit results, data analysis, corrective and preventive measures, and management reviews to continuously improve the effectiveness of the quality management system.
We hope that all relevant departments will conscientiously carry out their work according to their respective responsibilities and authorities, and decompose and implement the company's quality objectives within the framework of the quality policy, in order to achieve the implementation of the quality policy through the realization of the quality objectives.

General Manager：
Date： 2024.8.

0. 3 Management Representative Appointing Letter

Management Representative Appointing Letter

To ensure that our company complies with GB/T 19001-2016 "Quality Management System Requirements", GB/T 42061-2022/ISO 13485:2016, EN ISO 13485:2016+AC: 2018+A1:2021 "Medical Device Quality Management System Requirements for Regulatory Use", EU Medical Device Directive MDD 93/42/EEC+2007/47/EC Appendix II (excluding II.4), EU Medical Device Regulation EU 2017/745 (MDR) Article 120 (3), EU 2017/745 (MDR) Article 10 (9), as well as "Medical Device Production Quality Management Specification", "Medical Device Production Quality Management Specification Appendix Aseptic Medical Devices" and "Medical Device Production Quality Management Specification Appendix Implantable Medical Devices According to the requirements of, establish a quality management system, and implement, maintain, and continuously improve the quality management system. After research and decision, Ms. Shuhua, the Quality Department Manager, concurrently serves as the management representative of our company's quality management system.

The responsibilities and authorities of the management representative are as follows:

a) Ensure the establishment, implementation, and maintenance of our company's quality management system processes;

b) Responsible for reporting the performance of the quality management system and any improvement needs to the top management;

c) Ensure that personnel at all levels of the company raise awareness of meeting regulatory and customer requirements;

d) Responsible for liaising with external parties on matters related to the company's quality management system (including liaison with various levels of food and drug regulatory authorities, notified bodies, EU authorized representatives, etc.).

e) Implement relevant laws, regulations, rules, and standards related to medical devices.

f) Establish and implement a quality management system that is compatible with the medical devices produced, and maintain its scientific, reasonable, and effective operation. Report the operation status and improvement needs of the quality management

system to the responsible person of the enterprise.

g) Develop and organize the implementation of the audit plan for the enterprise quality management system, assist the enterprise leader in organizing management reviews according to the plan, prepare audit reports, and report the review results to the enterprise management.

h) Organize internal medical device quality management training to enhance employees' quality management capabilities and strengthen the company's awareness of integrity and compliance with the law.

i) Organize internal medical device quality management training to enhance employees' quality management capabilities and strengthen the company's awareness of integrity and compliance with the law.

j) Maintain communication with the inspection team, provide relevant information and materials, and cooperate with the inspection work when the production enterprise is subject to supervision and inspection by various levels of drug supervision and management departments; Organize relevant departments of the enterprise to rectify the problems found during the inspection in a timely manner according to the requirements.

k) When the production conditions of an enterprise no longer meet the requirements of the medical device quality management system, which may affect the safety and effectiveness of medical devices, it should immediately report to the person in charge of the enterprise, assist the person in charge of the enterprise in carrying out risk control measures such as stopping production activities, investigating the reasons, and recalling products in a timely manner, and proactively report to the drug supervision and administration department of the province, autonomous region, or municipality directly under the central government where it is located.

l) When major quality problems occur with medical devices produced by enterprises, they should immediately report to the responsible person of the enterprise, assist the responsible person in taking risk control measures quickly, and report to the drug supervision and administration department of the province, autonomous region, or municipality directly under the central government within 24 hours.

l) Organize the collection of information on product quality after listing, and promptly report relevant product complaints and incidents to the responsible person of the enterprise

Discovered during external audits such as monitoring of the situation, safety hazards of the product, and acceptance of supervision and inspection by drug regulatory authorities at all levels

Defects in the quality management system and their rectification status。

m) Regularly organize enterprises to conduct comprehensive self inspections of the quality management system operation in accordance with the requirements of the "Medical Device Production Quality Management Standards", and submit annual self inspection reports to the drug supervision and management departments of the provinces, autonomous regions, and municipalities directly under the central government before the end of each year.

n) Other work required by laws and regulations.

Hereby appointed.

General Manager：

Date： 2024.8.11

Appointment Letter of Compliance Manager

To ensure that the products produced by the company continue to meet the requirements of MDR 2017/745 EU Medical Device Regulation, according to Article 15 of MDR, the responsibilities and authorities of the compliance officer are as follows:

1. According to the quality management system, conduct appropriate checks on product regulatory compliance before product release;

2. Develop technical documents and EU conformity declarations and maintain their latest status;

3. Responsible for post listing supervision;

4. Warning system accident report;

5. Ensure the signing of clinical investigation statements.

We hope that all departments and employees of the company can work together and fulfill their quality responsibilities to ensure the effective implementation and continuous improvement of the quality management system.

Hereby appointed.

General Manager：

Date： 2024.8.11

0. 4 Company Introduction

Company Introduction

Changzhou Haida Medical Equipment Co.,Ltd Established in June 2004. The economic nature is a limited liability company. It is a specialized enterprise that integrates research, manufacturing, and sales of disposable electric endoscope staplers, medical anastomosis (suturing) devices, and other second-class abdominal surgical instruments.

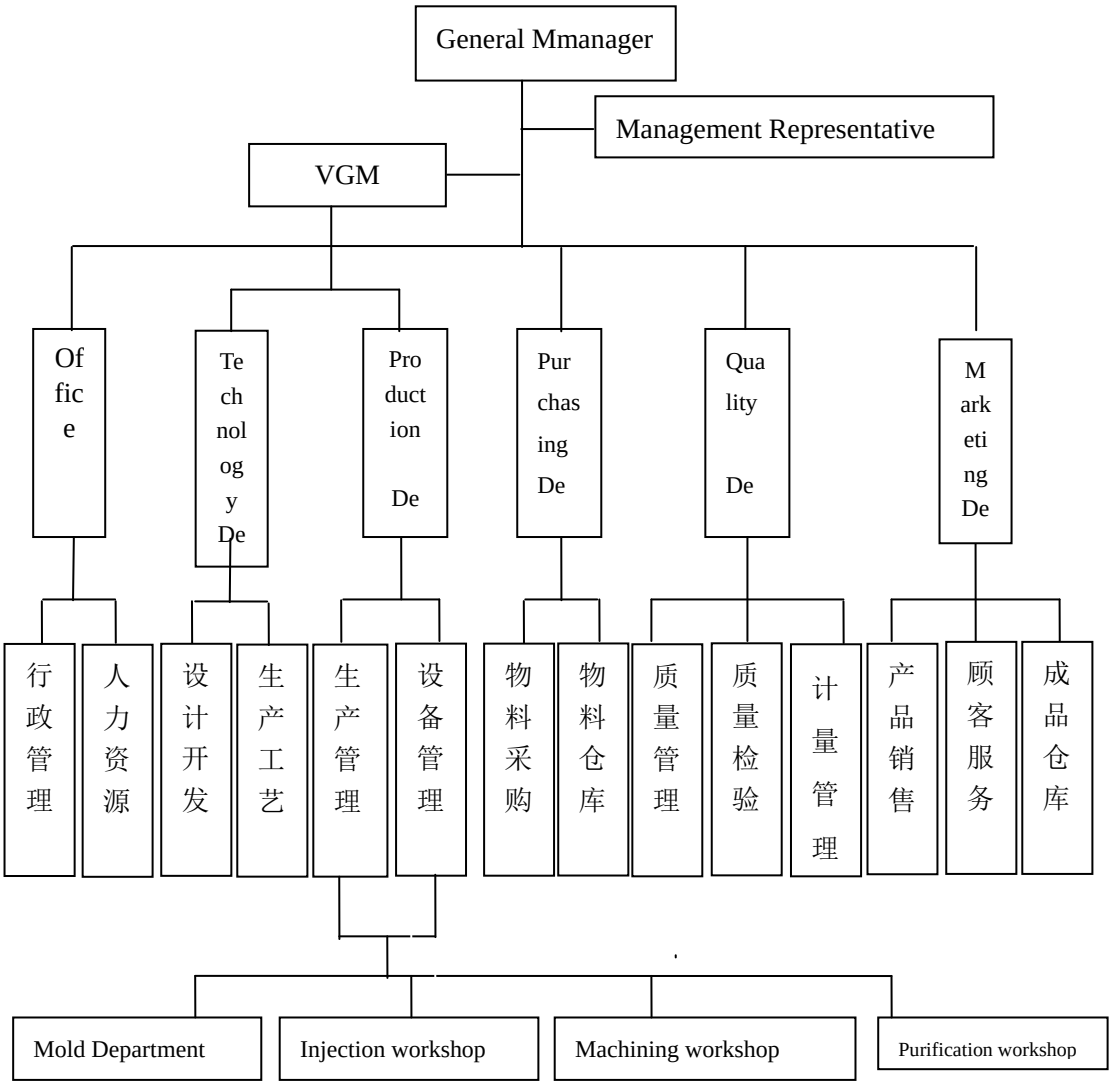
The company currently has a modern standard factory building of 8000 square meters, including a 100000 level purification workshop of 2000 square meters, 150 sets of various precision machining and testing equipment, and 80 employees, of which 30% are professional and technical personnel at or above the college level. It has strong research and development capabilities and complete testing methods.

The company researches, develops, produces, and sells 01-10 other surgical equipment, 02-12 surgical instruments - puncture guides, 02-13 surgical instruments - anastomosis instruments and materials, 02-15 surgical instruments - other instruments, 14-13 surgical room infection control supplies, 14-14 medical staff protective equipment, 18-01 obstetrics and gynecology surgical instruments and their supporting products, with the concept of "meeting customer needs, continuously developing new products, and continuously improving quality".

Our company is committed to the development of new medical device products, targeting domestic and international markets, implementing a development strategy of consolidating the first generation, researching and developing the first generation, and designing and conceptualizing the first generation. We have gradually cultivated a technical and employee team that can adapt to the development of the enterprise, and promoted modern management such as informatization and automation, making due contributions to the development of China's medical device industry. Our company's product catalog can be found in Attachment 4.

Company：**Changzhou Haida Medical Equipment Co.,Ltd**
Add:Sanhekou Industrial Park
Changzhou, Jiangsu ,P.R.China 213000
Tel:0086-519-83992059
E-mail: info@medicalstapler.com
Website: www.medicalstapler.com

0.5 Quality Management System Structure Chart



Note: The finance department is not covered within the scope of the quality system。

0.6 Quality Manual Management

Quality Manual Management

0.6.1 Preparation, Approval, and Release of Quality Manual

The purpose of this manual is to clarify the company's quality policy, quality objectives, requirements and procedures for determining quality activities, and to establish and implement an effective quality system.

0.6.1.2 This manual applies to the implementation process, management process, and supporting process of all products produced by our company.

The preparation, approval, distribution, modification, and retrieval of this manual shall be carried out in accordance with the Document Control Procedure.

0.6.1.4 This manual is a controlled document organized by the Quality Department, reviewed by the management representative, and approved by the General Manager before being issued and implemented.

0.6.1.5 The Quality Department is responsible for preparing a list of the distribution scope and quantity of controlled versions of manuals used within the company, and labeling them with numbers.

0.6.1.6 The holder of the quality manual should keep it properly. If it is lost, it should be registered with the quality department in a timely manner. When the holder is transferred from their position or leaves the company, they should handle the return procedures.

0.6.2 Distribution of Quality Manual

0.6.2.1 The quality manual is registered and distributed by the quality department, and the internal distribution scope includes company leaders, management representatives, and various departments. The manual distributed internally is a controlled version, stamped with the "controlled" seal. Issued to certification bodies as a controlled version, stamped with the "controlled" seal; The uncontrolled version sent to consulting agencies, customers, and higher-level supervisory departments shall be stamped with the "uncontrolled" seal.

0.6.2.2 The holder of the controlled version of the quality manual shall keep it properly and shall not lose, lend, change or copy it without authorization. When transferred from work or leaving the company, the quality manual shall be returned to the quality department for verification, registration and return procedures.

0.6.3 Changes and Versions of Quality Manual

0.6.3.1 The quality manual is bound in loose leaf format. The quality manual is revised by the quality department. When the controlled version of the manual is changed, it can be changed by marking or replacing the obsolete page with a change page. All changes are implemented by the quality department in a centralized and unified manner, and the quality department fills out the quality manual change record.

0.6.3.2 When the quality manual undergoes significant or multiple changes, or when the company's quality management system undergoes significant adjustments, the quality department shall submit a version change application, which shall be reviewed by the management representative and approved by the general manager before implementation. The updated version of the quality manual shall still comply with the relevant provisions of 0.6.1.

1 Range

1.1 General Provision

Our company complies with GB/T 19001-2016 "Quality Management System Requirements", GB/T 42061-2022/ISO 13485:2016, EN ISO 13485:2016+AC: 2018+A1:2021 "Requirements for the Use of Medical Device Quality Management Systems in Regulatory Applications", EU Medical Device Directive MDD 93/42/EEC+2007/47/EC Appendix II (excluding II.4), EU Medical Device Regulation EU 2017/745 (MDR) Article 120 (3), EU 2017/745 (MDR) Article 10 (9), as well as "Medical Device Production Quality Management Specification", "Medical Device Production Quality Management Specification Appendix Aseptic Medical Devices" and "Medical Device Production Quality Management Specification Appendix Implantable Medical Devices". The requirement is to prepare a quality manual and establish a quality management system.

Our company has established and effectively operates a quality management system to demonstrate our ability to provide products that meet customer requirements and applicable legal and regulatory requirements in a long-term and stable manner; And through the effective application of the system, including the effective application of the continuous improvement process of the system, as well as ensuring compliance with customer requirements and applicable legal and regulatory requirements, the aim is to enhance customer satisfaction.

The quality management system described in this manual covers all products of our company. This quality manual is applicable to the quality management and control of the entire process of design, production, sales, and service of the above-mentioned products of our company, as well as to quality assurance for customers and society, and third-party audits.

