Medical Device Good Distribution Practice
Case Book

Introduction

Hong Kong Medical and Healthcare Device Industries Association (HKMHDIA) and Hong Kong Productivity Council (HKPC) applied the "SME Development Fund" of the Trade and Industry Department to implement a project titled "To Upgrade the Overall Competence of the Local Medical and Healthcare Device Industry SMEs in Operation and Distribution in order to Enhance Their Competitiveness in the Global Market".

In this project, three local medical device distributors were selected to participate in a pilot scheme, in which they were assisted to establish a quality management system of the "Medical Device Good Distribution Practice" (MDGDP). The three pilot companies are representative among local medical device distributors due to their corporate size, business nature, operation model, etc. At the end, the three pilot companies have successfully passed the mock audit performed by the British Standards Institution (BSI). HKMHDIA expects that this project could serve as reference to local medical device distributors, for upgrade their distribution operations to get ready with the future local mandatory regulations and to fulfill the stringent international regulations on medical devices.

This case book will analyze the MDGDP documentation requirements, including defining what is the required documents, the document format requirements. This is to encourage the local industry to understand the detail operation procedures of MDGDP and establish effective operation procedures.

Based on the differences in category and post-distribution between different medical devices, MDGDP can be inclusive of different characteristics and requirements of distribution activities. This book will explain the basic requirements of the system, at the same time introduce the specialties of each of the three pilot companies to ensure that this book could match the needs of variety of local SMEs.

Disclaimer

Any opinions, findings, conclusions or recommendations expressed in this material or event (or by members of the project team) do not reflect the views of the Government of Hong Kong Special Administrative Region, Trade and Industry Department or the Vetting Committee for the SME Development Fund and the Dedicated Fund on Branding, Upgrading and Domestic Sales (Organisation Support Programme).

This case book or event is for information purpose only. Whilst every effort has been made to ensure the accuracy of the information supplied herein. The publisher of this material and the associated organization in this programme cannot be held responsible for any damage or claim resulting from the use of the information.

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Table of Content

CHAPTER 1. OVERVIEW 8

1.1 Structure of MDGDP 9

1.2 Comparison of the Main Elements of Three Routes 10

1.3 Main Elements under MDGDP 11

1.4 Relationship of MDGDP System Complexity and Organization Structure 12

1.5 Core Processes and Exemptions Depend on Corporate Structure 13

CHAPTER 2. DOCUMENT FORMAT 14

1.6 Format of Document List 15

1.7 Format of COPs (Cover) 17

1.8 Format of COPs (Content) 18

1.9 Format of Work Instruction 19

1.10 Format of Form 20

CHAPTER 3. SAMPLE OF QUALITY MANUAL 21

1.11 Sample of Quality Manual 22

CHAPTER 4. SAMPLE OF CORPORATE OPERATION PRACTICE 51

1.12 Document Control Procedures 52

1.13 Management Review Procedures 57

1.14 Regulatory Requirements Procedures 59

1.15 Staff Development Procedures 61

1.16 Internal Audit Procedures 64

1.17 Aftersales Service Procedures 66

1.18 Product Identification and Traceability Procedures 68

1.19 Customer Property Handling Procedures 70

1.20 Infrastructure and Work Environment Management Procedures 72

1.21 Receipt, Verification and Acceptance of Incoming Goods Procedures 76

1.22 Storage and Stock Monitoring Procedures 80

1.23 Customer Order Handling Procedures 82

1.24 Products Delivery Procedures 85

1.25 Customer Satisfaction, Feedback and Complaint Handling Procedures 87

1.26 Sterile Product Procedures 89

1.27 Control of Nonconforming Product and Service Procedures 91

1.28 Corrective and Preventive Action Procedures 94

1.29 Advisory Notice Handling Procedures 97

1.30 Product Recall Procedures 99

1.31 Risk Management Procedures 101

1.32 Adverse Incident Reporting Procedures 108

1.33 Supplier Evaluation Procedures 111

1.34 Purchasing Procedures 115

1.35 Calibration of Measuring Equipment Procedures 117
CHAPTER 5. WORK INSTRUCTION SAMPLE 119
1.36 Warehouse Instruction 120
1.37 Incoming Goods Inspection Instruction 123
1.38 Product Identification and Segregation Instruction 125
1.39 Product Disposal Instruction 126
CHAPTER 6. FORM SAMPLE 127
1.40 Quotation Record 128
1.41 Quotation 129
1.42 Tender Record 130
1.43 Purchase Order 131
1.44 Invoice Record 132
1.45 Invoice 133
1.46 Stock Record 134
1.47 Delivery Note 135
1.48 Warehouse Cleaning Record 136
1.49 Warehouse Temperature Record 137
1.50 Specific Competence Requirements of Third-party Employee 138
1.51 External Training Record 139
1.52 Third-party Logistic Supplier Monitoring Record 140
1.53 Third-party Logistic Supplier Re-evaluation Record 142
1.54 Product Maintenance Form 145
1.55 New Staff Training Record 146
1.56 Specific Competence Requirement List 148
1.57 Employee Training Record 149
1.58 Approved Supplier List 150
1.59 Supplier Evaluation Form 151
1.60 Supplier Re-evaluation Form 153
1.61 Customer Satisfactory Survey 155
1.62 Customer Complaint Feedback Form 156
1.63 Corrective and Preventive Action Record 157
1.64 Product Recall Form 159
1.65 Nonconforming Product Report 160
1.66 Risk Management Report 161
1.67 Internal Audit Checklist 166
1.68 Adverse Incident Report 168
1.69 Equipment Calibration Record 169
1.70 Document Distribution List 170
1.71 Regulatory Update Form 171
1.72 Record Disposal Form 172

