3A Medical Products Co., Ltd

Quality Manual

ISO13485:2016

MDD93/42/EEC Ax.v.3

QSR21 CFR PART 820

Confirmed by	Approved by	Issued by
Yan Dezheng	Zhang Yong	Liu Jin

1.0 Purpose

Our Quality Manual follows ISO13485:2016 and MDD93/42/EEC Ax.V.3, QSR 21CFR PART820 international standards and requirements to plan the quality system for 3A Medical Products Co., Limited. We ensure our products and services meet the customers' and regulated requirements through the quality management.

Main points of Quality Management System:

- ★ Continuously fulfill the customers and the regulated requirements for the products and services.
- ★ To satisfy the customers through effective system operations including the improvements of each procedures and prevent the non-conformance. We set up our Quality Management System according to international standards of ISO13485:2016 and MDD93/42/EEC Ax.V.3,QSR 21CFR PART820.
- ★ Establish the quality management system up to standard.
- ★ Emphasize the set up of the leadership and achievement of the organizational target.
- ★ Emphasize all employees anticipate to increase company's benefits.
- ★ Emphasize the procedure management mode.
- ★ Reinforce the system management between procedures.
- ★ Make effective decision according to the analysis.
- ★ Continuously improve the products, procedures and quality management system.
- ★ Reinforce the relationship with the suppliers to make the greatest benefits.

2.0 Scope

The below has to be deleted or not available for 3A Medical Products Co., Ltd.

The products are not involved in design process, In addition to the design transfer program, the rest of Section 7.3 shall be deleted

Company Introduction

3A Medical Products was found in 2016. It now has 33,000 square meter in space with 10,000 square meter construction area, The construction has been all finished and put into use. The workshop is 8,000 square meters, the number of current workers is around 50. The company has set up the local area network, which has increased the management level and efficiency.

3A Medical Products co., Ltd has a qualified management team and workers, and has the advanced production machines, such as single stitching, double stitching, ultra-sonic , automatic poppers and so on.

3A has been focusing on the disposable medical gowns, drape, pack and scrub suit, also can make some protective products with many category and good quality, such as coverall, lab coat, surgical caps, mask, shoe cover, boot cover. All these products are exported to US and Europe.

3A has very strict control system to all procedure from choosing material, manufacturing, packaging, which can make sure the stability and reliability of the quality. The quality manual is for clear statement to all requirement and content of the quality management system, then all products quality can be promised to be compliable with the requirement of customers and relevant parties.

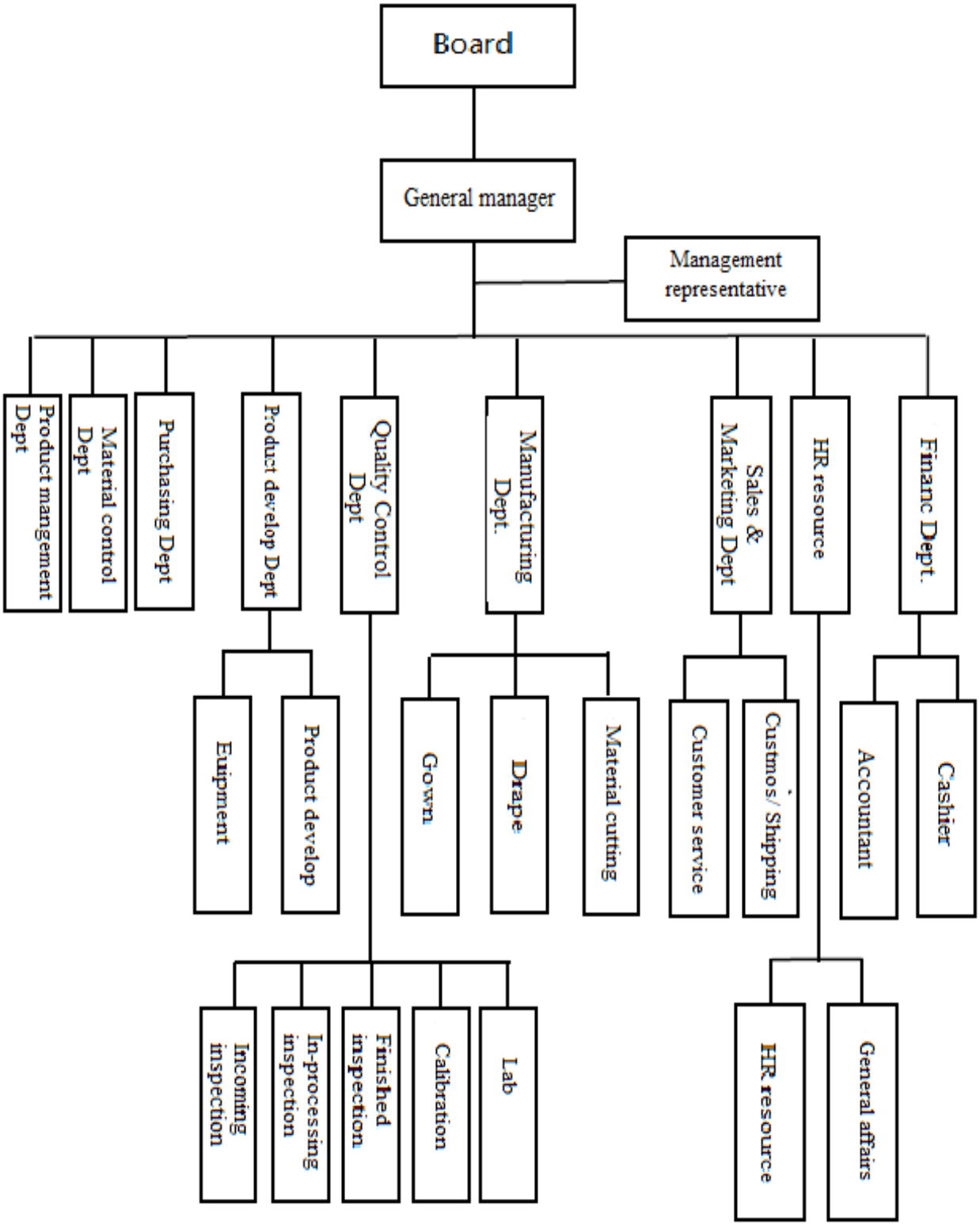
The quality management system is based on ISO13485:2016 and MDD93/42/EEC Ax.V.3,QSR 21CFR PART820 international standard. It includes the need of establishment for quality management system, such as organization right and responsibility, procedure and resource. It includes the responsibilities, procedures and resources etc. of the system. And we hope we can improve our business through continuous operation of the system. We also create the beneficial environment to grow our business and supply products and services which satisfy the customers' requirements.