1.2 Application

Our company's products comply with the requirements of ISO13485:2016, EN ISO 13485:2016+AC: 2018+A1:2021 standards, "Quality Management Specification for Medical Device Production", "Appendix to Quality Management Specification for Medical Device Production Aseptic Medical Devices", and "Appendix to Quality Management Specification for Medical Device Production Implantable Medical Devices". The clauses that are not

applicable are:

(1) 7.5.3 Installation activities: Our company is not involved in installation activities;

(2) 7.5.4 Service Activities: Our company is not involved in service activities

2 Normative References

2.1 GB/T 19001-2016 idt ISO 9001:2015 "Quality Management System Requirements"
2.2 GB/T 42061-2022 idt ISO 13485:2016, EN ISO 13485:2016+AC: 2018+A1:2021 Medical Device Quality Management System for Regulatory Requirements
2.3 EU Medical Device Directive 93/42/EEC+2007/47/EC Appendix II (excluding II.4)
2.4 "Quality Management Specification for Medical Device Production", "Appendix to Quality Management Specification for Medical Device Production Aseptic Medical Devices", and "Appendix to Quality Management Specification for Medical Device Production Implantable Medical Devices"
2.5 EU Medical Device Regulations EU 2017/745 (MDR) Article 120 (3), EU 2017/745 (MDR) Article 10 (9)

3 Terms and Definitions

3.1 This manual references terms and definitions from the following standards or regulations

3.1.1 GB/T 19001-2016 idt ISO9001:2015《Fundamentals and Terminology of Quality Management System》

3.1.2 GB/T 42061-2022 idt ISO 13485：2016、EN ISO 13485:2016+AC:2018+A11:2021《Medical Device Quality Management System for Regulatory Requirements》

3.1.3 《Specification for Quality Management of Medical Device Production》、《Appendix of Quality Management Specification for Medical Device Production - Aseptic Medical Devices》And《Appendix to the Quality Management Standards for Medical Device Production: Implanted Medical Devices》

3.1.4 EU Medical Device Directive 93/42/EEC +2007/47/EC Annex Ⅱ（Not Included Ⅱ.4）

3.1.5 EU Medical Device Regulations EU 2017/745(MDR) Article 120(3) 、EU 2017/745(MDR) Article 10(9)

3.2 The Commonly Used Terms and Definitions are as follows：

3.2.1 Medical devices: instruments, equipment, tools, machinery, appliances, implants, reagents for in vitro use, software, materials, or other similar or related items used for humans. Its intended use is determined by the manufacturer, whether used alone or in combination, to achieve one or more of the following specific medical purposes:

——Diagnosis, prevention, monitoring, treatment, or alleviation of diseases;

——Diagnosis, monitoring, treatment, alleviation or compensation of injuries;

—— The examination, substitution, regulation, or support of physiological structures or processes;

——Support or maintenance of life;

——Pregnancy control;

——Disinfection of medical devices;

——Provide information through in vitro examination of samples taken from the human body;

And its main expected utility in or on the human body is not achieved through pharmacological, immunological, or metabolic means, but these methods can assist in the

expected function.

3.2.2Medical Device Family

A group of medical devices with the same basic design and performance characteristics related to safety, intended use, and function, manufactured by or for the same organization.

3.2.3 Implantable medical device: a medical device that can only be removed through medical or surgical procedures and is expected to:

——Fully or partially introduced into the human body or natural cavity; or

——Replace the epithelial surface or ocular surface;

——And keep it for at least 30 days;

3.2.4 Advisory Notice

A notice issued by an organization after the delivery of medical devices, aimed at providing supplementary information or suggesting measures to be taken in the following areas:

——Medical device usage; Medical device modifications; Medical devices returned to the organization; Or the destruction of medical equipment.

3.2.5 Authorized Representative

A natural or legal person established within a country or jurisdiction, who accepts written authorization from the manufacturer to perform specific tasks related to the obligations stipulated by the laws of that country or jurisdiction on behalf of the manufacturer.

3.2.6 Clinical Evaluation

Evaluate and analyze clinical data related to medical devices to verify their clinical safety and performance when used as expected by the manufacturer.

3.2.7 Complaint

Written, electronic, or verbal communication regarding defects related to identification, quality, durability, reliability, availability, safety, or performance of medical devices that have been released from the company's control, or claims that there are deficiencies in services that affect the performance of such medical devices.

3.2.8 Distributor: A natural or legal person in the supply chain who represents themselves in facilitating end-users to obtain medical devices.

3.2.9 Importer: The first natural or legal person in the supply chain to make medical devices manufactured in other countries or jurisdictions available for sale in the country or jurisdiction where they are to be marketed.

3.2.10 Marking: Labels, usage instructions, and any other information related to the

identification, technical specifications, intended use, and proper use of medical devices, but not including shipping documents.

3.2.11 Lifecycle: All stages in the life of a medical device, from initial concept to final discontinuation and disposal.

3.2.12 Manufacturer

A natural or legal person who manufactures expected medical devices in their name and is responsible for the design and/or manufacture of medical devices, regardless of whether the design and/or manufacture of such medical devices is carried out by the natural or legal person or by someone else on their behalf.

3.2.13 Performance evaluation: Evaluating and analyzing data to establish or validate the ability of in vitro diagnostic medical devices to achieve their intended use.

3.2.14 Post listing supervision: a systematic process of collecting and analyzing the experience gained from medical devices that have already been listed.

3.2.15 Product: The result of the process.

3.2.16 Purchased products: products provided by a party outside the organization's quality management system.

3.2.17 Risk: The combination of the probability of injury occurring and the severity of the injury.

3.2.18 Risk management: The systematic application of management policies, procedures, and practices to analyze, evaluate, control, and monitor risks.

3.2.19 Aseptic barrier system: The smallest packaging that prevents microorganisms from entering and enables sterile access to the product at the point of use.

3.2.20 Aseptic medical devices: Medical devices that are expected to meet aseptic requirements.

3.2.21 Post market surveillance: All activities carried out by manufacturers in cooperation with other economic operators, establishing and maintaining systematic procedures, actively collecting and reviewing experience gained from the devices they put on the market to determine any necessary corrective or preventive measures that need to be immediately applied to maintain their availability or use in the market.

3.2.22 Market Surveillance (market surveillance) : The activities and measures taken by the competent authorities to inspect and ensure that the equipment complies with the requirements of relevant EU uniform regulations, and does not endanger health, safety or any other aspect of public interest protect

4 Quality Management System

4. Quality Management System and Organizational Environment

The quality management system is (Quality Management System, QMS) It refers to the management system that directs and controls the organization in terms of quality. Organizational environment refers to the combination of internal and external factors that influence the methods of establishing and achieving goals for an organization (hereinafter referred to as the company environment).

4.0.1 Understand The Company and its Environment

The company needs to identify various external and internal factors that are relevant to its goals and strategic direction and affect its ability to achieve the expected results of the management system.

External factors: such as law, technology, competition, market, documents, social and economic environment;

Internal factors: such as company values, documents, knowledge, and performance; The company needs to monitor and review relevant internal and external information; Follow the requirements of the 'Organizational Environment and Stakeholder Requirements Control Procedure' specifically.

4.0.2 Understand the needs and expectations of stakeholders

Due to the impact or potential impact of relevant parties on the company's ability to continuously provide products and services that meet customer requirements and applicable laws and regulations, the company needs to determine:

The stakeholders related to the quality management system mainly include: customers, end-users or beneficiaries, owners/shareholders, banks, external suppliers, employees and other company workers, government agencies, financial and tax agencies, legal and regulatory authorities, local community groups, non-governmental organizations, etc;

The requirements of these stakeholders are manifested in many aspects, such as:

--Customer requirements for products, such as compliance, price, and safety;

--Contracts already reached with customers or external suppliers;

--Permits, licenses, or other forms of authorization;

--Treaties, conventions, and drafts;

--Agreement between Public Institutions and Customers;

--Obligations of the company's contractual obligations;

The company should monitor and review the relevant information of these stakeholders and their requirements; Implement in accordance with the requirements of the 'Organizational Environment and Stakeholder Requirements Control Procedure'

4.1 GENERAL REQUIREMENTS

4.1.1 In order to ensure that our products and/or services meet customer and legal requirements, our company considers the role of a manufacturer, identifies and specifies necessary processes, and manages these processes, including identifying customer needs and evaluating customer satisfaction

The overall process of pricing also includes specific sub processes of various quality activities, such as research and development, production preparation, procurement, production, measurement and monitoring, packaging and storage, sales, and after-sales service. In order to implement and verify the prescribed processes, our company has established a system that meets the requirements of GB/T19001-2016/ISO9001:2015 "Quality Management Systems - Requirements" and GB/T 42061-2022/ISO13485:

2016, EN ISO 13485:2016+AC: 2018+A1:2021 "Quality Management Systems for Medical Devices - Requirements for Regulatory Use", 93/42/EEC+2007/47/EC Appendix II (excluding II-4), EU Medical Device Regulations EU 2017/745 (MDR) Article 120 (3), EU 2017/745 (MDR) Article 10 (9), as well as "Good Manufacturing Practice for Medical Devices", "Good Manufacturing Practice for Medical Devices - Sterile Medical Devices", and "Good Manufacturing Practice for Implanted Medical Devices", establish, implement, and maintain a documented quality management system based on product characteristics and customer requirements. Necessary measures are also taken to ensure implementation, maintenance, and Maintain its effectiveness. For this purpose, the following requirements should be made:

4.1.2 Based on risk management methods, our company identifies the processes required to establish a quality management system, determines the sequence and interaction of processes, and prepares corresponding procedural documents;

4.1.3 Clarify the methods of process control and the sequence and interface relationships between processes; Manage processes through identification, determination, monitoring, measurement, and analysis;

The purpose of managing processes is to implement a quality management system and achieve the organization's quality policy and objectives;

4.1.3.2 Measuring, monitoring, analyzing, and taking improvement measures on the process is to achieve the planned results and maintain their effectiveness;

4.1.4 According to ISO 13485：2016、EN ISO 13485:2016+AC:2018+A11:2021 Standard requirements and applicable regulatory requirements govern these quality management system processes. When changing these processes:

a. Evaluate the impact of process changes on the quality management system;

b. Evaluate the impact of process changes on the medical devices produced within the quality management system;

c. According to ISO 13485：2016、EN ISO 13485:2016+AC:2018+A11:2021 Control the requirements of standards and applicable regulations;

4.1.5 Our outsourcing process includes instrument calibration, irradiation sterilization, ethylene oxide (EO) sterilization, and product transportation; Outsourcing processing: product components, product packaging (boxes, cartons); The control methods for the outsourcing process shall comply with the requirements of Section 7.4 Procurement Control, and where appropriate, a written agreement shall be signed with the outsourcing party. The technical department shall identify and clarify the content and methods of control for the outsourcing processes involved in the implementation of our company's products, including other processes involved。

4.1.6 The company will document the confirmation procedure for the computer software application used in the quality management system. Before the software is first used, the software application should be confirmed, and when appropriate, the software or its application should also be confirmed after changes are made. The specific methods and activities related to software confirmation and reconfirmation should be adapted to the risks associated with software use. And keep records of these activities. Follow the 'Computer Software Application Confirmation Control Program' for specific execution。

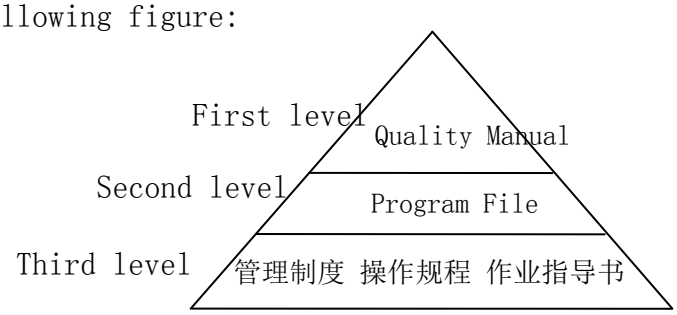
4.1.7 Relevant documents

《Computer Software Application Confirmation Control Program》

4.2 Documentation Requirement

4.2.1 General Principles

4.2.1.1 The structure of our company's quality management system documents is shown in the following figure:



a) First level document: Quality Manual, also known as this manual (including quality policy, quality objectives are written separately);

b) The second level document: program file: quality management system program file describes the quality activities involved in implementing the quality management system process in the company, which is used to clearly define the purpose, scope, responsibilities, activity procedures, related documents, records, etc. of the activities. (See Attachment 3 "List of Program Files");

c) Third level documents: management system, operating procedures, work instructions, etc.

d) GB/T 19001-2016、ISO13485：2016、EN ISO 13485:2016+AC:2018+A11:2021 The records required by the standards and specifications, as well as the "Medical Device Production Quality Management Specification", "Medical Device Production Quality Management Specification Appendix Aseptic Medical Devices", and "Medical Device Production Quality Management Specification Appendix Implantable Medical Devices", and the necessary records for the operation of our company's quality management system (see also the "Quality Record List")

e) External documents: EU and Chinese laws and regulations applicable to our company's medical device products, EU or international, national or industry standards related to our company's products, necessary reference materials;

f) Other documents related to the quality management system.

4.2.1.2 Basic requirements for document writing:

a) The quality manual is organized and compiled by the quality department; Program files and third level files should follow the principle of "whoever does, writes, executes", and be written by each department according to their respective responsibilities. The quality department is responsible for compiling the draft.

b) The document writing must be consistent with actual operation, and the quality management system documents should be revised in a timely manner with changes in the quality management system, quality policies, and quality objectives. The quality department organizes an annual review to ensure effectiveness, adequacy, and suitability. And implement the relevant provisions of the Document Control Procedure.

c) The level of detail in the document should depend on the size and product type of the company, the complexity of the process, and the abilities of the employees. It should be practical and easy to understand and apply. Quality records, as a special type of document, should be controlled in accordance with the provisions of the Record Control Procedure.

4.2.1.3 Files can be stored in any form or type of medium, such as paper, disk, CD, photos, etc., and should be managed in accordance with the 'File Control Procedure'.

4.2.2 Quality Manual

4.2.2.1The quality department should be responsible for establishing and maintaining a quality manual, which includes the following points:

a) The scope of our company's quality management system, including any deleted details and justifiable reasons;

b) The procedure for forming documents for the quality management system or referencing it;

c) The expression of the interaction between quality management system processes.

4.2.2.2 The quality manual is approved by the general manager and all employees of the company should strictly abide by and implement it.

4.2.3 Medical Device Documentation

The company establishes and maintains one or more documents for each type or family of medical devices, which include or reference documents to demonstrate compliance GB/T 42061-2022/ISO13485：2016、EN ISO 13485:2016+AC:2018+A11:2021 Standard requirements and applicable regulatory requirements.

The content of the document should include but not limited to:

a) Overview, intended use/purpose, and labeling of medical devices, including all instructions for use;

b) Product Specification

c) Specifications or procedures for manufacturing, packaging, storage, handling, and distribution;

d) Measurement and monitoring procedures

e) When appropriate, installation requirements;

f) When appropriate, maintain the program.

4.2.4 Document Control

The quality management system documents are controlled in accordance with the requirements of the "Document Control Procedure" prepared by our company, which mainly includes:

4.2.4.1 Our company's documents are divided into:

a) Management documents: quality manual, procedure documents, management system, quality record form;

b) Technical documents: technical standards, drawings, process documents,

inspection procedures, operating specifications, work instructions, etc;

c) External documents: national standards, industry standards, EU and international standards, relevant national and EU laws and regulations, technical documents provided by customers and suppliers。

4.2.4.2 Quality management system documents and materials must be reviewed and approved by relevant authorized personnel before they can become valid versions。

4.2.4.3 The department responsible for centralized management of documents is responsible for the distribution, modification, archiving, control, and management of quality management system documents。

4.2.4.4 All relevant positions within the scope of the quality management system operation must maintain and use corresponding effective versions of documents and materials.

4.2.4.5 The changes to documents should be implemented by the document management department and relevant departments according to their nature, while ensuring the effectiveness of the changes and appropriate labeling. Important changes should be accompanied by sufficient evidence and a designated person should be appointed to make the changes. They must be approved by the original approval department. If they are approved by the newly designated department for any reason, the background information required for the approval must be obtained。

4.2.4.6 After document changes, there should be records of distribution and retrieval, so that obsolete documents and materials can be promptly retrieved from all distribution or usage points, and to prevent non overdue use of obsolete documents. Document changes should indicate the modification status and version number.

4.2.4.7 If it is necessary to retain invalid documents, the words "Invalid and Retained" should be affixed to the documents, which are related to product technology and quality At least one invalid file should be saved for non documents. The general retention period for obsolete documents is three years, while the retention period for production specifications and technical documents is less than five years (the product lifespan is three years). Among them, the retention period for production specifications and technical obsolete documents with CE markings is fifteen years. The destruction of obsolete documents should be recorded and approved.