Medical Device Good Distribution Practice
Case Book

Chapter 1. Overview

1.1 Structure of MDGDP

Concerns have been raised among the local medical device distributors towards the mandatory regulation on medical devices to be imposed in the future. Local SMEs are expressing their worry about the regulation, including whether the regulation shall be too stringent to follow? How the industry shall be prepared for the enactment? Will there be enough grace period for the industry to adapt the regulatory requirements? If the corporate cannot fulfill MDGDP requirements after the grace period, will her business be terminated?

This project serves as a pioneering scheme to build up MDGDP in the local medical device industry. Up to now, local government does not impose any mandatory requirement to regulate medical device distribution process. When designing the MDGDP framework, the project implementation team and project steering committees have taken reference from the regulatory requirements of the EU, US and ASEAN countries, as well as the related specific requirements in the Medical Device Administrative Control System (MDACS) issued by the Medical Device Control Office (MDCO) of the Department of Health. We suggest the local medical device SMEs to compile with MDGDP by selecting the most suitable route out of the below three routes.

The three suggested MDGDP routes:

Routes	Description of requirements
Route 1	Only implement the related specific requirements issued by MDCO
Route 2	Implement both ISO 9001:2008 and the related specific requirements issued by MDCO
Route 3	Implement both ISO 13485:2003 and the related specific requirements by issued MDCO

The above three routes are sequenced in an order of system stringency. Route 1 only based on the related specific requirements by MDCO, and can be regarded as comparatively easier to handle; whereas Route 3 adopted ISO 13485:2003, and is generally regarded as comparatively harder to handle.

All the three routes are bound by the related specific requirements issued by MDCO, which are listed in the Medical Device Administrative Control System of MDCO in particular COP-01 “Code of Practice for Local Responsible Persons”, GN-01 “Overview of the Medical Device Administrative Control System” and GN-03 “Guidance Notes for Adverse Incident Reporting by Local Responsible Persons”.

1.2 Comparison of the Main Elements of Three Routes

System Requirements (Note 1: include sterile medical devices, active implantable medical devices)		Routes to conform with MDGDP		
		Route 1	Route 2	Route 3
		Only implement the related specific requirements issued by MDCO	Implement both ISO 9001:2008 and the related specific requirements issued by MDCO	Implement both ISO 13485:2003 and the related specific requirements issued by MDCO
Tier 1 Document: Quality Manual			✓	✓
Tier 2 Document: Corporate Operation Procedures				
1	Document Control	✓	✓	✓
2	Management Review		✓	✓
3	Regulatory Requirements	✓	✓	✓
4	Staff Development	✓	✓	✓
5	Internal Audit	✓	✓	✓
6	Aftersales Servicing	✓	✓	✓
7	Product Identification	✓	✓	✓
8	Product Traceability	✓	✓	✓
9	Customer Property Handling		✓	✓
10	Infrastructure and Work Environment Management	✓	✓	✓
11	Products Verification, Validation and Acceptance	✓	✓	✓
12	Warehouse Management	✓	✓	✓
13	Customer Order Handling	✓	✓	✓
14	Product Delivery		✓	✓
15	Customer Satisfaction Investigation		✓	
16	Customer Feedback and Complaint	✓	✓	✓
17	Specific Requirements for Medical Devices (Note 1)			✓
18	Nonconforming Product (and Service) Handling	✓	✓	✓
19	Corrective and Preventive Action	✓	✓	✓
20	Advisory Notice	✓	✓	✓
21	Products Recall	✓	✓	✓
22	Risk Management			✓
23	Adverse Incident Reporting	✓	✓	✓
24	Supplier Evaluation		✓	✓
25	Procurement		✓	✓
26	Calibration of Measuring Equipment	✓	✓	✓
27	Products Repair and Maintenance	✓	✓	✓
28	Medical Devices Installation		✓	✓
Tier 3 Document: Work Instruction			✓	✓
Tier 4 Document: Forms		✓	✓	✓

1.3 Main Elements under MDGDP

The related specific requirements are issued by MDCO, target to monitor local medical device distribution. These requirements focus on the remedial action(s) to be taken once incidents occurred to medical devices. Main elements of the related specific requirements are as follow.

- Complaint Handling
- Maintenance and Service Arrangements
- Product Traceability
- Tracking of Specific Medical Devices,
  - Specific Medical Devices target on some of the high-risk devices such as the mechanical heart valves, implantable pacemakers (including their electrodes and leads), implantable defibrillators (including their electrodes and leads), implantable ventricular support systems, and implantable drug infusion systems
- Product Alerts, Modifications and Recalls
- Managing Reportable Adverse Incidents in Hong Kong

ISO9001:2008 is a commonly adopted quality management system applicable to general products. The corporate shall establish a quality management system which **strictly** follow and implement all the ISO clauses. Main elements of ISO9001 are as follow.