Factory Address：Yu An Industrial Park, Liu An

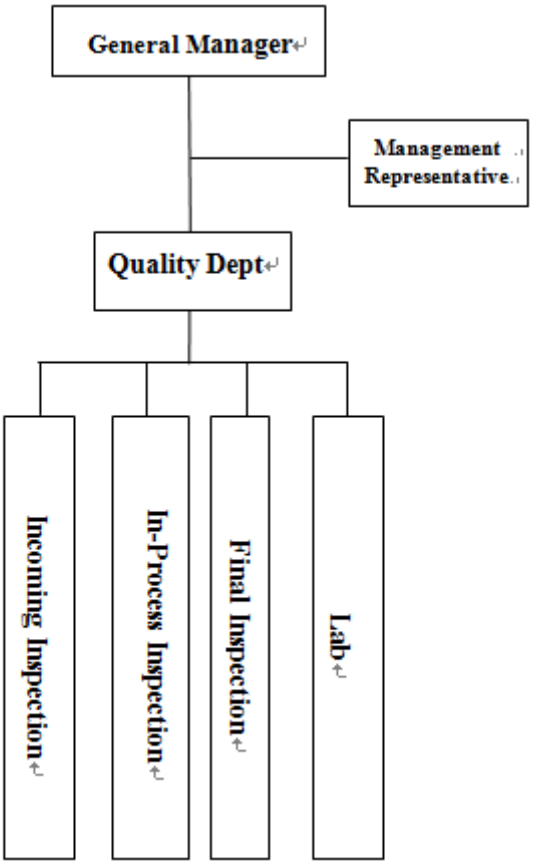
Phone No.：86-0564-3611700

Fax no.：86-0564-3611700

Organizational Chart



Quality Control Organizational Chart



Appointment Letter

In order to establish a quality management system that meets the ISO13485:2016 and MDD93/42/EEC Ax.V.3,QSR 21CFR PART820 international standards, improve products' quality, increase the management standard and have good reputation to get trust from the customers, we decided to appoint Mr. Chen Jun, to be the management representative. His responsibilities are as follows:

a) Ensure that we establish, implement and maintain the quality management system according to the ISO13485:2016 and MDD93/42/EEC Ax.V.3, QSR 21CFR PART820 international standards and regulated requirements. Also ensure that the products production procedures have effective identification, management and control.
b) Responsible for issuing and auditing the quality management system documents.
c) Report to the managing director about the operation status and performance of the quality management system including the need of improvement.
d) Reinforce the employees' understandings of satisfying the customers' requirements.
e) Plan for the internal audit for the quality management system.
f) Responsible for the external communication related to the quality management system.

3A Medical Products Co., Limited

Signature of General Manager_____

Jan 15, 2018

Promulgation Letter

Business Growth and development is guaranteed by the products' quality."3A Medical Products Co., Limited Quality Manual" (simply called Quality Manual) is set up according to ISO13485:2016 and MDD93/42/EEC Ax.V.3,QSR 21CFR PART820 international standards and regulated requirements, also with the actual operation in the company. It states our quality policy and target, and generally describes the quality management system. We shall follow these quality documents in a long-term basis in order to implement quality management and develop the regulations to the quality operation.

Through ISO13485:2016 and MDD93/42/EEC Ax.V.3,QSR 21CFR PART820, we hope our quality management system and regulations and improve company's business and create the beneficial environment to grow our business and supply products and services which satisfy the customers' requirements. ISO13485:2016 and MDD93/42/EEC Ax.V.3,QSR 21CFR PART820 quality management system and regulations was operated within our companion Jan 15, 2018.And the quality manual is approved to be effective after the checking date. All departments and employees shall follow the quality manual.

3A Medical Products Co., Limited

Signature of General Manager_____

Jan 15, 2018

Quality Policy

- ★ **Customers First**
- ★ **Quality First**
- ★ **Our Company is committed to growing our business through adherence to and continuous improvement of our policies and procedures**

In order to achieve the quality policy, we have the following responsibilities:

a) Customer-oriented, provide products and services that meets customers' requirement.

b) Continuously increase the products' quality standards.

c) Communicate with the suppliers so that the goods supplied meet our requirements.

d) Continuously grow and improve the management functions in order to achieve the management target of P (Product Function), Q (Quality), C (Cost), D (Delivery Date), S (Services and Safety).

e) Establish and follow ISO13485:2016 and MDD93/42/EEC Ax.V.3,QSR 21CFR PART820 international standards and regulated requirements to achieve the continuous improvement target.

3A Medical Products Co., Limited

Signature for General Manager_____

Jan 15, 2018

Quality Target

We set up the following quality targets according to the quality policy, ISO13485:2016 and MDD93/42/EEC Ax.V.3, QSR 21CFR PART820 international standards and regulated requirements:

- ★ **Incoming material of the products shall be 98.7% passed;**
- ★ **Procedure inspection shall be over or 99.1% passed;**
- ★ **Delivery of the products shall be 99.2% passed;**

Management Commitments

To ensure the effective operation and continuous improvement of the ISO13485:2016 and MDD93/42/EEC Ax.V.3, QSR 21CFR PART820 quality management system, General Manager promises the followings:

a) Responsible for transferring the requirements of the customers and regulations.

b) Responsible for establishing quality policy.

c) Responsible for establishing and leading the implementation of the quality targets and the management reviews.

d) Responsible for supplying essential resources.

3A Medical Products Co., Limited

Signature for General Manager_____

Jan 15, 2018

Definitions for Quality Policy & Target

A. Quality Policy

Quality Policy is the quality directions and aims of the business. It's part of the business policy and is issued by the managing director and the supervisors of each departments through discussion and communication to set up and promulgate. It states the understandings and the commitments of the managing team to the quality. Each person in the company shall remember and understand the policy, pay more attention to the products' quality. They shall product the goods strictly according to the customers' requirement to ensure that the products and services supplied by us can satisfy the customer's needs. Customers First, provide the best services to the customers. What we seek is the customers' requirements. Consider the customer's needs and our aim is to do everything that can satisfy our customers.

B. Quality Target

Quality target is issued according to the ISO13485:2016 and MDD93/42/EEC Ax.V.3, QSR 21CFR PART820 international standards and regulated requirements in order to achieve the estimated results.

C. Issue of Quality Policy and Target

a) National law regulations and industry standard requirements.

b) International market needs and customer's requirements on the products.

c) Organize internal quality management and operation requirements.

D. Notification of Quality Policy and Target

The quality policy and target are discussed and issued by the General Manager and the supervisors of each department. It will be promulgated as a written format also with the signature of the General Manager. And it will be placed in the quality manual. After the notification, all employees shall be taught about the policy and the target through posting and lessons etc. so that all the employees can understand and fully implement. Management review shall discuss and review the quality policy and target every year in order to ensure of they need to be changed. If there is a change in the quality policy and target, General Manager shall re-approve before release to the employees.

E. Understandings within the Company

★ **Policy Decision Level (Director Board, General Manager)**

As the policy decision level in the company, They need to ensure the implementation of the quality policy and target. They shall allocate the quality responsibilities of each staff, and the essential manpower and equipments (including the inspection, measuring and testing equipments) and other resources. They also need to make relevant changes if there is a change in the quality system requirements. At the same time, They shall check the implementation of the quality policy and target frequently and coordinate with the clause and regulation.

★ **Management Level (Management Representative, Department Manager and Supervisors)**

As the management level in the factory, they shall ensure the implementation of the quality policy and target and follow the requirements from the higher level and other documents to regulate the work. They shall identify and operate each related procedure, survey on the customers' satisfaction. Monitor and inspect the employees' work quality and products' quality. Any problems found shall be corrected and reported immediately. Provide training to the related employees to reduce and prevent re-occur of the same problems and make improvement in the quality management system.

★ **Operation Level (Primary Employees)**

As the primary employees in the factory, they have a direct reaction to the quality policy and target. Therefore, they shall be trained and pass the examinations so that they can fully understand the requirements of their work position. They also need to strictly follow the related documents. Any problems found in the production process shall report to the supervisors and inspect themselves and colleagues throughout the production process.

3.0 Quality Manual Management Regulations

3.1 Purpose

To ensure the methods of planning, changing and canceling the quality manual so that we can manage the manual in order to be released and implemented effectively

3.2 Scope

The regulations are suitable for planning, changing, canceling and implementing the quality manual.

3.3 Management Main Points

3.3.1 Quality Manual Serial Number

3A - QM - 01

Company Quality Manual Flow No.

3.3.2 Quality Manual Control

A. Quality manual is divided into two parts: “Controlled” and “Non-Controlled”. Controlled manual need to be numbered and stamp with the chop of “Controlled Document”. Both manuals shall have clear identification.