4.2.4.8 The company establishes and maintains a set of documents for each model/type of product, including product drawings (part drawings, component drawings, assembly drawings, packaging drawings, label drawings, etc.), product technical requirements, procurement details, production operation manuals, inspection specifications, and product user manuals.

4.2.4.9 There are various forms of file media, such as paper, disks, CDs, photos, samples, etc., all of which should be managed in accordance with the Document Control Procedure.

4.2.4.10 The CE technical documents for products with the CE mark are prepared and managed by the technical department, approved by the general manager, and implemented in accordance with the EC Technical Document Control Procedure.

4.2.4.11 Control of external documents: The Quality Department is responsible for collecting, identifying, registering, cataloging, and controlling the distribution of relevant laws and regulations (including domestic and EU); The technical department is responsible for collecting, identifying, registering, cataloging, and controlling the distribution of applicable standards (including national, industry, EU, and international standards).

4.2.4.12 Relevant documents

《Document Control Procedure》

《EC Technical Document Control Procedure》

《Collection and implementation control procedures for relevant laws, regulations, and standards》

4.2.5 Record Control

4.2.5.1 To provide evidence of compliance with requirements and effective operation of the quality management system, each department should keep records related to its own quality activities and regularly submit quality records to the Quality Department for centralized management.

4.2.5.2 Records should be kept clear, data should be truthful and reliable, and each record should be signed and verified by relevant personnel, with dates indicated.

4.2.5.3 The format of the record shall be proposed by the user department and uniformly identified (numbered) by the quality department after review.

4.2.5.4 Records should be stored in a suitable location. Prevent damage or loss while also facilitating access and retrieval.

4.2.5.5 The Quality Department categorizes and catalogs the saved records in chronological order by department for easy retrieval, and ensures proper storage, protection, retention, and disposal of the records. Customer inquiries can be accepted when required by the contract.

4.2.5.6 The retention period of our company's records shall not be less than the service life of the product. The retention period of our company's records related to product quality is set at five years (the validity period of the product is three years); The retention period for records related to the quality of products with CE markings is set at fifteen years; And it complies with relevant regulatory requirements and adverse event monitoring requirements, and is traceable.

4.2.5.7 To meet the requirement of traceability, our company keeps records of each batch of products, including production quantity, sales quantity, and records from suppliers, which have been recognized or verified by relevant personnel.

4.2.5.8 The destruction of records is registered and processed by the Quality Department, approved by the management representative, and carried out by two or more people.

4.2.5.9 Relevant Documents

《Record Control Procedure》

5 Management Responsibilities

5.1 Management Commitment

The head of the company (general manager) is the main person responsible for the quality of medical device products and bears the responsibility for the effectiveness of the quality management system. The general manager provides evidence of their commitment to establishing and implementing a quality management system and maintaining its effectiveness through the following activities:

a) Communicate the importance of meeting customer and applicable legal and regulatory requirements to company employees, create an atmosphere, promote, guide, and support employees' efforts to improve the effectiveness of quality management; Ensure that the company organizes production in accordance with the requirements of laws, regulations, and rules;

b) Organize the development of a quality policy that is consistent with the company's environment, internal and external affairs, strategic direction, and supports the overall business process. Provide a clear vision for the company by highlighting the quality concerns of all employees;

c) Ensure the formulation and implementation of quality objectives, and decompose them into various departments, consistent with the company's environment and strategic direction, and provide goals for all employees to strive for;

d) Organize and implement management reviews at designated times or in case of special circumstances, and inspect the required work; Ensure effective communication and promotion of improvement information and suggestions raised by internal audits, third-party audits, management reviews, etc. within the company;

e) Ensure the provision of suitable resources such as human resources, infrastructure, and work environment necessary for the establishment, effective operation, and continuous improvement of the quality management system;

f) Ensure that the medical device quality management system integrates regulatory requirements into the company's business processes;

g) Promote the use of process methods and risk-based thinking; Ensure constructive cooperation between departments, embody a systematic approach, with the aim of achieving effective interfaces between processes and the effectiveness of converting inputs into outputs, collaborate on risk assessment and risk management, and ensure the expected

results of quality management are achieved;

h) Support other management roles to fulfill their responsibilities in relevant fields, ensuring seamless integration of system processes and other functional process interfaces within the company; Provide support and guidance to other management functions in understanding and handling customer mandatory requirements and customer feedback.

5.2 Customer focus

The general manager should ensure that customer requirements are identified and met, with the goal of:

5.2.1 Determine customer needs

Implement process control procedures related to customers through market research, analysis, and forecasting, or direct contact with customers. These requirements include product requirements, process requirements, and quality management system requirements.

5.2.2 Ensure that certain requirements are met

a、Our company promises to meet the requirements of laws, regulations, and mandatory industry standards;

b、The requirements of customers, laws and regulations, and mandatory industry standards will also be revised over time. Therefore, the requirements for our company's transformation and the established quality management system should be updated accordingly, while also considering applicable legal and regulatory requirements (including domestic and EU laws and regulations)。Specific execution《Management Review Control Procedure》And《Document Control Procedure》the regulations

5.3 POLICY

5.3.1 The quality policy is the overall intention and direction regarding quality issued by the top management of an organization. Our company is based on the principles of quality management, with customers as the focus, ensuring compliance with laws and regulations as the premise, and combining with the actual situation of our company, we have formulated a quality policy (Refer to this manual 0.2《Approval Order for Quality Policy》) 。

5.3.2 Our company's quality policy indicates all our intentions and directions in terms of quality, and is in line with our company's purpose, including a commitment to meeting requirements and continuously improving the effectiveness of our quality management system, and providing a framework for developing and reviewing quality objectives。

5.3.3 The quality policy has been approved by the general manager and officially released. Managers at all levels ensure that the quality policy is communicated and understood within the company through document releases, meetings, training, inspections, and assessments, and resolutely implemented。

5.3.4 During the annual management review, the continuous suitability of the quality policy is evaluated and revised as necessary to adapt to changes in the company's internal and external environment (See《Management Review Control Procedure》) 。

5.3.5 When there are changes in customer requirements, social environment such as laws and regulations, and significant changes in the company, the general manager should seize the opportunity to review the suitability of the quality policy。

5.3.6 The quality policy is a controlled document, and its formulation, approval, release, review, and revision are in accordance with《Document Control Procedure》execute。

5.3.7 Relevant documents

《Management Review Control Procedure》

5.4 Plan and Organize

5.4.1 Quality Objectives

a) Quality objectives are the goals pursued by our company in terms of quality. The general manager should organize the management to formulate quality objectives for each year based on the company's quality policy and overall business objectives, and ensure that quality objectives are established at the relevant functions and levels of the company. Quality objectives must:

b) Quality objectives should be documented;

c) Quality objectives must include the necessary content to meet product

requirements;

d) Quality objectives should be measurable and assessable

e) Quality objectives should be consistent with the quality policy;

f) Quality objectives should be translated into achievable methods or procedures。

5.4.2 Quality Management System Planning

To ensure the achievement of quality objectives and the compliance of the quality management system with the overall requirements of 4.1 in this manual, the General Manager organizes relevant departments to plan the quality management system, including determining the input, output, and activity requirements, as well as resource allocation requirements for each quality management system process, and making corresponding regulations. The subsequent clauses of this chapter, along with chapters 6, 7, and 8 of this manual and corresponding procedural documents, describe the results of quality management system planning. For the planning of product realization processes for specific products, projects, or contracts, please refer to section 7.1 of this manual and the corresponding technical documents.

Plan the quality management system, taking into account internal and external factors that affect the company's goals, strategic direction, and management system performance, as well as relevant company requirements, to determine the risks and opportunities that need to be addressed

a) Ensure that the quality management system can achieve its expected results;

b) Enhance favorable impact;

c) Avoiding and reducing adverse effects;

d) Realize improvement

Whenever the following situations occur, the general manager shall analyze the necessity of changes to the quality management system and, if necessary, convene a temporary management review meeting to ultimately confirm the necessity of changes to the quality management system:

a) When improving the quality management system;

b) When there are significant changes in the company's quality policy, quality objectives, organizational structure, market environment, laws and regulations;

c) When there are special requirements for products, projects, and contracts, and our company's existing quality system documents cannot cover and meet the requirements.

The general manager should maintain the integrity of the quality management system when planning and implementing changes to the quality management system. When there are changes in the quality management system and CE marked products, the management representative shall be responsible for promptly informing the notified body and the EU authorized representative in accordance with the "Major Change Control Determination and Notification Procedure".

Based on the results of risk analysis, the company plans measures for these risks and opportunities, including risk avoidance, taking on risks to seek opportunities, eliminating risk sources, changing the likelihood and consequences of risks, sharing risks or delaying risks through wise decisions, implementing new practices, launching new products, opening up new markets, winning new customers, establishing partnerships, utilizing new technologies and other opportunities that can meet the needs of the organization or its customers, clarifying how to integrate and implement these measures in the quality management system process, evaluating the effectiveness of these measures, and adapting measures for risks and opportunities to their potential impact on product and service compliance. Follow the requirements of the 'Risk and Opportunity Response Control Procedure' specifically.

5.4.3 Relevant Documents

《Major Change Control Judgment and Notification Procedure》

《Risk and opportunity response and control procedures》

5.5 Responsibilities, Authorities, and Communication

5.5.1 Responsibility and authority

Our company has established an organizational structure in accordance with the requirements of the quality management system. Please refer to Chapter 0.5 of this manual for the company's organizational chart. The company has made clear regulations on the responsibilities and authorities related to the quality management system, achieving clear division of labor, clear responsibilities, and clear authorities, and ensuring that the division of labor is scientific and reasonable, and the responsibilities and authorities are in line, as shown in Annex 2 "Quality Management System Function Allocation Table". The general manager is responsible for formulating and approving the responsibilities and authorities of the positions set up by each department. The responsibilities and authorities of each position within the department are formulated by each department, reviewed by the office, and approved by the general manager. See 《Responsibilities and Authorities of Each Position 》。

《Responsibilities and Authorities of Each Position》 For controlled documents, the office must ensure that personnel at all positions have access to the above-mentioned documents, and departments and positions should understand their responsibilities and authorities through various means.

The responsibilities and authorities of company leaders and departments are as follows:

A. general manager

a) Organize the implementation of relevant laws and regulations, including those related to the supervision and management of medical devices in the European Union and China;

b) Approve the company's quality policy, quality objectives, and quality manual;

c) Responsible for establishing and improving the company's organizational structure, clarifying the responsibilities and authorities of each department and position;

d) Organize and plan the product implementation process to ensure that customer requirements are met

e) Ensure the human resources, infrastructure, and working environment required for the effective operation of the quality management system;

f) Appoint management representatives and grant them authority in accordance with the requirements of the quality management system standards;

g) Regularly preside over management reviews to determine the implementation and improvement measures related to quality policies and objectives

h) Responsible for fulfilling quality commitments to customers and handling major customer complaints and adverse events;

B vice general manager

Under the direct leadership of the General Manager, in charge of the production and technical departments of the company.

a) Assist the General Manager in formulating the company's quality policy and objectives, and assist the General Manager in coordinating and implementing the quality responsibilities of the responsible functional departments;

b)Responsible for organizing the production of medical device products in our company, ensuring that the production process control meets regulatory requirements。

c) Assist the General Manager in handling major quality accidents and issues;

d) Responsible for approving product standards, production process documents, operating procedures, and work instructions;

e) Organize and lead the maintenance, updating, and supplementation of equipment and fixtures to ensure safe production and environmental compliance with product quality requirements.

B. Management representativea) Entrusted by the general manager, be fully responsible for the establishment, implementation and normal operation of the quality system;

b) Report the operation of the quality management system to the general manager;

c) Timely coordinate and handle relevant issues affecting the normal operation of the quality system;

d) Be responsible for contacting with EU authorities, EU authorized representatives, relevant national competent departments, etc. on matters related to the quality management system;

e) Be responsible for reviewing or approving relevant documents, urging all functional departments and staff at relevant posts to conscientiously implement the provisions of various documents, and regularly inspect the implementation, and the inspection results shall be reported to the general manager;

f) Assist the general manager in organizing the implementation and verification of management review and improvement matters;

g) Be responsible for leading and organizing the internal audit of the quality system, and report the internal audit to the general manager。

h) Be responsible for the communication of the quality management system within the company, ensure that all staff understand the importance of the management of the quality management system, actively participate in the cooperation, promote employees to improve their quality, improve the effectiveness of the quality management system and management performance through assessment, training, etc.

C. office

a) Responsible for the company's human resource management;

b) Be responsible for the training of personnel at each post to ensure that the personnel at each post meet the requirements of employment;

c) Be responsible for the recruitment, employment, assessment, labor contract management and various social security procedures;

d) Responsible for the company's administrative affairs management, fire safety and property management;

D. Technology Department

Be responsible for the research and development of the company's new products and the design conversion activities; .

a) Be responsible for the preparation of quality plan, product design documents, procurement documents, process documents and production process technical support;

b) Be responsible for the determination of special processes in the production process, and organize the confirmation and reconfirmation of special processes;

c) Responsible for the preparation and management of CE technical documents of products with CE mark;

Responsible for the collection of applicable product standards (including Chinese and EU regulations, standards and international standards) and the management and control of technical documents provided by customers and suppliers.

E. Purchasing Department

a) Be responsible for the selection and evaluation of qualified suppliers, establish a list of qualified suppliers, and implement dynamic management of suppliers;

b) Be responsible for the formulation of procurement plan, and implement material procurement in strict accordance with procurement technical standards;

c) With the cooperation of the quality department, do a good job in the quality control of outsourced manufacturers to ensure the quality of outsourced products;

d) Cooperate with the quality department to conduct incoming inspection, and be responsible for returning or replacing the unqualified products;

e) Be responsible for the management of raw and auxiliary material warehouse。

F. Production Department

a) Be responsible for the preparation and implementation of production plans and ensure that production tasks are completed on time and according to quality;

b) Cooperate with the office to do a good job in the training of employees in various positions, especially the training of personnel in key processes and special processes;

c) Check and urge all workshops and production processes to operate in strict accordance with drawings, process cards and operation instructions, and make relevant records;

d) Be responsible for the acceptance, verification and software confirmation of production equipment and tooling fixtures, and organize the maintenance of production equipment and tooling fixtures;

e) Responsible for personnel and environmental management of purification production workshop;

f) Assist the technology department in the confirmation and reconfirmation of special processes, and do a good job in process quality control;

g) Responsible for quality information feedback in the production process;

h) Be responsible for the quality statistics of the production process。

G. Quality department

a) Carry out incoming inspection or verification, process inspection and final product inspection as required, and fill in inspection records and reports;

b) Be responsible for the review and disposal of nonconforming products, and have the right to approve or deny the use of all materials and intermediate products and the factory release of final products;

c) Assist the procurement department in evaluating the supplier and cooperate with the procurement department in quality control of outsourcing manufacturers;

d) Assist the marketing department to deal with customer complaints in a timely manner and continuously enhance customer satisfaction;

e) Responsible for the management of inspection and test instruments and measuring instruments;

f) Be responsible for the environmental inspection and water preparation inspection of the purification workshop, and supervise the control of the production environment of the workshop;

g) Responsible for centralized management of quality management system documents and quality records;

h) Be responsible for assisting the management representative in internal audit, and assisting the general manager in management review and tracking and verification of corrective / preventive / improvement measures;

i) Responsible for the implementation and management of the company's data analysis activities;

H. Marketing Department

a) Be responsible for product sales, continuously explore the market and expand market share;

b) Carry out market research, collect market technical information and market demand changes, and feed back to company leaders in time;

c) Responsible for communicating with customers, determining product related requirements, and organizing contract review;

d) Be responsible for conducting quality visits to customers, timely collecting users' opinions or suggestions on product quality, and timely feeding back to the quality department,In order to continuously improve product quality;

e) Do a good job in after-sales service and deal with customer complaints or complaints in time;

f) Responsible for the selection and management of dealers

I. Head of compliance (Person responsible for regulatory compliance)

a) According to the quality management system of the manufacturing device, the regulatory compliance of the device shall be properly checked before the release of the device。

b) Participate in the review of technical documents and EU declaration of conformity and keep them up-to-date。

c) Tracking the operation of the post listing regulatory system。

d) Responsible for analyzing serious events, including risk assessment of events and on-site safety corrective measures。

e) Responsible for regular summary reports, post marketing regulatory reports, PSUR and trend reports。

f) Sign clinical investigation statement。

g) Responsible for the docking and management of UDI database。

5.5.2 Management Representative

The general manager appoints a person as the management representative in the management. In addition to performing the duties of this position, he should also have the duties and authorities of the management representative (See page 8 of this manual for details《Letter of appointment of management representative》And 5.5.1.B) 。

5.5.3 Internal communication

The general manager shall ensure that an appropriate communication process is established within the company to ensure the communication of information on the effectiveness of the quality management system。

5.5.3.1 Our Company《Quality management system function allocation Table》The functional departments of each process and the relationship between them are clarified,(See Appendix 2《Quality management system function allocation Table》), That is to say, it clarifies the process to be communicated and the relationship between them.

5.5.3.2 Principle of communication: timely, fast and effective。

5.5.3.2 Communication methods: a) meeting; b) Talk and discussion; c) Documents and statements; d) Wall newspaper; e) E-mail, etc.

5.5.3.3 Ways of communication: the procedure documents related to each process specify the methods and ways of communication between relevant departments, such as:

a) Communication between the leadership and all departments: planning meeting, summary meeting, management review meeting, summary and report materials, system Accounting statement, etc (《Management review control procedure》、《Process and product monitoring and measurement control procedures》);

b) The office communicates with various departments on human resources: training application form, training plan, training effectiveness evaluation, post ability evaluation, etc (Human Resources Management Procedure));

c) The procurement department communicates with the technology department, production department and quality department on procurement activities: procurement details and technical quality Requirements ", warehouse inventory report, purchase application form, purchase plan, purchase inspection request form, purchase inspection report, warehousing form, supplier questionnaire, supplier evaluation form, supplier performance record form, etc (《Procurement control procedure》);

d) Communication among production department, technology department and quality department on product design and development and production process technology and quality: design and development review (design and development control procedure); Production planning meeting, production scheduling meeting (process and product monitoring and measurement control procedure)); Special process confirmation activities (confirmation team, confirmation scheme, confirmation record, confirmation report), operation instructions for each process, operation procedures, process discipline checklist, monthly production plan, production task list, production flow card, inspection specification, process inspection record, finished product inspection record, nonconforming product review sheet, production statistics, data analysis chart, etc(《Production process control procedure》《Nonconforming product control procedure》;

e) Communication between marketing department, quality department, production department and Technology Department on market information and customer information feedback:《Design and development proposal》、Contract review form, customer information feedback handling form, customer complaint / complaint handling record, customer

satisfaction questionnaire, etc(《Customer related process control procedures》《Customer information feedback processing procedure》 《Adverse event handling and reporting control procedure》)

f) The management representative communicates with each department on each process of the quality management system: internal audit activities, quality objective inspection and assessment records, corrective / preventive measures processing records (《Internal audit control procedure》 《Process and product monitoring and measurement control procedures》 etc) 。

5.6 Management Review

Prepared and implemented by the company《Management review control procedure》, And regularly organize management review to ensure the suitability, sufficiency and effectiveness of the quality management system.

5.6.1 The management review is generally held once a year and presided over by the general manager in person. The effectiveness, sufficiency and suitability of the quality management system should be evaluated according to the formulated quality policy and objectives. The review includes the evaluation of the opportunities for improvement of the quality management system and the need for change. The frequency of management review can be increased in case of one of the following circumstances:

a) When there are major changes in the organization, product scope and resource allocation;

b) When major quality accidents occur or serious complaints about quality occur continuously;

c) When laws, regulations, standards and other requirements change;

d) When the market demand changes significantly;

e) When the second or third party audit or the audit stipulated by laws and regulations is about to be conducted;

f) When serious nonconformities are found during quality audit。

5.6.2 Input for management review

The input for management review should include the following information:

a) The situation of measures taken in previous management reviews;

b) Changes in external and internal factors;

c) Information on the performance and effectiveness of the quality management system:

1) Customer satisfaction and feedback and complaint handling from other relevant parties; Stakeholder evaluation

2) The degree of achievement of quality objectives;

3) Process performance and the qualification of products and services;

4) Non conformance and corrective measures;

5) Monitoring and measurement results;

6) Audit results; When appropriate, including internal audit results, customer, regulatory or certification agency audit results;

7) Performance of external suppliers;

d) Adequacy of resources;

e) The effectiveness of measures taken to address risks and opportunities;

f) Opportunities for Improvement;

g) Report to regulatory agencies

h) Changes that may affect the quality management system;

i) Applicable new or revised regulatory requirements

5.6.3 Output of management review

The output of management review includes:

a) Improvement of the effectiveness of the quality management system and its process effectiveness;

b) Improvement of products related to customer requirements;

Resource demand

5.6.4 The implementation and results of the management review shall be documented by the management representative, approved by the general manager before distribution, and stored in accordance with the requirements of the Record Control Procedure.

5.6.5 The effectiveness of the improvement measures implemented in the management review shall be tracked and verified by the quality department or management representative

organization. The records formed by the management review shall be kept by the Quality Department.

5.6.6 Relevant documents

《Management Review Control Procedure》

6 Resource Management

6.1 Provision of Resources

To implement the quality policy and achieve quality objectives, the company optimizes resource allocation to ensure that various resources can meet the needs of design, production, sales, and service. Our company controls the personnel, production site, production equipment, monitoring and measuring equipment, inspection site, product sample room, storage site and other infrastructure and working environment required for each process in the quality management system based on relevant procedural documents. The production environment should comply with the requirements of relevant laws and technical standards. To ensure the implementation and maintenance of the quality management system, and to continuously improve its effectiveness in order to meet customer requirements and legal regulations.

6.1.1 Our company's resource requirements come from the following three aspects:

a) Implement, maintain and continuously improve the effectiveness of the quality management system;

b) Meet regulatory requirements;

c) By meeting customer requirements, enhance customer satisfaction。

6.1.2 The determination of resource requirements can be described from the following three aspects:

a) In the planning of the quality management system, including the planning of changes to the quality management system (see section 5.4.2 of this manual), the resource requirements for establishing, implementing, and maintaining the quality management system and continuously improving its effectiveness are clearly defined. The resource requirements for changes to the quality management system are mainly determined through management reviews, including temporary management reviews. Sections 6.2, 6.3, and 6.4 respectively describe the management of three major types of resources: human resources, infrastructure, and work environment;

b) Specific resource requirements for specific products, projects, or contracts should be clearly defined in the product implementation planning process (see section 7.1 of this manual);

c) Due to changes in regulations and customer requirements, corresponding changes in resource demands may occur. In order to ensure compliance with regulatory and customer requirements and enhance customer satisfaction, relevant departments need to pay attention to changes in resource demands in this area. The determination of such changes is mainly achieved through management reviews or product planning.

6.1.3 Organization Knowledge

Each department shall organize the determination of necessary knowledge to operate the process and obtain qualified products and services. These knowledge come from:

6.1.3.1 Internal (such as technology, professional knowledge and experience of internal personnel, experience and lessons learned from failures and successes, improvement results of processes, product sales and services, etc.) and external (such as relevant regulations, standards, policies, knowledge obtained from customers, partners, industry literature, professional conferences, etc.)

These knowledge should be maintained and accessible within the required scope.

To cope with constantly changing demands and development trends, companies should examine their existing knowledge and determine how to acquire or access more necessary knowledge and knowledge updates.

6.1.3.2 Each department is responsible for acquiring, sharing, and applying knowledge within their functional scope (such as updating workflow and work standards, organizing training and learning, communication, etc.), and continuously accumulating and updating it. Specifically, manage and control according to the 'Knowledge Management Control Procedure'.

6.1.4 Relevant Documents

《Knowledge Management Control Program》

6.2 Human Resources

Our company manages human resources according to the following requirements to meet the requirements of the quality management system for human resources.

6.2.1 The office is responsible for organizing relevant departments to identify and determine the positions that affect the compliance of the company's medical device products and requirements, specifying the necessary abilities for these positions, and preparing job requirements for each position, including education, training, skills, experience, and other requirements.

The production, technology, and quality management personnel of implantable animal derived medical devices should have corresponding professional knowledge in biology, biochemistry, microbiology, medicine, immunology, and have corresponding practical experience to ensure the ability to fulfill their responsibilities in production and quality management.

6.2.2 Provide training or take other measures to acquire the required skills for personnel who do not meet the competency requirements.

6.2.3 The office is responsible for preparing an annual training plan in accordance with the requirements of the "Human Resources Management Procedure" and implementing training according to the plan. Through training, every employee is made aware of the relevance and importance of their work to product quality, and their awareness of contributing to the achievement of the company's quality policy and quality objectives is enhanced, to ensure that personnel in various positions related to product quality are competent in their work.

6.2.4 The ability requirements of personnel engaged in activities that affect quality should be identified, and training needs should be developed and implemented for new employees, current employees, transferred employees, various professionals, special workers, internal auditors, etc. based on their job ability requirements. Only those who pass the written or operational assessment can be employed.

6.2.5 Personnel engaged in aseptic and implantable medical device production operations and quality inspection should receive targeted training on relevant laws and regulations, basic theoretical knowledge, professional operating skills, process quality control skills, quality inspection skills, as well as basic knowledge of hygiene and microbiology

and clean technology;

6.2.6 Internal auditors, inspectors, metrologists, water production and key process operators should receive appropriate training.

6.2.7 The office evaluates the effectiveness of training and measures taken through theoretical assessments, operational assessments, performance evaluations, and other methods, and evaluates and re evaluates the abilities of personnel in various positions.

6.2.8 The office establishes a personal training history for each employee。

6.2.9 Keep training records in the office。

6.2.10 Relevant Documents

《Human Resources Management Procedure》

6.3 Infrastructure

Infrastructure is the material guarantee that ensures product compliance. Our company's infrastructure includes buildings, production, inspection, warehousing sites, production and inspection equipment (including hardware and software), fixtures, and related facilities (such as water and electricity supply facilities), as well as supporting services (such as transportation, communication, or information systems). Our company manages infrastructure in the following ways:

6.3.1 The technical department, in conjunction with relevant departments, will determine the equipment, workplaces, fixtures, software

Communication facilities, supporting services, transportation facilities, etc.

6.3.2 The provision of facilities shall be requested by the department in need and approved by the general manager before procurement.

6.3.3 The production department conducts acceptance and confirmation of the equipment, and only when it meets the requirements can it be put into use。

6.3.4 The production workshop cooperates with the production department to maintain and upkeep the facilities to prevent their failure。

6.3.5 The maintenance of equipment is the responsibility of production department maintenance personnel, including planned maintenance and fault maintenance。

6.3.6 The equipment administrator of the production department regularly measures the accuracy and integrity of the equipment to ensure that it can meet the processing and production requirements。

6.3.7 Equipment and facilities that cannot be repaired shall be scrapped with the approval of the general manager。

6.3.8 Relevant Documents

《Infrastructure Control Program》

6.4 Working environment and pollution control

The working environment refers to the conditions in which work is carried out, including physical, environmental, and other factors such as noise, temperature, humidity, lighting, or weather. Pollution is the control of microbial or particulate contamination to maintain the cleanliness of the assembly and packaging process. Our company determines and manages the working environment and pollution control required to achieve product compliance from the following aspects.

6.4.1 The technical department is responsible for determining the environmental conditions required to achieve product requirements (such as temperature, humidity, cleanliness, environmental hygiene, etc.) and specifying them in relevant process documents.

6.4.2 Our company provides corresponding facilities for the 100000 level purification production workshop required for the production of sterile and implantable medical devices, meeting the production environment, regulatory requirements, and technical standards.

6.4.3 The production department and the purification production workshop are responsible for managing the purification workshop in accordance with the requirements of the process documents and the environmental management system of the purification workshop, including personnel health and hygiene, cleaning and clothing, equipment and workstation cleaning, and environmental hygiene inside and outside the purification workshop; The health administrator is responsible for controlling personnel who need to temporarily enter the purification workshop due to work requirements according to the purification procedures for entering the purification workshop. Ensure that the environmental control of the 100000 level clean workshop meets the specified requirements.

6.4.4 To prevent contamination of the working environment, personnel, or products, the Quality Department has documented and monitored the environmental requirements for the purification workshop in accordance with GB/T16294 and GB/T16292. Simultaneously, in accordance with the requirements of GB/T19973/ISO11737-1 standard, document and monitor the initial contamination bacteria requirements for personnel, products, and initial packaging materials。

6.4.5 Our company conducts rough washing on the outsourced parts after they enter the factory, and then uses purified water that complies with the Pharmacopoeia of the People's Republic of China for fine washing in the purification workshop before entering the product assembly. Both the rough washing and fine washing processes are identified as special processes, and the process control parameters are confirmed. Based on the confirmation, a cleaning operation manual is prepared to ensure that the cleanliness of the product meets the specified requirements.

6.4.6 Our company controls the products that are delivered and then returned to the company. First, they are labeled and isolated, and then contaminated products are disinfected in designated disinfection areas to prevent contaminated returned products from contaminating normal production products and personnel. The specific implementation is as follows:《Return to the product processing instruction manual》。

6.4.7 The Quality Department organizes the Technical Department and Production Department to conduct regular or irregular inspections of the environmental control in the purification workshop.

6.4.8 Relevant Documents

《Work environment control pr

7 Product Realization

7.1 Planning of Product Realization

Established by the Technical Department《Product Implementation and Quality Planning Control Procedure》, Plan the process of product implementation and its corresponding relationships, which must be consistent with the requirements of other processes in the quality management system. In the process of product implementation, a process flow document for risk management should be prepared and records should be kept.

7.1.1 Planning Content

When planning, the following should be determined:

a) Determine appropriate product quality objectives. Including identifying product quality characteristics, establishing target quality requirements and constraints, and meeting all customer and legal requirements as well as appropriate technical standards;

b) Determine the processes and documents required for product implementation, and provide the necessary resources for the product. The product implementation process includes a series of processes related to customers, procurement, production and service, inspection, product protection, and follow-up services. The company should identify these processes, determine which processes need to be managed and controlled, which documents are needed to support the effective operation of the processes, and which resources are needed to ensure the implementation of these processes. These documents include production flowcharts, operating specifications, work instructions, etc.

c) Determine the required inspection activities and acceptance criteria. Activities such as review, verification, and confirmation of product design and process development, monitoring and measurement activities in production and service provision, inspection and testing activities before product delivery, etc;

d) The verification, confirmation, monitoring, inspection and testing, disposal, storage, circulation and traceability activities required for the product, as well as the product acceptance criteria. These documents include purchase inspection procedures, process inspection procedures, product inspection standards, etc.

e) To provide evidence that the process and its products meet the requirements, the company should establish relevant records that demonstrate the effectiveness of the product process and the compliance of the product with regulatory requirements, and ensure the adequacy of these records。

f) When there are requirements for specific product projects or contracts, each department shall prepare corresponding quality plans based on the planning results, and implement control over specific products, projects, or contracts;

g) “MDD 、MDR Instruction” The relevant requirements.