B. Controlled Quality Manual Management: The copy of the original manual shall have serial numbers and kept by the Documents Control Center. All the copies shall be stamped as “Controlled Documents”. Release of the quality manual shall be recorded in the “Quality Manual Released List”

3.3.3 Issue of the Quality Manual

A. Outline: Written by each Department manager, and the document staff collect to make together.

B. Review: Reviewed by the Management Representative.

C. Approve：Approved by General Manager.

D. Promulgate：Promulgated by the General Manager.

E. Release: Released by the Document control department.

F. Implement：Each related department and unit shall implement the manual.

3.3.4 Change of the Quality Manual

A. When Quality Manual needs to be changed, “Document Changed Application Form” shall be filled. Management Representative review and approve the change and make the changes. After changing the documents, They shall report to the factory manager and approved by the General Manager. Also they have to make record on the “Quality Manual Changed/Canceled Record”.

B. There are three main changes: Contents changed, pages changed and versions changed.

C. When Management Representative distributes the new (or revised) quality manual, they shall at the same time take back the old documents and stamp “Canceled” to prevent mixing up the documents. New documents (or revised documents) shall be saved in the computer

3.3.5 The times changing the Quality Manual is reflected on the version numbers.

Version numbers shall be shown as A, B, C...and the number 1,2,3.... If the version number is A/1 ,that means the manual is the second version and has been changed at the second time.

3.3.6 Using and Preserving the Quality Manual

A. The manual shall be placed in where the staff can easily read and review.

B. The manual shall be well preserved to prevent any damages or to prevent losing it. There shall not be any writing, changes or corrections on the manual. If the manual is lost or damaged, management Representative shall approve so that the ISO group can reissue or replace another one immediately.

3.3.7 Quality Manual Re-audit

Quality manual shall be re-audited once a year in order to ensure the accuracy and practicability.

3.3.8 Authority to Interpret the Quality Manual

General Manager or Management Representative has the authority to interpret the Quality Manual.

3.3.9 Related Form

A. “Quality Manual Changed/Canceled Record” (Please see Attachment 1)

B. “Quality Manual Released List” (Please see attachment 2)

Attachment 1 Quality Manual Changed/Canceled Record

Version	Changes			Changed Contents	Made By	Reviewed By	Approved By	Date
	Times	Page	Section					
A0				New	Liu Jin	Zhang Yong	Yan De Zheng	Jan,3rd,2016
A1	2	1.3	0.1;2.0	See the change list	Liu Jin	Zhang Yong	Yan De Zheng	Jan,15,2018

Attachment 2 Quality Manual Released List

File No.	Distribution	Issue No.	Version	Date	Remark
3A-QM-01	Document control	01	A/1	Jan15,2018	
	Quality dept.	02	A/1	Jan15,2018	
	Manufacture	03	A/1	Jan15,2018	
	Product management dept.	04	A/1	Jan15,2018	
	Customer service	05	A/1	Jan15,2018	
	Product develop dept.	06	A/1	Jan15,2018	
	HR resource	07	A/1	Jan15,2018	
	Material control	08	A/1	Jan15,2018	
	Purchasing dept.	09	A/1	Jan15,2018	
	General manager office	10	A/1	Jan15,2018	

4.0 Quality Management System Requirements

4.1 Purpose

To ensure we can establish, implement and preserve one complete set of documented quality management system according to the ISO13485:2016 and MDD93/42/EEC Ax.V.3, QSR 21CFR PART820 international standards and regulated requirements in order to make improvements continuously

4.2 Scope

All the documents and records that are related to the quality management system.

4.3 Management Main Points

4.3.1 Quality Management System Normal Requirements.

A. Identify the procedures required in the quality management system and apply to the organization.

B. Decide the sequence and the interaction of the procedures.

C. Decide necessary standards and methods to ensure that the procedures are operated and controlled effectively.

D. Ensure the adequacy and the usability of the resources and information in order to support operating and the monitoring the procedures.

E. Measuring, Monitoring and Analyzing the procedures.

F. Implement the procedures in order to achieve the planned results and make improvements continuously.

4.3.2 Documentation Requirements:

4.3.2.1 Our Quality Management System Documents included:

A. Quality policy and target

B. Quality Manual

C. Procedure Documents

D. Management Principle and Quality Record

E. other documents from country or local area law

4.3.2.2 Quality Manual

We have established and preserved a set of Quality Manual. The contents

are as follows:

A. The scope of quality management system.

B. A written procedures and other related documents for the quality management system.

C. Describe each procedures and relationship among the procedures in the quality management system.

D. Quality Manual shall be controlled according to the management regulations.

4.3.2.3 Documents Control

A. We control the documents required in the quality management system. Quality record is special document and is controlled according to section 4.3.2.3.

B. We issued the “Control of Documents” for controlling the quality system documents.

a) Documents shall be reviewed and approved before release.

b) Change the documents and re-review and approve if necessary.

c) Ensure that the revised or new documents are identified.

d) Ensure the latest documents can be reached in the related places.

e) Ensure the documents are easy to read, identify, especially the identification and control of the external documents.

f) To prevent the old version document from unexpected use, when they are kept, the documents shall be properly remarked

4.3.2.4 Quality Record Control:

A. We established and preserved the records required in the quality management system so that the system can meets the requirements and can implemented effectively.

B. Quality records shall be easy to read, identify and review.

C. We have issued the “Control of Quality Record” for identifying, storing, preserving, reviewing and handling the quality records.

4.4 Related Documents and Information

4.4.1 “Control of Documents”

4.4.2 “Control of Quality Record”

5.0 Management Responsibilities

5.1 Purpose

Establish and preserve the effective operation of our Quality Management System in order to meet our customers’ requirements and make continuous improvements.

5.2 Scope

All the procedures and departments covered by the implementation of our Quality Management System.

5.3 Management Main Points

5.3.1 Commitments of the Management Level:

Our highest management levels promise the following in order to develop and improve our Quality Management System effectively:

A. Ensure all employees can understand our customers’ requirements and related government regulations.

B. Issue our Quality Policy and targets. Be responsible for our management level audit.

C. Ensure the necessary resources can be obtained and used.

5.3.2 Customer’s Focus:

We have issued the “Control of Survey on Customers’ Satisfaction” to measure the customers’ satisfaction level to our products and services. Also we make sure that we understand customers’ needs and expectations in order to satisfy them.

5.3.3 Quality Policy

A. We have issued our Quality Policy (see 2.1) and our highest management levels shall ensure our Quality Policy.

B. Meets our company’s requirements.

C. Includes effective commitments to continuously improve our Quality Management System.

D. Provides the framework for establishing and auditing our Quality Targets.

E. Being communicated and fully understood within the company.

F. Audit of Application for the quality policy.

5.3.4 Planning

5.3.4.1 Quality Targets

A. We have issued our Quality Targets (see 2.2).

B. Our Quality Targets include products and can be measured by data analysis.

C. The commitments of our Quality Targets and Policy are consistent.

5.3.4.2 Quality Plan

A. We have planned our Quality Management System in order to meet our Quality Targets (see 5.3.4.1) and Quality Management System requirements (see 5.3.1)

B. When our Quality Management System needs to be changed during the planning and implementation process, the system shall maintain its adequacy.

5.3.5 Responsibilities, Authority and Communication

5.3.5.1 Our management team has determined the responsibilities and authority of each department with the supervisors and prepared a document --- “Job Position Description”. It states the identification and communication of the responsibilities and authority within the company.

5.3.5.1.1 General Manager Responsibilities

A. General Manager has the foremost responsibility for quality. He shall lead the operations of our Quality System and he shall bear the responsibilities for the production, system management and quality management.

B. He is responsible for issuing, promulgating and approving our Quality Policy and targets. He also needs to review the Quality Manual and other important documents.