7.1.2 Requirements for Product Implementation Process Planning

a) Consistent with other requirements of the company's quality management system.

b) Formulate documents for the operation of the company, namely through the planning of the product realization process, such as quality plans, product realization flowcharts, market research plans, etc

7.1.3 The Technical Department shall prepare the "Medical Device Risk Management Control Procedure" to ensure that the implementation process of each product can establish and form risk management control documents to determine the hazards related to the entire product implementation process, estimate, evaluate, and control these risks, and monitor and control them

Effectiveness. The records of risk management should be maintained.

7.1.4 Implementation of Product Implementation Process Planning

The head of the technical department is responsible for leading the product implementation process.

7.1.5 Relevant documents

《Product Implementation and Quality Planning Control Procedure》

《Medical Device Risk Management Control Procedure》

7.2 Customer related processes

7.2.1 Determination of requirements related to the product

The marketing department is responsible for developing, implementing, and maintaining the 'Customer Related Process Control Procedure' to determine customer requirements, including:

a) Clear requirements: usually specified in the contract or order, including the model, specifications, and quantity of product features

Quantity, performance, etc; Requirements for delivery and post delivery activities, including delivery time, packaging, after-sales service, etc;

b) Implied requirement: Although not explicitly stated by the customer, it is a requirement for the expected or intended use of the product by the customer,

Such as product lifespan, etc;

c) Legal and regulatory requirements: such as product safety performance and other requirements; (including mandatory standards and legal requirements of China or EU countries)

d) Ensure any user training required for the specific performance and safe use of medical devices;

e) Any additional requirements determined by the company.

7.2.2 Review of requirements related to the product

The marketing department should organize a review of requirements related to the product. The review should be conducted before making a commitment to provide the product to the customer, and

It should be ensured that:

a) Product requirements are specified and form orders or contracts;

b) The contract or order requirements that are inconsistent with previous statements (such as bidding or quotation) have been resolved;

c) Meet applicable regulatory requirements; (including mandatory standards and legal requirements of China or EU countries)

d) The company has the ability to meet the prescribed requirements;

e) Is any user training or training program required for the specific performance and safe use of medical devices available;

f) The records of the review results and measures arising from the review should be maintained;

g) Our company has no customer requests that have not been documented;

h) When there is a change in product requirements, the marketing department is responsible for modifying the relevant documents and notifying the relevant departments in writing,

确保相关人员知道已变更的要求。

7.2.3 顾客沟通

通过与顾客有效沟通，了解顾客对产品和服务的满意程度，作为实施持续改进的输入。应针对以下方面，识别需进行的沟通活动：

a)公司通过传真、E-MAIL、电话、网站等形式向顾客介绍本公司销售产品相关的产品信息;

b) 销售部对顾客的来电、来函、传真等方式的问讯和咨询予以解答并记录，及时处理合同或订单，如对合同进行修改需重新评审以满足顾客的新要求;

c) 在产品提交后，主动征询顾客对产品的意见，记录顾客的反馈，包括顾客投诉，及时采取措施处理顾客的抱怨，用最短时间答复顾客，争取顾客的满意;

d) 当已销售的医疗器械未能达到预期用途及可能对病人有伤害或潜在伤害或违背法规要求时, 销售部按《忠告性通知发布与实施控制程序》对当地主管部门发出忠告性通知,并实施召回。

7.2.4 相关文件

《与顾客有关的过程控制程序》

7.3 设计和开发

7.3.1 总则

为确保设计开发活动的有序进行，公司策划和建立《设计和开发控制程序》

7.3.2 设计和开发策划

设计开发过程是产品实现过程的关键环节。它将决定产品的固有特性。设计和开发策划是确保设计达到预期目标和设计质量的有效手段。

7.3.2.1 策划的输入及内容

策划的输入包括对产品有关的技术资料，对顾客签订的合同，适用的法律法规和专业标准。

设计和开发策划的重点是对设计和开发过程的控制，因此设计开发策划应该包括以下内容：

a、应根据产品的特点、公司的能力和以往的经验等因素，明确划分设计开发过程的阶段，规定每一阶段的工作内容和要求;

b、应明确规定在每个设计开发阶段需展开的适当的评审、验证和确认和设计转换活动，包括活动的时机、参与人员和活动要求;

c、应明确各有关部门和人员在参加设计开发活动中的职责和权限;

d、对参与设计开发活动的不同部门之间的关系做出规定，确保既能各负其责，又能保持工作

有效衔接与信息正确交流；

e、设计和开发更改后的更新；

f、 确保设计和开发输出追溯至设计和开发输入的方法；

g、设计开发活动所需的资源，包括必要的人员能力。

7.3.2.2 策划的输出及评审

设计和开发策划的输出应形成文件，其形式是设计任务书和设计开发计划，随着设计开发的进展，可能发生设计要求的变更或情况的变化，因而应适时修改或更新输出。

设计任务书批准前应由项目负责人组织有关人员评审，对设计要求是否明确和合适进行评审。对不完备的已明确的要求，应对提出者研究解决。对策划过程中形成的文件、记录应于保存。

7.3.2.3 策划的实施

设计和开发策划输出的实施由项目小组织实施。

7.3.3 设计和开发输入

正确确定并保持设计和开发输入记录是保证设计和开发质量的必要前题和验证设计开发输出的依据，设计和开发输入包括以下内容：

a)　《设计和开发任务书》规定的各项功能、性能、可用性和安全要求；

b) 产品的类别（国内分类按国家食品药品监督管理局分类规则，CE 标志产品分类按 MDD 指令附录IX或本公司的《医疗器械分类程序》）；

c) 产品适用的法律法规要求（包括我国和欧盟相关法律法规）；

d) 欧盟或国际标准、国家标准、行业标准的要求;

e) 适用时，以前类似设计开发提供的信息（包括本公司或市场上同类产品以往设计开发信息。）

f) 设计和开发公司必需的其他要求；

g) 风险管理的输出。

技术部负责人组织对设计和开发的输入进行评审，以确保其充分性与适宜性；确保各项要求是完整、清楚的，并且不能自相矛盾。设计和开发输入评审应形成记录，并经技术部负责人或总经理批准。

7.3.4 设计和开发输出

设计和开发输出是产品设计和开发的成果，提供了关于产品固有的全面信息，应得到控制。其内容应：

a、满足设计和开发输入的要求；

b、给出采购、生产和服务提供的适当信息；

c、包含或引用产品接收准则；

d、规定对产品的安全和正确使用所必需的产品特性。

设计和开发输出的方式应适合于对照设计和开发的输入进行验证，设计和开发输出应在发布前得到批准。并保留设计和开发输出的记录。

设计和开发的输出形式，通常采用产品图样、产品规范、验收准则、产品说明书、工艺文件、调试要求、维修说明、关键重要件目录、采购产品目录等文件形式表达，各种形式的文件在发布前均按规定由研发部负责人审查批准。应保持设计和开发输出的记录。

7.3.5 设计和开发评审

设计和开发评审，是评价设计开发的各阶段成果满足要求的能力，以确定是否能转入设计开发的下一阶段，并识别问题采取改进措施。各阶段的评审方法和结果应形成记录并于保存。评审的参加者包括与所评审的设计和开发阶段有关的职能的代表和其他的专家人员。

7.3.6 设计和开发验证

设计和开发验证是确定设计和开发输出是否满足输入的要求，应依据所策划并形成文件的安排对设计和开发进行验证。其方法可以是：

a、与公司已证实的类似产品设计相比较；

b、试验和演示。

当验证结果表明设计和开发输出未能或部分没有满足输入要求时，应决定采取有效的措施（包括更改设计）来满足要求，验证的方法结果和决定采取的措施应记录并保持。

组织应将验证计划形成文件，验证计划包括方法、接收准则，适当时包括确定样本量的统计技术说明

如果产品的预期用途要求医疗器械连接至或通过接口连接至其他的一个或多个医疗器械，验证应包括证实当这样连接或通过接口连接时设计输出满足设计输入。

应保留验证结果和结论及必要措施的记录

7.3.7 设计和开发确认

设计和开发确认是确保所设计开发的产品满足规定的或预期使用的要求。依据《设计和开发控制程序》对设计和开发进行确认。确认计划应形成文件，确认计划应包括方法、接收准则，适当时包括确定样本量的统计技术说明。

设计确认应选择有代表性产品进行。有代表性产品包括最初生产的单元、批次或其等同品。并记录用于确认的产品选择的理由说明。

作为设计和开发确认的一部分，研发部应按照适用的法规要求进行医疗器械临床评价或性能评价。用于临床评价或性能评价的医疗器械不视为放行给顾客使用。作为医疗器械必须进行临床试验或验证或试用，或通过临床文献评价途径进行临床评价。临床试验或临床验证或临床试用的有关活动必须符合国家食品药品监督管理局有关文件的规定，带 CE 标志产品的临床评价还应符合欧盟 MDD 93/42/EEC+2007/47/EC 以及《临床评估指南》有关临床调查或临床资料评估的规定，确

认应在向客户放行使用之前完成。确认结果及改进措施的记录应保存。具体见《医疗器械产品临床调查/临床资料汇编程序》

如果预期用途要求医疗器械连接至或通过接口连接至其他的一个或多个医疗器械，确认应包括证实当这样连接或通过接口连接时已满足规定的应用要求或预期用途要求。确认应在向顾客放行产品使用之前完成。

公司应保留确认结果和结论及必要措施的记录。

7.3.8 设计和开发的转换

研发部负责编制《设计和开发控制程序》，并将设计和开发输出转换为制造的活动形成文件。这些文件应确保设计和开发输出在成为最终生产规范之前经验证适合于制造并确保生产能力能满足产品要求。

应记录转换的结果和结论。

7.3.9 设计和开发更改的控制

设计和开发的更改对产品是否满足法规和顾客要求有直接关系，从而必须予以控制。

设计和开发更改应经评审在认定合理可行的基础上，包括评审更改对产品组成部分和已交付产品的影响。

更改在实施之前应经：a）评审；b）验证；c）适当时，确认；d）批准。

应确定更改对于医疗器械功能、性能、可用性、安全、适用的法规要求及其预期用途等的重要程度。应识别设计和开发的更改

设计和开发更改的评审应包括评价更改对在制或已交付的组成部件和产品的影响，以及对风险管理的输入或输出和产品实现过程的影响

应保留更改及其评审和任何必要的措施的记录。

7.3.10 设计和开发文档

公司保留每个医疗器械类型或医疗器械族的设计和开发文档。

该文档应包括或引用为证实符合设计和开发要求所形成的记录，以及设计和开发更改的记录。

7.3.11 相关文件

《设计和开发控制程序》

《医疗器械产品分类程序》

《医疗器械产品临床调查/临床资料汇编程序》

7.4 采购

策划和建立《采购控制程序》对采购产品及供方进行采购控制，以确保采购产品在质量、交付和服务等方面符合规定的采购要求。

7.4.1 采购过程

采购过程包括：对采购需求的识别，确定采购产品的性能、价格和交付情况，对供方能力进行确认、订货，对采购产品的验证等，过程的具体采用应根据采购产品的质量控制要求来确定，

对供方及采购的产品控制的类型和程度应取决于采购的产品对随后的产品实现或最终产品的影响。本条明确了对采购产品需求的识别，对供方能力确认及对其的控制。

7.4.1.1 对采购产品需求的识别

识别的输出应形成文件即“产品物料清单”，目录中应明确采购产品类别即 A 类（重要物资）、B（一般物资） 、C 类（辅助物资）。按此类别实施不同控制。

7.4.1.2 合格供方的评定及管理

建立评价和选择供方的准则，考虑供方的绩效，并与医疗器械相关风险相适应。

a、供应链中心应根据采购产品分类，对供方评定制定评定和重新评定准则。

b、供应链中心应组织研发设计中心、质量部等相关部门按评定准则来选择并对供方进行评定和重新评定，并保持评定的结果及跟踪措施记录。

c、评定为合格供方后，供应链中心建立“合格供方名录”，分别建立合格供方档案，实施动态管理。

公司监视供方满足采购产品的要求的绩效。监测结果作为供方再评价过程提供输入。

对未实现采购要求的供方的处置应与所采购产品有关的风险相适应，并符合适用的法规要求。

保留供方能力或绩效的评价、选择、监视和再评价的结果及由这些活动所引起的任何必要措施的记录。

7.4.2 采购信息

采购信息应正确表达拟采购要求，是采购产品控制的重要内容。信息应包括：

a、采购产品的质量规范或接受准则；

b、有关提交产品程序等（如供方提交产品的程序；供方生产或服务提供的过程要求；供方设备方面的要求）要求；

c、有关供方人员资格的要求；

d、有关供方质量管理体系的要求。

采购信息的形式可以是合同、订单、技术协议（含技术文件、图样）、询价单及采购计划等。在与供方洽谈合同询价或招标以至发出订单前，一般应经审批可采取由相应责任人员审批的方法，确保其采购要求充分和适宜性。

按可追溯性要求的范围和程度，保持相关的采购信息，如：文件和记录。

7.4.3 采购产品的验证

验证活动的范围应基于对供方评价的结果，并与采购产品有关的风险相适应。

其内容包括：

a、产品名称、型号或规格、供方名称、验证依据的技术文件（技术标准）、验证的方式；

b、验证不合格产品的处置；

c、验证合格产品入库的办理；

d、当觉察到采购产品的任何更改时，公司应确定这些更改是否影响产品实现过程或医疗器械最终产品；

e、当公司或顾客拟在供方的现场实施验证时，公司应在采购信息中对拟验证的安排和产品放行的方法做出规定；

应保持验证记录

7.4.4 相关文件

《采购控制程序》

7.5 生产和服务的提供

7.5.1 生产和服务提供过程的控制

7.5.1.1 总要求

对本公司而言，生产和服务提供是指产品的生产、放行、交付和交付后活动的过程。在质量管理体系策划（见本手册 5.4.2 条）和产品实现策划（见 7.1 条）中包括了对生产和服务提供控制的策划，有关部门必须确保按照策划的要求对生产和服务提供进行控制，具体而言包括如下方面：

a) 技术部编制产品图样、工艺规程、包装要求等技术文件；生产部负责对生产设备进行控制，并定期维护和保养；

b) 生产部确保生产计划编制合理，并能顺利完成；

c) 技术部应制定指导生产和服务的作业指导书为相关工序提供操作的依据；

d) 技术部应明确特殊过程和关键工序，生产部和质量部按“质量控制点的管理办法”对特殊过程和关键工序进行重点监视和控制，并做好记录。

e) 质量部按《产品的监视和测量控制程序》来监控过程工艺和制造能力并保证和满足顾客的所有要求；

f) 质量部应考虑配置合适的测量和监控设备，以满足测量产品特性和过程特性的需要；对产品特性形成的那些过程相关的作业文件采用过程监控手段保证过程满足需要；

g) 质量部负责按规定要求对产品放行、市场部负责交付和交付后活动的控制；

h) 市场部负责为顾客提供售前、售中、售后服务；

i) 市场部负责及时做好顾客投诉或抱怨的处理，责任部门采取纠正和预防措施，确保处理结果满足顾客要求。

j）技术部负责规定产品标签和包装要求，生产部负责标签和包装操作实施；

k）本公司建立并保持每一批医疗器械的记录，以提供规定的可追溯的范围和程度的记录，并标明生产数量和批准销售的数量，对每批的记录加以验证和批准。

7.5.1.2 本公司产品的委外加工的零部件在进入净化车间前对产品表面的油污用超声波清洗机进行清洗，并在产品组装前又在十万级净化车间内用纯化水进行末道清洗，（详见产品清洗作业指导书）本公司产品的零部件末道清洗、产品组装、塑焊和热封包装在十万级净化间内进行，产品经过环氧乙烷灭菌或辐照灭菌，在灭菌有效期内，且包装完好，使用前不必进行灭菌处理。

7.5.1.3 本公司对产品委外环氧乙烷灭菌或辐照灭菌进行控制，在灭菌协议中要求灭菌站对灭菌过程按 ISO11135 或 ISO11137 标准要求进行确认，做好灭菌过程常规控制，保留每一灭菌批的过程参数记录，并向本公司提供每一灭菌批的灭菌报告，报告上记录灭菌参数、灭菌批号和生产批号等。质量部负责保存灭菌报告。具体执行《委外 EO 灭菌控制程序》和《委外辐照灭菌控制程序》。

7.5.1.4 本公司对产品生产现场实行清场管理，防止不同批的物料、产品、余料、零部件、作业文件、图纸等混淆，以便追溯。清场情况记录于《清场记录》。具体执行《清场管理制度》

7.5.2 产品的清洁

公司生产的产品为无菌医疗器械产品，产品在灭菌前不进行清洁，要按照 6.4 要求保持产品要求所需要的工作环境.