C. He is responsible for appointing the Management Representative, and ensuring that the Management Representative has the right to monitor the establishment and implementation of our Quality Systems.

D. He shall create and amend our organizational chart. He shall also provide sufficient resources to establish and implement our Quality Systems.

E. He shall plan for a regular management review.

F. He shall lead all departments to proceed the work, and in charge of internal quality activity.

G. Responsibility for the product incidents.

5.3.5.1.2 Management Representative Responsibilities

A. Ensure the essential procedures of our Quality Management System is established, implemented and preserved.

B. Lead the ISO Group directly and plan for Internal Quality Audits.

C. Report the performance and the required improvements of our Quality System to the highest management level.

D. Ensure and accelerate the understanding of the customers' needs within the company.

E. Be responsible for events and external communications of our Quality System;

5.3.5.1.3 Document control Responsibilities

A. Responsible for issuing the Management Review plan.

B. Responsible for issuing the Internal Quality System audit.

C. Responsible for managing documents and information.

D. Responsible for staff training of quality system.

E. Responsible for storing quality records.

F. Responsible for editing the Quality Manual.

G. Responsible for inspecting of 5S;

5.3.5.1.4 Quality Control Department Responsibilities

A. Responsible for issuing and implementing the specifications for raw material, accessories, semi-finished and finished goods.
B. Responsible for testing and inspection of each production process.
C. Responsible for managing the identification of testing and inspection.
D. Responsible for issuing and implementing the quality plan and inspection plan.
E. Prepare date analysis and quality analysis and make relevant records.
F. Be responsible for determining non-conforming products.
G. Be responsible for tracing non-conforming products and verifying corrective and preventive actions.
H. Be responsible for identifying products and tracing quality problems.
I. The Supervisor of the Quality Control Department has authority over the products' quality. If there are any quality problems, he can report to the highest management level and find a solution.
J. Be responsible for issuing and implementing the plan of machine calibration.
K. Be responsible for Lab management.

5.3.5.1.5 Production Control Department Responsibilities

A. Be responsible for contract review.
B. Be responsible for issuing and implementing a production and deliver plan.
C. Be responsible for changing orders and contracts.
D. Be responsible for tracking of each department production process.
E. Be responsible for production Non-conformity handling.

F. Be responsible for analyzing production reports and managing the sewing room in order to ensure quality production.

G. Be responsible for Strictly implement the Quality Policy and support the Quality Control Department.

H. Be responsible for holding the production plan meeting and meeting result tracking.

5.3.5.1.6 Purchasing department responsibilities

A. Be responsible for supplier development, selection and evaluation(first evaluation, second evaluation)

B. Be responsible for purchasing of the accessories and raw material based on the purchasing requirement list.

C. Be responsible for marketing price checking.

D. Be responsible for material tracking.

E. Be responsible for imported material procurement.

5.3.5.1.7 Material department responsibilities

A. Be responsible for receiving and dispatching of the raw material, accessories, semi-product and finished product.

B. Be responsible for monthly accounting.

C. Be responsible for shipment l based on shipment plan.

D. Be responsible for finished goods shipment and container loading.

E. Be responsible for material management based on First-in and First-out regulation.

F. Be responsible for report of stacked material.

G. Be responsible for a hygienic environment and disciplines within the department.

5.3.5.1.8 Production Department Responsibilities

A. Be responsible for issuing an operation plan according to the production plan, including the work allocation of each group, production quantity, progress and the individual quality standards

etc.

B. Be responsible for monitoring the operations progress of each production group, controlling the delivery dates and ensuring the products' quality.

C. Be responsible for work guidelines and technical instructions.

D. Be responsible for the production process management and monitoring packing inspections, finished goods inspections and input to the warehouse.

E. Be responsible for guiding each group to handle quality problems and implement corrective and preventive actions. Also they shall implement the non-conforming control and re-make products.

F. Identification management of the semi-finished goods, finished goods and temporary stock inspections and testing.

G. Be responsible for a hygienic environment and disciplines within the department.

H. Be responsible for creating Operation Instructions and technical information.

I. Be responsible for production process management and managing each sewing room to prepare a suitable production plan.

J. Responsible for coordinating work and preventing conflicts among the sewing rooms.

K. Responsible for staff training within the department.

L. Support the Production Control Department and Quality Control Department.

5.3.5.1.9 Human Resources Department Responsibilities

A. Responsible for employing and arranging new employees.

B. Responsible for approving and recording attendance and casual leave of staff.

C. Responsible for confirming and releasing staff cards, uniforms, attendance cards and mess cards etc.
D. Responsible for monitoring staff messing.
E. Responsible for handling staff resignations.
F. Responsible for staff training and evaluations.
G. Responsible for issuing and storing staff records.
H. Responsible for KPI Salary plan and organizing the implement.
I. Responsible for work position analysis and the human resources plan.
J. Responsible for fire prevention, burglary prevention and the factory environmental hygiene.
K. Responsible for factory safety measures.
L. Responsible for preserving the live-in facilities, fire prevention equipment and hygienic equipment.
M. Responsible for handling staff conflicts, help with staff resignations.
N. Responsible for recreational activities and facilities preservation.
O. Responsible for hygienic environment and disciplines within the department.

5.3.5.1.10 Sales and Marketing Department Responsibilities

A. Responsible for communication with customers.
B. Responsible for customers' complaint tracking.
C. Responsible for order receiving, issuing and communication with customer for order delivery issue.
D. Responsible for communication with customers for ordering process and goods inspection.
E. Responsible for offering the customers' product specification (quality requirement, shipping mark and package, etc)
F. Responsible for samples follow-up issue.

G. Responsible for receiving the information , translation and reply.
H. Responsible for a hygienic environment and disciplines within the department.

5.3.5.1.11 Financing Department Responsibilities

A. Prepare accounts receivable and payable.
B. Prepare cash books, bank books、profit and loss accounts and wages record.
C. Calculate the cost and profit of the products and orders.
D. Responsible for reporting the business performance to the Board of Directors.
E. Monitor receipts and the release of material from the Production Control Department, also the wastage of the Production Department.
F. Handle the tax administration.
G. Prepare the financial analysis and report every season and submit to the Board of Directors.
H. Be responsible for a hygienic environment and disciplines within the department.

5.3.5.1.12 Technical department responsibilities

A. Responsible for product specification drafting and revision.
B. Responsible for drafting and revising of the cutting layout.
C. Responsible for product usage drafting and revision.
D. Responsible for samples making ,technical document drafting and original samples records.
E. Responsible for material procurement of all the samples making.
F. Responsible for material standard usage and material requirement of each order.
G. Responsible for equipment procurement, installation, maintenance.

5.3.5.1.13 Internal Auditor Responsibilities

A. Responsible for implementing internal audits and reviewing the audit result reports.
B. Responsible for verifying corrective and preventive actions of non-conforming items.
C. Responsible for a hygienic environment and disciplines of the work position.

5.3.5.1.14 The above documents covered and clearly regulate the responsibilities and authority of each employee in order to implement the above work.

A. Carry out effective actions to prevent the problems and non-conformances related to products, production process, internal audit and the management review.
B. Implement the suggestions or provide solutions and verify the implementation result.
C. Control non-conforming products to prevent re-occurrence and delivery.

5.3.5.2 Management Representative

General manager has appointed a staff to be the management representative. His responsibilities and authority are stated in3.5.1.2

5.3.5.3 Internal Communications

5.3.5.4 We have issued the “Control of Communications”. Internal communications shall be performed through meetings, contact lists, telephone and notices etc. Contents of communication include:.

A. Results of evaluations of Procedures.
B. Customers’ feedback (Returned goods, complaints and satisfaction survey etc.)
C. Non-conformance Statistical Reports and Production Process evaluation results.

D. Quality Policy implementation status.

E. Management Review records.

5.3.6 Management Review

5.3.6.1 We have issued the “Control of Management Review” to be referred to as the management commitments and audits.

5.3.6.2 The General Manager shall audit the implementation of our Quality System once a year in order to ensure the system is implemented consistently, appropriately and effectively.

5.3.6.3 The audit shall include our Quality Policy and targets in order to check if it is possible to make improvements or adjustments.

5.3.6.4 The Management Review shall include the following information:

A. The verification analysis of each corrective and preventive action in the previous management review.

B. Our Quality Policy and target implementation and completion status.

C. The internal and external audit results and report.

D. The handling methods of any significant quality problems.

E. Complaints, suggestions and comments from customers and related parties and also the handling methods.

F. Our Quality System process, procedures and product’s’ quality trends. Products’ quality analysis and process analysis etc.

G. The need to change our Quality System documents.

H. Any improvement suggestion.

I. New or revised regulation requirement.

5.3.6.5 The Management Review shall summarize the following

A. Any effective improvements of our Quality System and its procedures.

B. Improvements of the customers’ required products.

C. Resources needed for implementing our Quality System procedures.

5.3.6.6 Management Review shall be recorded.

5.4 Related Documents and Information

5.4.1 The Management Review shall summarize the following

A. Any effective improvements of our Quality System and its procedures;

B. Improvements of the customers' required products.

C. Resources needed for implementing our Quality System procedures.

5.4.2 Management Review shall be recorded

6.0 Resources Management

6.1 Purpose

To supply essential resources in order to satisfy customers, implement and improve our Quality Management System.

6.2 Scope

The resources include manpower, equipment and work environment that meets the requirements for producing our products.

6.3 Management Main Points

6.3.1 Supply of Resources

We determine and provide resources according to the manpower, equipment and work environment:

A. To implement and preserve our Quality System and continuously improve its effectiveness.

B. Satisfy customers' needs.

6.3.2 Human Resources

For employees who are regulated by quality procedures and influence the products' quality.

A. Provide training based on suitable education, techniques and experiences.

B. Ensure the related employees have the ability to implement their jobs and the related procedures.

6.3.3 Ability, Training, Qualification and Cognition

6.3.3.1 We have issued the "Control of Human Resources" and we have determined the qualifications for the critical work positions or special work position in order to provide training.

6.3.3.2 We evaluate the ability, training, qualifications and cognition based on the following.

A. The ability required for employees who are responsible for procedures related to quality.

B. Provide training or carry out any actions to fulfill these requirements.

C. Evaluate the effectiveness of actions taken.

D. Ensure the employees know their relationship with and importance to the quality procedures and how they can contribute to meet quality targets.

E. Keep education, training, technique and experience records.

6.3.4 We have issued the “Control of Equipment and Workshop Environment” so that we have effective control of buildings, workspaces and other related equipments.

6.4 Related Documents and Information

6.4.1 “Control of Human Resources”

7.0 Manufactured Goods Production

7.1 Purpose

To plan the production procedures according to their priority in our Quality System and develop the required procedures.

7.2 Scope

All our Quality System plans issued for the manufactured goods production.

7.3 Management Main Points

7.3.1 Plan for the production procedures

7.3.1.1 We have issued the “Product Specification” as a guidance to implement our Quality Plan.

7.3.1.2 We have issued the “Quality Management System Flow Chart” to show the required procedures and development of the manufactured goods production. And the requirements are the same as that of the Quality Plan.

7.3.1.3 Our Quality System determines the production procedures plan according to the following requirements.

A. Refer to the quality target and the manufactured goods requirements.
B. Work together with the Quality System requirements to set up the related procedures and documents in order to have enough resources for the manufactured goods production.
C. Verification, confirmation, monitoring, inspection and testing procedures for the products delivery and set up acceptable standards for the incoming material and finished goods.
D. Store the records necessary for the incoming material, production and the delivery process for the procedures and production of the final products.

7.3.1.4 We have established the “Risk management procedure” as resolving plan to accomplish to production procedure.

7.3.1.5 Risk management must be recorded.

7.3.2 Customers’ Related Processes.

7.3.2.1 We determine the products’ requirements according to the following items.

A. The requirements stated on the customers’ orders or written information (including Faxes) or other specified requirements.
B. The essential requirements related to the products functions, characteristics and use can be listed as the products’ requirements although customers do not clearly specify or request.
C. The requirements related to the product regulations.
D. We determine extra requirements based on the products.

7.3.3 Review of Customers’ Related Requirements

7.3.3.1 We have issued the “Control of Customers’ Related Processes” for reviewing customers’ requirements.

7.3.3.2 The Production Control Department, Quality Control Department, General Manager and other related departments shall review the orders when receiving or changing orders so that the Production Control Department can promise customers to deliver goods on time.

7.3.3.3 During the order review, we shall include and ensure the following.

A. The product names, specifications, quantity, delivery date and the customer's specified requirements are stated on the orders.

B. Through the order review, we shall confirm that we can satisfy customers' requirements also the requirements stated in sections 3.2 and 3.3. The Production Control Department can then accept customers' orders.

C. The order review records and handling records (including acceptance and change of the orders) shall be preserved and stored according to the "Quality Control Record"

7.3.4 Communication with Customers

7.3.4.1 We have issued "Control of Communications" in order to communicate with the customers effectively and satisfy their requirements.

7.3.4.2 The Production Control Department shall communicate with customer's on the following items:

A. Communicate and provide related products' information.

B. Quotation for customers and the handling of customers' orders and changed orders.

C. Report the implementation and progress of orders to customers. If product requirements change, we shall fill in the "Order Changed Notice" so that each related department and customer gets consistent information.

D. After the delivery of goods, we shall collect feedback from customers and handle complaints in order to satisfy each customer. Also we shall follow the regulations in the "Control of Survey on Customers' Satisfaction"

E. Advice. If we got any bad feedbacks from any customer regarding to one product, we have right to advice the other customers. Any complaints is without corrective action and preventive action, the

product shall be released by customer's approval. If national or regional regulations comply with the advice requirement, we will inform the local authorities in the written letters

7.3.5 Design and Development

We are an OEM factory, all our products are made according to samples or specifications provided by the customers. Therefore we do not design and develop the products ourselves.

7.3.6 Purchasing

7.3.6.1 Purchasing Process: We have issued the "Control of Purchasing" for purchasing procedures, choosing and evaluating suppliers. So we can ensure purchasing meets our regulations and customers' requirements.

7.3.6.1.1 During purchasing, we shall fill in the "Purchase Order" according to the material required for each department and the "Purchasing List" from the warehouse supervisors. The purchase orders shall state clearly the suppliers' names, item names, styles, quantity, delivery date and specified products' requirements. We can only purchase goods after receiving the factory manager's approval.

7.3.6.1.2 When we need to choose new suppliers, we shall consider the production capacity of the required products and also evaluate and choose the suppliers with the Quality Control Department.

7.3.6.1.3 Based on the evaluation results, we shall set up a qualified suppliers list and have it approved by the General Manager. The quality department shall re-evaluate the qualified suppliers once a year about the delivery status and their performance. For the suppliers who cannot meet our requirements repeatedly, their qualifications shall be canceled. When the products supplied have critical quality problems, the Purchasing Department shall push supplier to correcte.

7.3.6.1.4 The records of choosing and evaluating suppliers as well as other measures shall be preserved and stored.

7.3.6.2 Purchasing Information

7.3.6.2.1 Purchasing information includes product names, styles, quantity, quality, prices and services required. Before issuing purchase orders to the suppliers, we shall first approve and compare the “Purchasing List” with the “Purchase Orders” so that what we purchased is consistent with the regulated requirements. If they match and have no mistakes, then we can purchase products.