7.5.3 安装活动

因公司生产的无菌医疗产品，不需要安装，故该条款不适用。

7.5.4 服务活动

为了满足顾客要求，公司对产品售前、售中和售后进行服务，市场部负责服务信息的接收，质量部负责对用户反馈的信息进行调查处理，并提出纠正、预防和改进措施。

a） 售前服务：市场部通过展会、客户要求收集相关产品信息；

b） 售中服务：通过面谈或电话沟通回复顾客咨询的问题以及实施快速、简便、有效的交付手续；

c） 售后服务：提供顾客要求的“检验报告”及”“三证””以及定期或不定期走访顾客，并对经销商进行培训，必要时进行临床现场操作指导

7.5.4.1 相关文件

《服务提供控制程序》

7.5.5 无菌医疗器械的专用要求

公司生产的产品为无菌医疗器械产品，产品的灭菌为委外灭菌，分别为辐照灭菌和 EO 灭菌，每年与委外灭菌单位对产品灭菌过程进行一次灭菌确认，并保留相关的确认记录，在每批产品委

外灭菌后，委外方提供相关灭菌过程参数，公司质量部对灭菌产品进行无菌和环氧乙烷残留检测，检测合格后入库，并保留相关的检测记录。

7.5.5.1 相关文件

《委外 EO 灭菌控制程序》

《委外辐照灭菌控制程序》

7.5.6 生产和服务提供过程的确认

7.5.6.1 当生产和服务提供过程的输出不能由后续的监视或测量加以验证，使问题在产品使用后或服务交付后才显现时；或是对形成的产品是否合格不易或不能经济地进行验证的过程，本公司对任何这样的过程（以下统称“特殊过程”）实施确认。由技术部负责对特殊过程进行识别、并组织确认。确认应证实这些过程实现公司策划的结果的能力。

1） 技术部负责识别、确定生产流程中的特殊过程，在工艺流程中设立控制点，明确所控制的产品特性和工艺参数，对特殊过程的工艺、设备进行验证。

2） 对特殊过程所使用的设备由技术部协助生产部编写验证方案，并组织实施确认，对操作人员进行考核，考核合格后持证上岗。

3） 特殊过程的操作人员按特定的工艺文件进行操作，对产品特性或工艺参数进行监控。保持工艺过程的稳定。

7.5.6.2 本公司需确认的特殊过程：零件粗洗、零件末道清洗、超声波焊接（管形刀组件、产品外壳等）、胶粘（腔镜与弧形产品外壳粘接等）灭菌包装热合封口，由技术部组织生产部、质量部相关人员参加的确认小组进行确认，通过确认获得正确参数，以确保过程产品符合规定要求。对委外的灭菌过程（EO 灭菌与辐照灭菌），由技术部负责，与辐照公司和环氧乙烷灭菌站共同组成确认小组进行确认，具体执行《特殊过程确认与监视控制程序》，并获取灭菌过程确认报告，具体实施见《委外 EO 灭菌控制程序》和《委外辐照灭菌控制程序》。

7.5.6.3 当材料、产品参数、工艺、设备及相关设施、环境、操作人员有变化时，特殊过程应进行再确认。正常生产情况下每年进行一次再确认。

7.5.6.4 技术部负责保存材料、工艺、设备与相关设施、环境确认和人员资格考核的记录。

7.5.6.5 本公司产品生产过程中的关键工序：注塑、装钉、制水为关键工序，由技术部组织生产部、质量部相关人员参加的验证小组，制定验证方案，对注塑工序的重要工艺参数进行验证，通过验证获得正确的工艺参数，以确保注塑零件符合规定要求。在验证的基础上编制并提供作业指导书。对装钉过程的控制主要是加强装钉检验，确保装钉的数量与位置等符合要求。对制水操作控制主要是对操作工培训上岗，操作工严格按制水规程进行操作，并通过对电导率监测和全性能监测。

7.5.6.6 技术部和生产部对特殊过程和关键工序设立质量控制点，并按“质量控制点的管理办法”

对其重要工艺参数和特性进行监视控制，并做好记录。（需要时对设备环境要求进行监控）

7.5.6.7 在产品实现过程中，各部门按《标识和可追溯性控制程序》实施产品标识和检验状态标识。

7.5.6.8 对产品满足规定要求的能力有影响的生产和服务提供的计算机软件的应用在开始使用前应予以确认。由生产部负责按《计算机软件应用确认控制程序》对带有计算机软件的生产设备在使用前进行软件确认。

7.5.6.9 相关文件

《生产过程控制程序》

《特殊过程确认与监视控制程序》

7.5.7 灭菌过程和无菌屏障系统确认的专用要求

7.5.7.1 灭菌是通过使产品无任何形式存活微生物的确认过程，最终使产品上无存活微生物，公司生产的产品为无菌医疗器械产品，产品的灭菌为委外灭菌，分别为辐照灭菌和 EO 灭菌，每年与委外灭菌单位对产品灭菌过程进行一次灭菌确认。

7.5.7.2 无菌屏障系统是在规定条件下防止微生物进入的能力，公司生产的无菌医疗器械产品产品包装为 PET 的吸塑盒与特卫强的透析纸或医用透析纸和复合膜（PE/PET）热合而成，为保证产品在有效期内无菌，产品的包装委托第三方有资质的检测单位进行包装验证试验,根据 ISO11607 标准要求分别进行真空泄露试验、渗透性试验、琼脂接触攻击试验、封口剥离试验和加速老化试验，检验合格后进行使用，并且公司质量部对每批产品均要进行密封性性能和剥离强度检验，并保留相关的验证和检验记录。具体见《无菌屏障系统控制程序》

7.5.7.3 相关文件

《无菌屏障系统控制程序》

7.5.8 -7.5.9 标识和可追溯性

本公司建立《标识和可追溯性控制程序》，确定追溯范围和追溯程度，便于采取纠正和预防措施。

a) 对原材料、外协件、半成品、成品都建立了产品“名称、型号、规格、批号”的产品标识体系；

b) 在生产的不同阶段都以“待加工”、“已加工” “待检验”等作为状态标识；

c) 对返回公司进行处理的产品以“返回品”作标识，并与其它产品分别堆放，确保识别和区分；

d) 本公司规定对产品追溯到代理商、经销商，并要求其保持分销记录；

e) 对与组织和粘膜接触的零部件追溯到供方及原料供方。

f）为实现以上追溯，在有关记录中应记录每批产品的批号、零部件批号及其原料批号

g）产品说明书、标签和包装标识的内容，国内市场销售的应符合国家局 6 号令及相关标准的规定；到欧盟市场销售的应符合 EN980、EN1041 及销往的欧盟成员国相关法规和相关标准的规定。

相关文件：

《标识和可追溯性控制程序》

《医疗器械产品标签和语言控制程序》

7.5.10 顾客财产

7.5.10.1 本公司顾客财产是指顾客可能提供的原料、样品、图纸、标签样本、知识产权等，或是在销售和服务过程中可能接触的顾客个人信息（如患者的健康信息）。市场部负责与顾客签订相应协议或合同时，规定履行保护这部分属于顾客财产的责任条款；市场部负责顾客可能提供的样品、图纸、标签样本的接受、标识或封样、登记，需转交有关部门使用时应做好相关交接签收手续，相关部门应负责做好顾客财产使用期间的防护，详见《顾客财产控制程序》。

7.5.10.2 市场部、质量部等部门负责做好在销售、服务或售后信息反馈处理中可能接触到的顾客个人信息的保护和保密。

7.5.10.2 质量部负责做好顾客提供原料的检验或验证。

7.5.10.3 仓库保管员应负责做好顾客提供的原料的防护，并做好标识。

7.5.10.4 当出现顾客财产丢失、损坏、不适用等情况时，相关部门告知市场部，由市场部负责与顾客联系，与顾客协商处理或补救措施。

7.5.10.5 相关文件

《顾客财产控制程序》

7.5.11 产品防护

本公司产品在生产、包装、搬运、贮存、交付过程中的各个阶段，操作者和相关人员均应注意保护产品和产品标识（包括原辅料、半成品、成品），防止损坏，以确保交付产品符合质量要求。

7.5.11.1 生产过程中的防护；所有的操作者在生产的各个阶段应小心搬运原辅料、半成品、成品以防止损坏，如需要则制定相应的工作指导书。

7.5.11.2 搬运过程中的防护：

对原辅料、半成品及成品搬运时应根据不同的产品采用不同的搬运工具和适当的搬运方法，防止跌落、磕碰等。对搬运人员要进行岗位培训。

7.5.11.3 贮存和防护

a) 为原辅料、半成品和成品提供安全的适宜的储存条件；

b) 所有储存产品都有明显的标识；

c) 建立控制产品进出的手续；

d) 定期检查并验证产品的储存状态，对不合格的储存状态进行纠正；

e) 对有特殊储存条件和储存期限的产品，对其储存期限和储存条件进行有效控制，并加以记录。

7.5.11.4 包装和交付

a) 所有产品依据包装工艺规定进行适当的包装和打包以防止运输过程中损坏；

b) 所有包装都清晰标明产品标识和其它必要的信息；

c) 对产品的防护要延续到支付目的地，仓库在产品发货记录中记入收货人姓名和地址。

7.5.11.5 相关文件

《产品防护控制程序》

7.6 监视和测量设备的控制

7.6.1 技术部应确定产品实现所需的监视和测量以及所需的监视和测量设备，质量部提出申请，总经理批准后由采购部负责采购。

7.6.2 质量部负责对新购进的和在用的测量设备进行登记、编号、建立台帐。

7.6.3 质量部对新购进的测量设备进行核准、校准或外送检定，送检过程中采取相应的防护措施，确保其不受损。经检定合格后才能发放使用。

7.6.4 对在用的测量设备由质量部编制周期检定的计划，并负责按时送检，检定合格后贴上合格标识，并做好检定记录，发放使用。

7.6.5 质量部负责将损坏的或失准的测量设备外送有资格的单位进行检修。

7.6.6 当发现使用的测量设备偏离状态时，对以往测量结果的有效性由质量部评定。

7.6.7 各部门必须安排具有相应资格的人员使用、校准测量设备。

7.6.8 所有在用的和存储的测量设备的使用说明书、合格证、检定和维修记录由质量部负责保存。

7.6.9 测量设备应存放适宜的环境中。

7.6.10 对自制的测量设备，由计量员按校验文件校准，并做好校准记录。

7.6.11 当计算机软件用于规定要求的监视和测量时，应确认其满足预期用途的能力。确认应在初次使用前进行，必要时再确认。确认计量机软件满足预期用途的能力的典型方法包括验证和保持其适用性的配置管理。

7.6.12 相关文件

《监视和测量设备控制程序》

8 测量、分析和改进

8.1 总则

8.1.1 本公司对监视、测量和改进过程进行策划，以确保：

a、证实产品的符合性；

b、质量管理体系的符合性;

c、持续保持质量管理体系的有效性。

8.1.2 本公司在《生产过程控制程序》、《产品监视和测量控制程序》、《内部审核控制程序》等质量文件中对监视、测量、分析和改进的方法以及作用做出了详细的规定。

8.1.3 按《数据分析控制程序》的规定，在过程控制，检验和试验等方面逐步推广应用排列图、因果分析图、控制图等统计技术，在其它工作中可根据需要采用，以便分析、报告、处理各类质量问题。

8.1.4 为了正确有效地使用适当的统计技术，需要对有关部门进行统计技术的培训。

8.1.5 统计技术的应用应本着科学、经济、适用的原则。

8.2 监视和测量

8.2.1 反馈

8.2.1.1 本公司制定《顾客信息反馈与处理控制程序》和《顾客满意监视和测量控制程序》对顾客反馈的信息进行监视和管理。

8.2.1.2 质量部负责对顾客的投诉组织调查，确定纠正和预防措施，以确保及时有效地处理顾客投诉。

8.2.1.3 从反馈过程中收集的信息应用作监视和保持产品要求的风险管理的潜在输入以及产品实现或改进过程的潜在输入。

8.2.1.4 建立了《 质量预警反馈系统早期报警控制程序》，完善早期报警的反馈系统，并对生产后阶段的经验进行评审，这样的评审也构成该反馈系统的一部分。

8.2.1.5 相关文件

《顾客信息反馈与处理控制程序》

《顾客满意监视和测量控制程序》

《质量预警反馈系统早期报警控制程序》

8.2.2 抱怨处理

公司制定《顾客抱怨处理控制程序》；程序应包括对以下方面的要求和职责

a、接收和记录信息；

b、评价信息以确定反馈是否构成抱怨；

c、调查抱怨；

d、确定向监管机构报告信息的需要；

e、处理与抱怨有关的产品；

f、确定启动纠正和预防措施的需要。

对任何没有经过调查的抱怨，质量部应记录理由。应记录由抱怨处理过程形成的任何纠正和预防措施。

如果一项调查确定是组织之外的活动导致了抱怨，则相关信息应在组织和所涉及的外部方之间交换。应保留抱怨处理记录。

8.2.3 相关文件

《顾客抱怨处理控制程序》

8.2.3 向监管机构报告

8.2.3.1 如果适用的法规要求将符合不良事件规定的报告准则或符合发布忠告性通知的抱怨上报，公司按照所建立的《忠告性通知发布和实施控制程序》、《不良事件处理与报告及再评价控制程序》将向有关的监管机构上报的程序形成文件。