7.3.6.2.2 We have documentation for the purchasing information mainly the “Purchasing List” and the “Purchase Order”. The “Purchasing List” and “Purchase Order” shall state the material purchased and the product requirements and shall be attached and stored with the corresponding orders.

7.3.6.3 Purchasing Verification

7.3.6.3.1 When the suppliers deliver products, the warehouse staff shall receive and put the material into the warehouse according to the “Control of Products’ Preservation”. The Quality Control Department shall inspect and test the incoming material according to the “Control of Inspection and Testing”

a) The Production supervisors and engineers are responsible for verifying the equipment and the moulds;
b) The related units are responsible for verifying the other material.
c) The production materials are verified by IQC

7.3.6.3.2 For products or items (such as non woven material) that we cannot inspect ourselves, we shall request the suppliers to provide the products’ inspection report. For raw materials and accessories that need to be used urgently and cannot be inspected and tested, the Production Control Department shall fill in the “Special Release Application Form” and have it approved by the factory manager. The special released material or the products made by it shall be

quarantined and recorded. At the same time they shall be labeled as "Special Release" so that Quality Control Department can inspect and test the goods as well as trace the goods if there are any problems.

7.3.7 Production and Services Provided

7.3.7.1 Control of Providing Production and Services

7.3.7.1.1 The Production Control Department shall understand the specified products' characteristics through the "Product Manual", "Control of Services" and the products' charts. They shall also obtain the essential information according to the production process plan results and the customers' requirements review results.

7.3.7.1.2 The Quality Control Department is responsible for compiling the "Product Manual". It shall include the Production Process Regulations and Quality Control Regulations etc.

7.3.7.1.3 The Production Department shall consider the warehouse status, sewing room status, production capacity, production time arrangement and the production plan according to the purchase orders. The statisticians shall generalize the production status and report to the Production Department.

7.3.7.1.4 The Production Control Department shall arrange suitable equipment for each sewing room. Each sewing room shall preserve and maintain the equipment according to the "Control of Equipment and Workshop Environment" in order to ensure the operation capacity is regulated. Each sewing room shall arrange and use suitable measuring and monitoring equipment to monitor products and processes according to the "Control of Monitoring and Measuring Devices".

7.3.7.2 Confirm the Process for Providing Production and Services

The process confirmation methods and contents:

7.3.7.2.1 Cleaning and contamination of the product

For the cleaning and contamination of the product, it is only the

material itself without outer package, it is accordance with ‘product specification” and testing standard regulation

7.3.7.2.2 Installation process

The company's products, its instructions are defined in the specification, requires no installation activities.

7.3.7.2.3 Service activities:

A. Customer service department reply to the customer’s enquiries, and make survey of our product and service to customers irregularly.

B. Production department makes the evaluation of the customer order, inform the customer service staff if the result is not up to the customers requested delivery time, then customer service staff will coordinate with customer.

C. Quality department makes the evaluation of the customers complaint, organize the relative person to discuss, define the improvement plan, proceed the plan and track the performance.

D. Technical department makes samples based on customers requirement, inform the result to Customer service department, ask them to communicate with customers if there is any difficulty.

7.3.7.2.4 Requirement of Sterile Medical Devices

All our sterilization process is subcontracted. Subcontracted company must records every sterilization parameter for trace. Evaluating the subcontracted supplier based on Evaluation of the supplier Standard. For the sterilization proceeded by customers, we only offer the Production.

7.3.7.3 Confirmation process of production and service

7.3.7.3.1 Confirmation process of production is as follows:

A. Whether the product realization process meets to the requirement and effective implementation.

B. Whether all the machines are maintained according the maintenance plan, all the employees are trained so as to qualification for production.

C. Whether monitoring and recording the production process.

D. Re-confirm the process based on regulated time interval, or reconfirm when the production condition was changed, so as to make the quick response on process change.

7.3.7.3.2 Requirement of Sterile Medical Devices

All our sterilization process are subcontracted, before sterilization, we must measure the bioburden and make records for each sterilization process of each Lot. For sterilization handled by customer, we only offer the production before sterilization .

7.3.7.4 Product Identification and Traceability

7.3.7.4.1 We have issued the “Control of Identification and Traceability” for identifying and tracing incoming material, production processes and finished goods.

7.3.7.4.2 Identify the production and inspection status according to the identification and monitoring results.

7.3.7.4.3 Status identification includes the inspection status labels and special release labels. Inspection status labels include conforming goods, non-conforming goods and Goods To be Inspected and shall be stated on the identification cards. Special release labels include goods that need to be used urgently and inspection has not been completed. The identification cards shall show as urgent released and the cards shall be put in the product storage places.

7.3.7.4.4 The product identification and traceability records shall be preserved and stored.

7.3.7.4.5 Active implantable medical devices and implantable medical devices ‘s requirement, our products do not have this requirement

7.3.7.5 Customers' Property

7.3.7.5.1 We have issued the "Control of Customers' Property" for controlling and using the customers' property.

7.3.7.5.2 For the raw material, semi-finished goods, finished goods and products' charts provided by the customers, they shall be identified, verified, and preserved and protected according to the regulations.

7.3.7.5.3 If the customers' property is lost, damaged or inappropriate for use, Production Control Department shall report to the customers and make the relevant records.

7.3.7.6 Products' Preservation

7.3.7.6.1 We have issued "Control of Products' Preservation". It is regulated to preserve the products from receipt, production, packing and delivery to the destination.

7.3.7.6.2 Preservation shall include the identification, movement, packing, storage and protection of products in order to effectively prevent their deterioration, damage, and misuse

7.3.7.7 Measuring and Monitoring Devices Control

7.3.7.7.1 We have issued "Control of Monitoring and Measuring Devices" for controlling the monitoring and measuring devices so that the products meet the requirements. Also ensure the effectiveness of the results.

7.3.7.7.2 All the monitoring and measuring devices shall be identified with serial numbers, calibrated regularly and preserved suitably according to regulations.

7.3.7.7.3 When the calibration of the devices does not meet their requirements, they shall be re-inspected or repaired. Also we shall stop using these devices and make relevant records.

7.4 Related Documents and Information

7.4.1 "Product Manual"

7.4.2 "Control of Customers' Related Process

7.4.3 “Control of Equipment and Workshop Environment”

7.4.4 “Control of Purchasing”

7.4.5 “Control of Production Processes”

7.4.6 “Control of Identification and Traceability”

7.4.7 “Control of Customers’ Property”

7.4.8 “Control of Products’ Preservation”

7.4.9 “Control of Monitoring and Measuring Devices”

7.4.10 “Control of Inspection and Testing”

7.4.11 “Control of Quality Records”

7.4.12 “Control of Customers’ Services”

8.0 Measuring, Analysis and Improvements

8.1 Purpose

Plan and implement the measuring, monitoring, analysis and continuous improvements of the production process. Ensure the quality system, procedures, products or services can meet our process and customers’ requirements.

8.2 Scope

All the measuring and monitoring procedures related to our Quality Management System, process, products and services.

8.3 Management Main Points

8.3.1 Overview

We have planned the required methods (including the statistical methods for data analysis) for the “Internal Quality Audit”, “Process Monitoring and Measuring”, “Product Monitoring and Measuring”. Therefore the products and services can meet customers’ requirements and international standards requirements in order to continue implementing and improving the quality system effectively.

8.3.2 Measuring and Monitoring

8.3.2.1 Customers satisfaction

We have issued the “Customer Service Control Procedure” and “Control of Survey on Customers’ Satisfaction for planning, monitoring and measuring

the customers' satisfaction and dissatisfaction level to show the performance of the quality system. Through Customer service department, we inform our customers about our relative product information as first alert. While for customers compliant, we must reply to our customer and verify it. For any complaint which was not take the preventive action and corrective actions, it will be recorded as customer approved it If national or regional regulations comply with the advice requirement, we will inform the local authorities in the written letters.

8.3.3 Internal Quality Audit

8.3.3.1 We have issued the "Control of Internal Audit" for planning and implementing the internal audit regularly and also specifying the responsibilities and requirements of the audit.

8.3.3.2 Auditors shall be fair and objective during the internal audit in order to ensure the integrity of the audit.

8.3.3.3 Internal audit shall be recorded according to the "Control of Quality Record"

8.3.3.4 Internal audit result shall include:

A. Non-conforming items. The responsible unit is responsible to investigate the cause and carry out corrective and preventive actions in order to eliminate the non-conformances.

B. Auditors shall verify the results of the corrective and preventive actions in order to ensure the effectiveness of these actions.

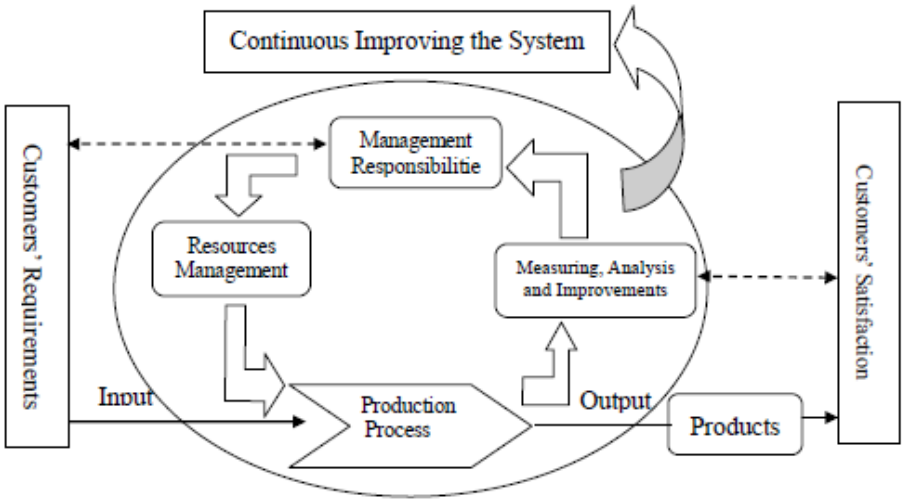
8.3.4 Process Monitoring and Measuring

8.3.4.1 Our process monitoring and measuring target is our Quality System Procedures including all processes and sub-processes issued according to the products' attributes. The Production Control Department shall identify the processes which shall be measured and monitored.

8.3.4.2 The purpose of process monitoring and measuring is verifying if the process is performing and meets its expected results. Each quality

procedures shall be resolved and become part of the Quality Policy. Through process monitoring and measuring, the implementation of quality policy can be measured.

8.3.4.3 We established the following flow chart for continuous improvement of the Quality System according to the Quality Management System :



8.3.4.4 We implement internal audits every year according to section 3.3 “Control of Internal Audits”. We shall fulfill the expected results of every procedure in order to make improvements continuously.

8.3.4.5 We monitor and measure the procedures according to section 3.4.4. If any non-conformance is found or the expected results cannot be achieved, we shall take actions according to the “Control of Corrective and Preventive Actions” in order to ensure our Quality System and products are appropriate.

8.3.5 Monitoring and Measuring Products

8.3.5.1 We have issued the “Control of Inspection and Testing” for monitoring and measuring production including incoming material, production in-process and finished goods. This inspection will be done according to our Quality Plan in order to ensure our products meet requirements.

8.3.5.2 Incoming material, production in-process and finished goods inspections shall be implemented according to “Inspection Regulations”.

8.3.5.3 Incoming material, production in-process and finished goods shall pass the inspection. Passed goods shall be labeled and approved by the Quality Control Supervisors before being put into the warehouse. Warehouse staff shall handle the goods according to the “Control of Products’ Preservation”

8.3.5.4 If any non-conformance is found or if customers’ requirements are not satisfied during the inspection, we cannot put those goods into the warehouse or release them for shipment. The goods shall be handled according to the “Control of Non-Conforming Products”.

8.3.5.5 Active implantable medical devices and implantable medical devices‘s requirement, our products do not have this requirement.

8.3.6 Non-Conforming Products Control

8.3.6.1 We have issued the “Control of Non-Conforming Products” to ensure that non-conformances and products’ requirements are identified and under control. We also can prevent delayed shipments and regulate the responsibilities and authority for the units to handle and solve non-conforming products.

8.3.6.2 Non-conforming Products Control includes determination, identification, records and handling methods etc. Non-conforming products handling methods are as follows:

8.3.6.2.1 Eliminate non-conforming products by remaking or reworking. For mass product reworking, it needs documents to support.

8.3.6.2.2 During special situations, we can purchase non-conforming products if the General Manager approves or customers agree.

8.3.6.2.3 Change the use or function of the product, for example obsolete a product.

8.3.6.3 We shall use one or more than one of the above methods to handle non-conforming products according to the actual situation and the customers’ requirements. The identification and handling methods of

non-conforming products which are found during the delivery and usage of the incoming material, production process and finished goods are regulated clearly in the “Control of Non-Conforming Products”.

8.3.6.4 The handling and tracing of non-conforming products shall be recorded and stored according to the “Control of Quality Record”

8.3.7 Data Analysis

8.3.7.1 We have issued the “Control of Data Analysis” for collecting and analyzing the data to verify the suitability and effectiveness of our Quality System. Through data analysis the system can be continuously improved.

8.3.7.2 Data analysis shall include the following:

A. Customers’ satisfaction level.
B. The characteristics of the process and products, also the data of the critical procedures.
C. Data about the product qualification rate.
D. Data related to the capacity of equipment; and the production efficiency and effectiveness.
E. Data and information related to the suppliers’ performance.
F. Data about Human Resources and work environment.
G. Data about the effectiveness of our entire Quality Management System.

8.3.7.3 The methods for collecting, transferring and analyzing the data are clearly regulated in the “Control of Data Analysis”

8.3.7.4 The Quality Control Department is responsible for provide statistical methods training to the related employees in order to ensure the scientific and authenticity of the statistical analysis data.

8.3.7.5 The Quality Control Department monitors and checks the records of the statistical methods applied by each department regularly. For the critical quality problems, the responsible departments shall take relevant corrective and preventive actions to make improvements.

8.3.7.6 The ISO Group shall review and evaluate our Quality System according to the data analysis results. The conclusion of the data analysis shall be submitted for Management Review as the foundation for improvement.

8.3.8 Improvements

8.3.8.1 Continuous Improvement

8.3.8.1.1 Through our Quality Policy, policy targets, audit results, data analysis, corrective and preventive actions and the management level audit, we can improve the products continuously and improve the efficiency of our Quality System effectively.

8.3.8.1.2 In order to continue improving our Quality System, we shall do the following:

A. Motivate the employees to make improvements by issuing and implementing our Quality Policy.
B. Set up clear quality targets for improvements.
C. Summarize the data analysis results and the internal audit results in order to analyze deviations.
D. Take effective corrective and preventive actions to correct problems. Verify and evaluate the results and confirm new improvement plans.
E. If national or regional regulations comply with the advice requirement, we will inform the local authorities in the written letters.

8.3.8.2 Corrective Actions

8.3.8.2.1 We have issued the “Control of Corrective and Preventive Actions” for eliminating the causes of non-conforming products and our Quality System in order to prevent re-occurrence of these problems.