8.2.3.2 应保留向监管机构报告的记录。

8.2.3.3 欧盟国家不良事件的报告需按照《警戒系统控制程序》进行。

8.2.3.4 相关文件

《忠告性通知发布和实施控制程序》

《不良事件处理与报告及再评价控制程序》

《警戒系统控制程序》

8.2.4 内部审核

8.2.4.1 管理者代表制订年度内审计划。

8.2.4.2 管理者代表根据内审计划组织内审，审核组长编制审核实施计划，内审员编制检查表。

8.2.4.3 内审员应接受过国家认可审核机构的专门培训，取得内审员资格。

8.2.4.4 公司每年进行不少于一次内部质量管理体系审核；

8.2.4.5 质量管理体系中各个过程及涉及到的职能部门，每年至少审核一次。

8.2.4.6 内审员不能审核自己的工作。

8.2.4.7 审核结果作出书面的结论，对审核中发现的不合格项、作出原因分析和提出纠正措施建议。

8.2.4.8 对不合格项有关责任部门要采取纠正措施。

8.2.4.9 内审员对纠正措施进行跟踪和验证，质量部将结果输入管理评审。

8.2.4.10 质量部按“记录控制程序”保管内审记录。

8.2.4.11 相关文件

《内部审核控制程序》

8.2.5 过程的监视和测量

8.2.5.1 本公司制定并执行《过程与产品的监视和测量控制程序》，对管理职责、资源管理、产品实现、测量、分析和改进四大过程及其子过程进行监视，并在适当时进行测量，以证实这些过程实现公司策划的结果的能力，当未能达到公司策划的结果时，采取适当的纠正和预防措施，以确保产品的符合性。

8.2.5.2 过程监视和测量的方法

a）管理职责：本公司每年定期召开管理评审会及月、季或年度工作总结会等，对各部门管理职责进行监视和评审；各部门根据公司的质量目标，在本部门进行质量目标展开，建立
各个过程的目标，并采取措施实现各个过程的目标，质量部协助管理者代表的对各部门质量目标的情况按月、季或年度进行检查考核并形成记录，以确保公司质量目标的实现、

b）资源管理：由各部门负责对本部门的人力资源进行监视，由办公室负责人员配备、培训，并利用培训合格率、人员岗位考核等对培训有效性进行评价；由生产部对基础设施进行管理和日常使用监视；由质量部负责对检测设备进行管理和监视，对净化车间生产环境进行监视和测量。

c）产品实现：由市场部对生产计划进行监视和测量；质量部配合技术部对产品设计进行验证；生产部对关键工序进行监视和测量；质量部通过质量分析会、质量统计分析等对不合格品和客户信息反馈进行监视和测量；采购部通过供方现场考察和建立供方业绩记录表，对供方生产过程控制及供货质量进行监视和测量。

d）测量、分析和改进：由市场部负责组织相关人员对顾客满意度进行测量与评价；质量部负责收集质量管理体系各过程的质量信息，判断过程是否达到了预期的效果，如没有达到预期效果，质量部应组织有关部门分析原因，制定纠正措施。纠正措施的制定与实施应符合 《纠正/预防措施控制程序》。

8.2.5.2 相关文件

《过程与产品的监视和测量控制程序》

8.2.6 产品的监视和测量

为了验证产品要求已得到满足，必须对产品的特性进行监视和测量，包括采购产品、中间产品、最终产品，其规定如下：

a）技术部负责识别在生产过程中需要进行的产品检验活动，并在相关指导书中作出规定

b）质量部配置检验所需的测试仪器和设备，并按规定进行控制；

c）质量部对关键过程和特殊过程进行监视和测量，根据测定出的能力指数来判断过程能力是

d)否满足要求；

e) 当过程能力不足时，采取改进措施；

f) 产品的监视和测量。

8.2.6.1 进货检验或验证

a) 对采购部采购人员购进物料，仓库保管员核对送货单，确认物料品名、规格、数量等无误、包装无损后，置于待检区做“待检”标识，通知质量部检验员进行检验或验证。

b) 检验员依据《进货检验规程》进行全数或抽样检验或验证，填写《进货检验或验证记录》，仓库保管员根据检验合格报告办理入库手续；检验或验证不合格时，检验员在物料上贴不合格标识，按《不合格品控制程序》处理。

c) 采购产品的验证方式可包括检验、测量、观察、验证供方质量保证书或检测报告及委外检验等方式，根据物资类别，在相应的规程中规定不同类别物料的检验或验证方式。

8.2.6.2 过程检验或试验

a) 生产过程中根据实际需要实施首件“三检制”即自检、互检，专检；并在生产过程中实施巡检；

b) 质量部检验员根据过程检验规范和进行工序完工检验；

c) 确保没有经过检验或验证证明是合格的原材料、过程产品不准投入使用或转入下道工序。

8.2.6.3 最终检验和试验

a) 质量部负责在所有规定的进货检验和过程检验均完成，且合格才能进行最终产品的检验或验证

b) 质量部成品检验员根据成品检验规程和产品标准进行成品的检验和验证；

c) 在确定已完成产品实现所规定的全部生产过程及全部出厂检验项目后，才能对产品进行放行和交付. 由质量部成品检验员检验合格,并经质量部负责人审核批准后,成品仓库才能办理成品入库手续和向顾客交付产品.

d) 对产品的检验或试验中，如不合格则按“不合格品控制程序”执行。

8.2.6.4 检验和试验的记录

a) 所有质量记录应清楚地表明产品已按规定的要求通过了检验和试验，并记录检验和试验人员的身份；

b) 检验和试验记录由质量部负责按“记录控制程序”管理。

8.2.6.5 相关文件

《过程与产品的监视和测量控制程序》

8.3 不合格品控制

8.3.1 总则

本公司为确保不符合要求的产品得到识别和控制，以防止非预期的使用或交付，制定并实施《不合格品控制程序》，对不合格品进行识别、记录、隔离、评价和处置的有关职责和权限进行规定。

8.3.2 交付之前发现不合格品的响应措施

公司通过下列几种途径处置不合格品，确保不合格品仅在提供理由、获得批准和满足法规要求的情况下才能让步接收，并保留让步接收和授权可让步接收的人员身份记录。

a）采取措施以消除已发现的不合格；

b)采取措施预防其原预期使用或应用；

c)授权让步使用、放行或接收。

8.3.2.1 不合格品的识别、记录、标识和隔离

a）不合格品分外购外协件中的不合格品、半成品中的不合格品和成品中的不合格品。

b）不合格品由质量部检验员负责识别、标识和隔离存放，仓库管理人员和操作工协助做好不合格品的隔离和存放

c）检验员应做好不合格品情况的记录

8.3.2.2 不合格品的评审

a) 少量不合格品由检验员负责评审，决定处置的方法；

b）批量不合格品由质量部会同技术部等部门一起进行评审、决定处置的方法，必要时须采取纠正和预防措施。

8.3.2.3 不合格品的处置方法

a）返工：评审后的不合格品，可以进行返工，在必要时由技术部制订返工的作业指导书，确定返工对产品的不利影响，并有与原作业指导书相同的审批程序，返工后仍需再次进行检验；

b）报废：不能返工的作报废处置，对进货中出现的不合格品拒收；

c）让步接收：经返工仍有个别次要项目不合格对最终产品无影响或基本无影响，需经总经理批准作为让步接收，适用时还需经顾客同意，但法律不允许的除外。

8.3.3 交付之后发现不合格品的响应措施

产品在交付或开始使用后发现不合格时，公司应采取与不合格的影响或潜在影响的程度相适应的措施，按照适用的法规要求发布忠告性通知，并保留忠告性通知和相关措施的记录。

a）质量部及时有效地评审和处置，必要时发布忠告性通知；

b）质量部汇同各部门采取纠正措施，改进产品质量；

c）市场部及时与顾客沟通处理办法；

d）质量部保存所有不合格品的评审和处置的记录。

e）如涉及带有 CE 标识的产品的处理，应主动通知欧代，进口商，分销商，经销商，与其协

商对不合格品处理的相应措施。必要时，执行《警戒系统控制程序》

8.3.4 返工

公司不合格产品评审后需要返工时，要考虑到返工对产品潜在不良影响，返工过程应经过与作业指导相同的评审和批准，返工完成后，产品应经验证以确保其满足适用的接收准则和法规要求，并保留相关返工记录。

8.3.5 相关文件

《不合格品控制程序》

8.4 数据分析

为了证实质量管理体系的适宜性和有效性，并进一步识别改进质量管理体系有效性的机会，有关部门对相关的数据进行收集和分析。

8.4.1 数据分析提供以下方面的信息：

a) 顾客反馈；

b) 产品要求的符合性；

c) 过程产品的特性现状及发展趋势，包括改进的机会；

d) 供方的信息；

e）审核；

f）适当时，服务报告。

8.4.2 收集分析与处理

a) 由质量部对内部外部的信息进行汇总、筛选，找出最重要的质量信息；

b) 一般质量信息由质量部通知有关部门负责纠正，对数据分析表明质量管理体系不是适宜的、充分的活有效的，由质量部报告管理者代表输入到纠正预防措施。

8.4.3 在确定分析方法时，质量部必须考虑适当的统计技术的运用。

8.4.4 相关文件

《数据分析控制程序》

8.5 改进

8.5.1 总则 /持续改进

公司通过管理评审质量方针、质量目标、审核结果、上市后监督、数据分析、纠正和预防措施和管理评审来识别和实施任何必要的更改，寻找改进的机会，并进行实施。以确保质量管理体系的持续性和有效性并持续改进质量管理体系的有效性。

a) 针对已交付的产品，有关产品的使用、改动、召回、销毁等方面的补充信息和/或措施，由市场部及时向顾客、经销商发布通告。发布忠告性通知的形式：信函、电话、传真、公告等。

b）公司保持所有顾客抱怨的调查记录，当通过抱怨调查确实是在本公司之外开展的活动导致了顾客的抱怨，则相关的资料应在所涉及的组织之间传送；

c）对顾客的抱怨没有采取纠正和预防措施的，则其理由应予以批准并记录；

d）对于确因本公司产品质量问题引起应报告的不良反应，应按规定由管理者代表或质量部负责人及时向江苏省医疗器械不良事件监测技术机构报告，具体执行《不良事件处理与报告控制程序》。

e）对带 CE 标志产品销售到欧盟市场的，不良事件的报告执行《警戒系统控制程序》

8.5.2 纠正措施

本公司采取纠正措施以消除不合格的原因，防止不合格的再次发生，纠正措施应与所发现问题的影响性相适应。纠正措施的程序化文件应规定：

a）评审不合格（包括顾客抱怨）；

b）确定不合格的原因；

c）评价确保不合格不再发生的措施的需求；

d）确定和实施所需措施策划、形成文件并实施，适当时，包括更新文件；

e）验证纠正措施对满足适用的法规要求的能力或对医疗器械的安全好性能没有不利影响；

f）评审所采取纠正措施的有效性。

8.5.3 预防措施

本公司确定措施以消除潜在不合格原因，防止不合格的发生。预防措施与潜在的不合格的影响程度相适应。预防措施的文件化程序应规定：

a）确定潜在的不合格及其原因；

b）评价和防止不合格发生措施的需求；

c）对所需的措施策划、形成文件并实施、适当时，包括更新文档；

d）验证预防措施对满足适用的法规要求的能力或对医疗器械的安全好性能没有不利影响；

e）评审所采取的预防措施的有效性。

8.5.4 公司建立信息反馈系统以提供质量问题的早期报警，由质量部负责汇总信息，需要时输入纠正预防措施系统，以制定纠正预防和改进措施。

8.5.5 相关文件

《纠正/预防措施控制程序》

9 欧盟医疗器械指令 MDD93/42/EEC 和欧盟医疗器械法规 EU 2017/745(MDR) Article 120(3)、EU 2017/745(MDR) Article 10(9)的要求

9.1 总则

确保带有 CE 标志的产品满足 MDD93/42/EEC 指令、EU 2017/745(MDR) Article 120(3)、EU 2017/745(MDR) Article 10(9)法规和相关协调标准的要求。

9.2 适用范围

适用于带有 CE 标志产品的控制和技术文档的编制。

9.3 欧盟制造商和器械的注册

公司应按照欧盟医疗器械法规 ReEgulation (EU) 2017/745（以下简称 MDR）的要求在 Eudamed 相关数据库中对制造商进行注册，并提交医疗器械资料在计划营销和分销的辖区范围内进行产品注册备案，以确保医疗器械在欧盟销售的合法和合规性，具体参照《欧盟制造商注册和器械注册控制程序》。

9.4 CE 标志产品的管理

9.4.1 公司确保与质量管理体系及带 CE 标志医疗器械产品相关的国内、欧盟理事会、欧盟成员国法律法规和欧盟标准或国际标准得到及时收集并贯彻实施，具体执行参照《相关法律法规与标准收集与贯彻实施控制程序》；

9.4.2 公司预销往欧盟市场的产品分类按照 MDD 93/42/EEC 附录 IX 或 MDR EU2017/745 附录 VIII 的要求进行，分类过程执行《医疗器械产品分类控制程序》；

9.4.3 公司预销往欧盟市场的产品在准许带有 CE 标志前，应满足 MDD93/42/EEC 附录 I 的基本要求或 MDR EU2017/745 附录 I 的通用安全与性能要求以保证在欧盟市场上流通的产品是安全和有效的，技术部负责编制带 CE 标志产品的技术文件并对相关文件进行管理，具体执行参照《EC 技术文件控制程序》；

9.4.4 对于公司 CE 标志产品需进行上市后临床跟踪活动的产品进行判定，并按照《欧盟上市后临床跟踪控制程序》获取产品相关临床数据作为产品上市后监督控制活动的输入对相关文件进行更新，产品上市后的监督活动具体执行参照《上市后监督控制程序》、《定期安全性更新报告控制程序》及《不良事件趋势报告管理控制程序》；

9.4.5 公司需遵照 MDR 2017/745 法规和医疗器械警戒系统指南（2.12-1 rev.8）的要求,为使产品的质量事故得到有效鉴别、对警戒系统运作实施控制，具体执行参照《警戒系统控制程序》；

9.4.6 公司应对销往欧盟成员国家的产品随附文件中的语言文字进行控制，确保翻译准确，具体执行参照《医疗器械产品标签和语言控制程序》。

9.4.7 公司应按照 MDR 2017/745 法规 MDR Art. 13 及 Art. 14 对进口商经销商进行管理，并签订相关协议，具体执行参照《经销商和进口商管理控制程序》

9.5 带 CE 标志的医疗器械产品和体系变化

企业应确保当医疗器械产品和质量管理体系发生重大变更时能及时通知公告机构，管理者代表及相关部门应按照《重大变更控制判定和通知程序》完成变更的评估、通知、判定与确认。

9.6 制造商的义务

9.6.1 制造商应确保采取必要程序，以使批量生产符合本法规的要求，应及时充分考虑器械设计或特性的更改和协调标准或器械符合性所声明的 CS 的更改。器械（非研究用器械）制造商应以最有效的及根据风险等级和器械类别的方式确立、记录、实现、维护、不断更新和不断改善一个能确保器械符合本法规规定的质量管理体系。

9.6.2 质量管理体系包括制造商组织的所有处理流程、程序和器械质量的组成部分。它管理着结构、职责、程序、流程和管理资源，以贯彻所需的原则和行动，以遵守本法规的规定。

9.6.3 质量管理体系应至少解决以下方面的问题：

a）法规符合性战略，包括符合性评估流程的符合性和系统所涵盖的器械的变更管理程序；

b）确定适用的通用安全与性能要求，寻找可选择的解决这些要求的方法；

c）管理责任；

d）资源管理，包括选择和管理供应商和分包商；

e）制造商应建立、实施、记录和维护风险管理体系。

f）临床评价，包括 PMCF；

g）产品实现规划，包括规划、设计、研发、生产和服务提供；

h）验证所有相关器械的 UDI 分配，确保提供的信息的一致性和有效性；

i）建立、实施和维护上市后监督体系；

j）与主管机构、公告机构、其他经济运营商、客户和/或其他利益相关人沟通；

k）警戒情况下的严重事件和现场安全纠正措施的报告流程；

l）纠正措施和预防措施的管理及其有效性的验证；

m）产品的监督和测量流程，数据分析和产品改进。

9.6 相关文件

《欧盟制造商注册和器械注册控制程序》

《相关法律法规与标准收集与贯彻实施控制程序》

《医疗器械产品分类控制程序》

《欧盟上市后临床跟踪控制程序》

《上市后监督控制程序》

《定期安全性更新报告控制程序》

《不良事件趋势报告管理控制程序》

《警戒系统控制程序》

《医疗器械产品标签和语言控制程序》

《经销商和进口商管理控制程序》

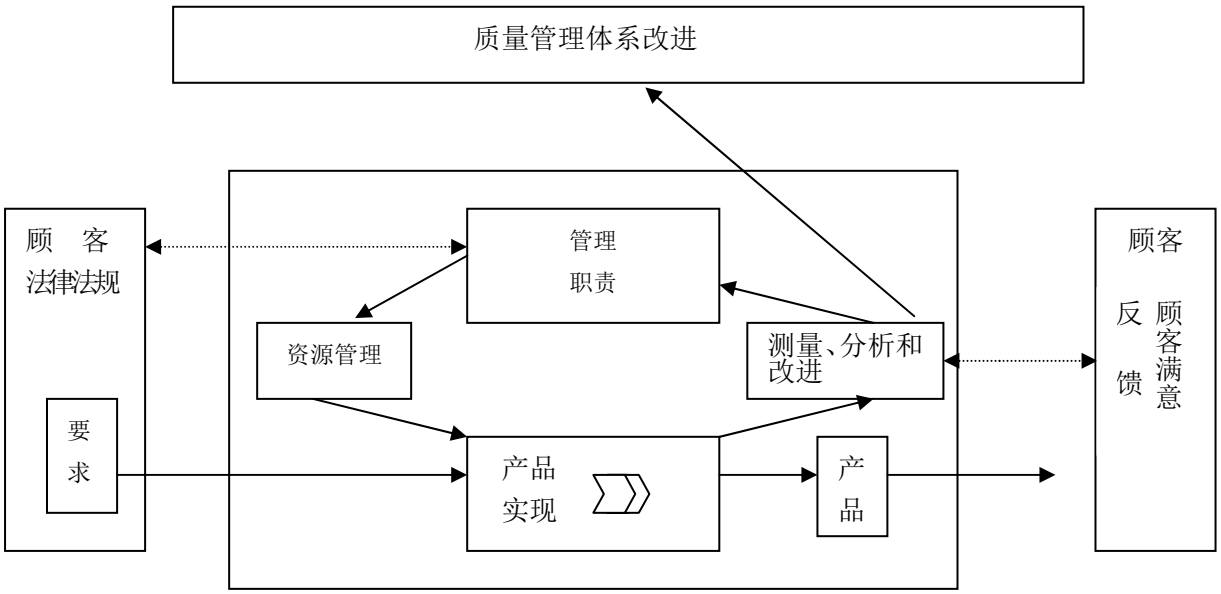
《重大变更控制判定和通知程序》

《医疗器械基本安全和性能控制程序》

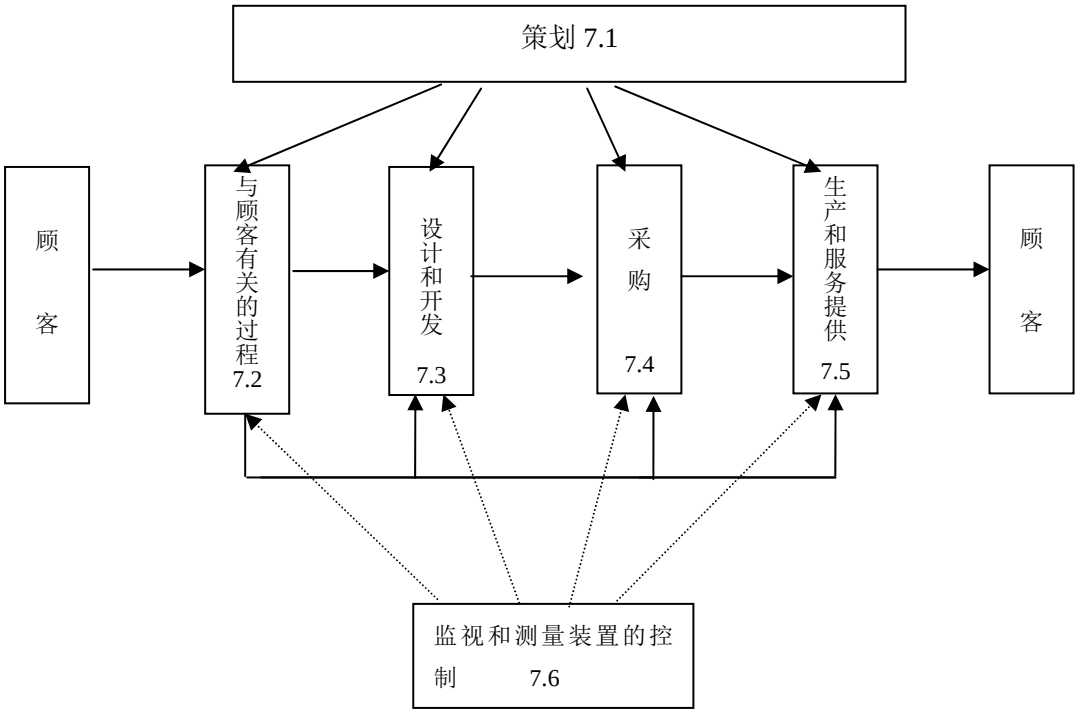
《MDR 合规性战略控制程序》

质量管理体系流程图

1、 以过程为基础的质量管理体系模式



2、产品实现过程图



质量管理体系职能分配表

标准条款号	职能部门 / 职能划分 / 条款名称	总经理	副总经理	管代	合规负责人	办公室	技术部	采购部	生产部及车间	质量部	市场部
4	质量管理体系	▲	△	▲	△	△	△	△	△	△	△
4.1	总要求	▲	△	△	△	△	△	△	△	△	△
4.2	文体要求	▲	△	▲	△	△	△	△	△	△	△
4.2.1	总则	▲	△	▲	△	△	△	△	△	△	△
4.2.2	质量手册	▲	△	▲	△	△	△	△	△	▲	△
4.2.3	医疗器械文档	△	△	△	△	△	▲	△	△	▲	△
4.2.4	文件控制	△	△	△	△	△	△	△	△	▲	△
4.2.5	记录控制	△	△	△	△	△	△	△	△	▲	△
5	管理职责	▲	△	△	△	△	△	△	△	△	△
6.1	资源的提供	▲	△	△	△	△	△	△	△	△	△
6.2	人力资源	△	△	△	△	▲	△	△	△	△	△
6.3	基础设施	△	▲	△	△	△	△	△	▲	▲	△
6.4	工作环境和污染控制	△	△	△	△	△	△	△	▲	▲	△
7.1	产品实现的策划	▲	▲	△	△	△	▲	△	▲	△	△
7.2	与顾客有关的过程	△	△	△	△	△	△	△	△	△	▲
7.3	设计和开发	△	▲	△	△	△	▲	△	△	△	△
7.4	采购	△	△	△	△	△	△	▲	△	△	△
7.5	生产和服务提供	△	▲	△	△	△	△	△	▲	△	▲
7.6	监视和测量设备的控制	△	△	△	△	△	△	△	△	▲	△
8.1	总则	▲	△	▲	△	△	△	△	△	△	△
8.2.1	反馈/顾客满意	△	△	△	△	△	△	△	△	△	▲
8.2.2	投诉处置	△	△	△	△	△	△	△	△	△	▲
8.2.3	向监管机构报告	▲	△	▲	△	△	△	△	△	△	△
8.2.4	内部审核	△	△	▲	△	△	△	△	△	▲	△
8.2.5	过程的监视和测量	△	△	▲	△	△	△	△	△	▲	△
8.2.6	产品的监视和测量	△	△	△	△	△	△	△	△	▲	△
8.3	不合格品控制	△	△	△	△	△	△	△	▲	▲	△
8.4	数据分析	△	△	△	△	△	△	△	△	▲	△
8.5.1	持续改进	▲	△	△	△	△	△	△	△	△	△
8.5.2	纠正措施	△	△	▲	△	△	△	△	△	▲	△
8.5.3	预防措施	△	△	▲	△	△	△	△	△	▲	△
9	MDD93/42/EEC 和 EU 2017/745(MDR) Article 120(3) 、EU 2017/745(MDR) Article 10(9)的要求	△	△	△	▲	△	△	△	△	△	△

注：▲代表责任部门，△代表配合部门

程序文件清单

序号	文件编号	文件标题	版本号
1	HD/QP-01	组织环境与相关方要求控制程序	E/1
2	HD/QP-02	计算机软件应用确认控制程序	E/1
3	HD/QP-03	风险和机遇应对措施控制程序	E/1
4	HD/QP-04	文件控制程序	E/1
5	HD/QP-05	相关法律法规与标准收集与贯彻实施控制程序	E/1
6	HD/QP-06	EC 技术文件控制程序	E/1
7	HD/QP-07	记录控制程序	E/1
8	HD/QP-08	管理评审控制程序	E/1
9	HD/QP-09	人力资源管理程序	E/1
10	HD/QP-10	知识管理控制程序	E/1
11	HD/QP-11	基础设施控制程序	E/1
12	HD/QP-12	工作环境控制程序	E/1
13	HD/QP-13	产品实现策划控制程序	E/1
14	HD/QP-14	医疗器械产品风险管理控制程序	E/1
15	HD/QP-15	与顾客有关的过程控制程序	E/1
16	HD/QP-16	设计和开发控制程序	E/1
17	HD/QP-17	忠告性通知发布与实施控制程序	E/1
18	HD/QP-18	医疗器械产品分类控制程序	E/1
19	HD/QP-19	医疗器械产品临床调查临床资料汇编程序	E/1
20	HD/QP-20	采购控制程序	E/1
21	HD/QP-21	生产过程控制程序	E/1
22	HD/QP-22	服务提供控制程序	E/1
23	HD/QP-23	委外 EO 灭菌控制程序	E/1
24	HD/QP-24	委外辐照灭菌控制程序	E/1
25	HD/QP-25	特殊过程确认与监视控制程序	E/1
26	HD/QP-26	无菌屏障系统控制程序	E/1
27	HD/QP-27	标识和可追溯性控制程序	E/1
28	HD/QP-28	产品防护控制程序	E/1

程序文件清单

序号	文件编号	文件标题	版本号
29	HD/QP-29	医疗器械产品标签和语言控制程序	E/1
30	HD/QP-30	顾客财产控制程序	E/1
31	HD/QP-31	监视和测量设备控制程序	E/1
32	HD/QP-32	顾客信息反馈与处理控制程序	E/1
33	HD/QP-33	顾客满意监视和测量控制程序	E/1
34	HD/QP-34	警戒系统控制程序	E/1
35	HD/QP-35	质量预警反馈系统早期报警控制程序	E/1
36	HD/QP-36	顾客抱怨处理控制程序	E/1
37	HD/QP-37	数据分析控制程序	E/1
38	HD/QP-38	不良事件处理与报告及再评价控制程序	E/1
39	HD/QP-39	内部审核控制程序	E/1
40	HD/QP-40	过程与产品的监视和测量控制程序	E/1
41	HD/QP-41	不合格品控制程序	E/1
42	HD/QP-42	纠正/预防措施控制程序	E/1
43	HD/QP-43	产品和体系变化通知程序	E/1
44	HD/QP-44	重大变更控制判定和通知程序	E/1
45	HD/QP-45	欧盟制造商注册和器械注册控制程序	E/1
46	HD/QP-46	欧盟上市后临床跟踪控制程序	E/1
47	HD/QP-47	上市后监督控制程序	E/1
48	HD/QP-48	定期安全性更新报告控制程序	E/1
49	HD/QP-49	不良事件趋势报告管理控制程序	E/1
50	HD/QP-50	经销商和进口商管理控制程序	E/1
51	HD/QP-51	MDR 合规战略控制程序	E/1
51	HD/QP-52	医疗器械基本安全和性能控制程序	E/1

产品目录

序号	产品名称	产品技术要求编号	注册号
1	一次性使用管型消化道吻合器	苏械注准 20162020446	苏械注准 20162020446
2	一次性使用直线型缝合器及组件	苏械注准 20162020448	苏械注准 20162020448
3	一次性使用肛肠吻合器	苏械注准 20162020449	苏械注准 20162020449
4	一次性使用直线型切割吻合器及组件	苏械注准 20162020450	苏械注准 20162020450
5	一次性使用圆形吻合器	苏械注准 20162020447	苏械注准 20162020447
6	一次性使用皮肤缝合器	苏械注准 20152021027	苏械注准 20152021027
7	直线型缝合器及组件	苏械注准 20162020087	苏械注准 20162020087
8	管型消化道吻合器及组件	苏械注准 20162020086	苏械注准 20162020086
9	肛肠吻合器及一次性组件	苏械注准 20162020444	苏械注准 20162020444
10	一次性使用腔镜下切割吻合器及组件	苏械注准 20162020184	苏械注准 20162020184
11	一次性使用弧形切割吻合器	苏械注准 20162020183	苏械注准 20162020183
12	一次性使用直线切割吻合器	苏械注准 20162020451	苏械注准 20162020451
13	一次性使用直线型吻合器及组件	苏械注准 20162020445	苏械注准 20162020445
14	一次性使用穿刺导入器	苏械注准 20162020838	苏械注准 20162020838
15	一次性使用选切型肛肠吻合器及组件	苏械注准 20172020040	苏械注准 20172020040
16	一次性使用切口牵开固定器	苏械注准 20172021896	苏械注准 20172021896
17	一次性使用荷包吻合器	苏械注准 20142020429	苏械注准 20142020429
18	一次性使用腹腔镜用穿刺器	苏械注准 20162020877	苏械注准 20162020877
19	一次性使用管型吻合器	苏械注准 20162020876	苏械注准 20162020876
20	一次性使用直线型切割吻合器及切割组件	苏械注准 20162020878	苏械注准 20162020878
21	一次性使用直线型缝（吻）合器及组件	苏械注准 20172020858	苏械注准 20172020858
22	一次性使用包皮切割吻合器	苏械注准 20172020859	苏械注准 20172020859
23	一次性腔镜切割吻合器及组件	苏械注准 20202021081	苏械注准 20202021081
24	一次性使用包皮环切吻合器	苏械注准 20202021285	苏械注准 20202021285
25	一次性使用穿刺器及套装	苏械注准 20202021305	苏械注准 20202021305
26	一次性使用医用口罩	苏械注准 20222140079	苏械注准 20222140079
27	医用外科口罩	苏械注准 20222140581	苏械注准 20222140581
28	一次性使用子宫颈活体取样钳	苏械注准 20222181328	苏械注准 20222181328
29	一次性使用肛肠套扎器及辅件	苏械注准 20222021370	苏械注准 20222021370
30	一次性使用电动腔镜切割吻合器及组件	苏械注准 20222011657	苏械注准 20222011657