8.3.8.2.2 Through survey analysis, find out the causes of non-conformances. The Quality Control Department shall draft the corrective actions to prevent the re-occurrence of the problems and also to verify results.

8.3.8.2.3 We shall pay more attention on the non-conformance review caused by customers' complaints. The corrective actions and communication with the customers shall be implemented according to the "Control of Corrective and Preventive Action" and "Control of Customers' Services"

8.3.8.2.4 For the documents needed to be amended, we must revise it in time.

8.3.8.3 Preventive Actions

8.3.8.3.1 We have issued the "Control of Corrective and Preventive Actions" for eliminating the potential causes of the non-conformance of products and our Quality System (including the customers' complaints) in order to prevent the re-occurrence of problems.

8.3.8.3.2 We shall analyze data and information from each procedure (supply quantity, product quantity, market analysis and customers' satisfaction survey etc.) in order to understand the effectiveness of our operation, quantity trends of products and customer's needs and expectations.

8.3.8.3.3 If any potential non-conformance is found, the Quality Control Department shall investigate and discuss with the related departments. They shall take preventive actions according to the effects of the non-conformance. Also they shall verify the results and re-analyze actions which do not have significant results.

8.3.8.3.4 For our Quality System documents that need to be changed because of continuous improvements and the implementation of corrective and preventive actions, the changes shall be made according to the "Control of Documents" and the related records shall be stored and submitted for management review.

8.4 Related Documents and Information

8.4.1 Control of Survey on Customers' Satisfaction"

8.4.2 "Control of Internal Audit"

8.4.3 "Control of Inspection and Testing"

8.4.4 “Control of Non-Conforming Products”

8.4.5 “Control of Data Analysis”

8.4.6 “Control of Corrective and Preventive Action”

8.4.7 “Control of Customers’ Services”

8.4.8 “Control of Quality Record”

8.4.9 “Control of Products’ Preservation”

8.4.10 “Product Manual”

8.4.11 “Inspection Regulations”

9.0 Medical Device Directive

9.1 Purpose

To make sure all products with CE mark can match the requirement of EU Medical Device directive and standard.

9.2 Scope

For the control all technical file and products with CE mark.

9.3 Management Main Points

9.3.1 edit and act the procedure document of medical device directive control;

9.3.2 Basic Requirement

9.3.2.1 to guarantee the products to marker is safe and valid.

9.3.2.2 Before the CE mark, the products has satisfied the basic requirement from Attachment I of MDD93/42/EEC.

9.3.3 Product Category

The category for all CE marked products is following the attachment IX of MDD93/42/EEC

9.3.4 Product Risk Analysis

The risk analysis of the CE marked is following ISO14971.

9.3.5 Product Approval/ Documentation

9.3.5.1 The products could be CE marked with the compliance of MDD93/42/EEC and qualified quality system.

9.3.5.2 The content of CE marked products shall be preserved as available

principles.

9.3.5.3 Each products category with CE marked shall be kept as a technical file following MDD93/42/EEC attachment II.

9.3.6 Product Label and Language

All CE marked products labels shall follow attachment II AND attachment XII of MDD93/42/EEC, and the language shall match the requirement of the EU countries that the products sell to.

9.3.7 Clinical Evaluation

The clinical evaluation shall follow the attachment X and MEDDEV 2.7/1 Rev. 4 .

9.3.8 Follow up after sales

After sales for the CE marked products shall follow MDD93/42/EEC

9.3.9 Report

When the products have the following incidents, it shall inform the validation party with the report.

9.3.9.1 The damage or breakdown of the products nature or performance, and the improper labels or instructions may lead or has led the user seriously worsen or death.

9.3.9.2 All products shall be returned due to the technical or medical nature or performance in above incidents.

9.3.10 Package validation

The small, medium and outer package material shall be validated to follow ISO11607.

9.3.11 Sterilization Validation

The products shall be sterilized with the follow of ISO11135 and ISO13485 and the sterilization result shall be validated to make sure if it is compliant with the standard.

9.4 Procedure documents

9.4.1 CE control procedure of technical document

9.4.2 Product category procedure

9.4.3 Risk Analysis Procedure

9.4.4 Clinical Evaluation Procedure

9.4.5 Follow up after sales Procedure

9.4.6 Package validation

9.4.7 Sterilization control procedure

9.4.8 Product Label and Language control Procedure

9.4.9 Notification to validation part procedure for the product and system change

9.4.10 Warning System Procedure

9.4.11 Edition Procedure of the compliance notification

10.0 Responsibility List

ISO13485:2016 Clause		Procedure document	Doc No		Dept.							
				General manager	Management Representative	Matenial Dept	Manufacturing	Quality Control	Sales	Product Develop	HR	Purchasing
4quality management system	4.2.3	document control	3A-QP-01	○	●	○	○	○	○	○	○	○
	4.2.4	Record Control	3A-QP-02		●	○	○	●	○	○	○	○
5management responsibility	5.5.3	Internal communication	3A-QP-03		●	○	○	○	○	○	○	○
	5.6	Management review	3A-QP-04	●	●	○	○	○	○	○	○	○
6 Resource Management	6.2	HR management control	3A-QP-05	○	○	○	○	○	○	○	●	○
	6.3/6.4	Environment and settings control	3A-QP-06	○	○	○	●	○	○	○	○	○
7 Product Realization	7.1	Quality plan control	3A-QP-07	○	○	○	○	●	○	○	○	○
	7.2	Procedure Related to Customer	3A-QP-08	○	○	○	○	○	●	○		○
	7.3	Design transfer control	3A-QP-09		○	○	○	○	○	●		○
	7.4	Purchase control	3A-QP-10			○	○	○	○	○		●
	7.5	Production process	3A-QP-11			○	●	●	○	○	○	○
	7.5.3	identification and trace	3A-QP-12		○	○	○	●	○	○		○
	7.5.4	Customer property control	3A-QP-13			●	○	○	○	○		○
	7.5.5	Product protective control	3A-QP-14			●	○	○	○	○		○
	7.6	Measure and monitor control	3A-QP-15			○	○	●	○	○		○

8analysis, measurement and improvement	8.2.1	Customer service control	3A-QP-16		○	○	○	○	●	○		○
		Customer satisfaction	3A-QP-17		○	○	○	○	●	○		○
	8.2.2	Internal audit control	3A-QP-18	○	●	○	○	○	○	○	○	○
	8.2.3/ 8.2.4	Inspection and test control	3A-QP-19		○	○	○	●	○	○		○
	8.3	Unqualified products	3A-QP-20		○	○	○	●	○	○		○
	8.4	Data analysis control	3A-QP-21		●	○	○	●	○	○	○	○
	8.5.2/ 8.5.3	CAPA control	3A-QP-22	○	●	○	○	●	○	○	○	○

●Responsible ；○Co-help

MDD93/42/EEC Ax.V.3 Procedure document	Doc No	Dept.							
		General manager	Management Representative	Product Management	Manufacturing	Quality Control	sales	EU representative	Distributor
CE Technical Document control	3A-QP-30	●	●	○	○	○	○		
Product category	3A-QP-31		●	○	○	●	○		
Risk analysis	3A-QP-32		●	○	○	○	○		
Clinical Evaluation	3A-QP-33		○	○	○	●	○		
After sales follow up	3A-QP-34		●	○	○	○	●	○	○
Package validation	3A-QP-35		○	○	○	●	○		
Sterilization control	3A-QP-36		○	○	○	●	○		
Label and Language control	3A-QP-37		○	○	○	●	○	○	
Notification to validation part procedure for the product and system change	3A-QP-38		●	○	○	○	○		
Warning System	3A-QP-39		●	○	○	○	○	○	○
Edition Procedure of the compliance notification	3A-QP-40	●	●	○	○	○	○	○	

●Responsible ； ○Co-help