- Document Control
- Management Review
- Resource Management
- Staff Development
- Infrastructure and Work Environment Monitoring
- Product Design and Development
- Procurement
- Service Provision
- Control of Monitoring and Measuring Device
- Customer Satisfactory Investigation
- Internal Audit
- Control of Production and Service Provision
- Control of Nonconforming Product
- Analysis of Data
- Continual Improvement of Products and Services
- Corrective and Preventive Action

ISO13485:2003 is built based on ISO9001, with additional, medical device specific requirements on the quality management system. Main elements of ISO13485 are as follow:

- Product Traceability
- Product Risk Management
- Particular Requirement for Sterile Medical Devices
- Particular Requirement for Active Implantable Medical Devices and Implantable Medical Devices
- Identification and Segregation
- Local Medical Device Related Regulatory Monitoring
- Cleanliness of Employee Clothing
- Preventive Actions for Product Pollution
- Medical Device Advisory Notice Handling
- Medical Device Installation and Maintenance Activities
- Customer Feedback and Complaint Handling

1.4 Relationship of MDGDP System Complexity and Organization Structure

After a brief introduction of MDGDP key elements in the previous sections, may be it sound quite complicated, and you may wonder how such a complex system be built. May be the resources required can only be affordable by multinational corporates? Local medical device distributors are mostly SMEs, do they have the ability to afford the resources required for MDGDP particularly in this competitive market?

In real situation, MDGDP provides certain extent of flexibility on drafting documented procedures. By considering their resources and business models, local SMEs can choose the most appropriate route in order to fulfill MDGDP requirements.

MDGDP of a multinational corporate can be complex, as there are more procedures and usually involving more departments and employees. It is expected to have more coverage to clearly define the responsibility and technical requirements of specific position, the communication channels between departments, the regulatory requirements of various products, the approval process of documentation, etc. Alternatively, the MDGDP system of a SME is expected to be relatively simpler, due to a relatively simpler organization structure and operations.

MDGDP is applicable to corporates of different sizes, from multinational corporates to SME. But one shall note that corporates of different sizes shall follow the same fundamental MDGDP requirements.

1.5 Core Processes and Exemptions Depend on Corporate Structure

Since different corporates have different organization structure and business models, the complexity of their MDGDP shall also be different.

Core Process

Prior to the establishment of MDGDP, the corporate shall perform a Gap Analysis to better understand the nonconformities of the current system when comparing with MDGDP, and to enhance surveillance on those nonconformities.

Local medical device industry shall pay extra attention to the below situation:

- Distributors shall record secondary packaging and labeling processes, which includes devices' package design, Instruction for Use (IFU), label design, etc.

- If the corporate subcontracts parts of her distribution processes to a third-party supplier and these processes may directly or indirectly affect the products/services quality, these processes shall be closely monitored. Examples include device transportation, storages, re-labeling and packaging, device quality inspection, etc.

Exemption Processes

There are requirements in MDGDP for handling specific medical devices, however, if companies do not involve in those specific devices, some of the clauses may be exempted.

In the local medical device industry, it is common that:

- If the manufacturer has no specific storage requirements for its medical device and distributor agrees the medical devices shall have no specific storage requirements after evaluating device properties, local distributor may consider the necessity to install the temperature and humidity monitoring device at the warehouse.

Chapter 2. Document Format

1.6 Format of Document List

Four-tiers documentation content (Document Names For Reference Only)		
I. Quality Manual		
Doc No.	**Doc Name**	**Version**
QM	Quality Manual	
II. Corporate Operation Practice (COP)		
Doc No.	**Doc Name**	**Version**
COP-1	Document Control Procedures	
COP-2	Management Review Procedures	
COP-3	Regulatory Requirements Procedures	
COP-4	Staff Development Procedures	
COP-5	Internal Audit Procedures	
COP-6	Aftersales Servicing Procedures	
COP-7	Product Identification and Traceability Procedures	
COP-8	Customer Property Handling Procedures	
COP-9	Infrastructure and Work Environment Management Procedures	
COP-10	Receipt, Verification and Acceptance of Incoming Goods Procedures	
COP-11	Storage and Stock Monitoring Procedures	
COP-12	Customer Order Handling Procedures	
COP-13	Products Delivery Procedures	
COP-14	Customer Satisfaction, Feedback and Complaint Handling Procedures	
COP-15	Sterile Products Procedures	
COP-16	Control of Nonconforming Products and Services Procedures	
COP-17	Corrective and Preventive Action Procedures	
COP-18	Advisory Notice Handling Procedures	
COP-19	Products Recall Procedures	
COP-20	Risk Management Procedures	
COP-21	Adverse Incident Reporting Procedures	
COP-22	Supplier Evaluation Procedures	
COP-23	Purchasing Procedures	
COP-24	Calibration of Measuring Equipment Procedures	
III. Work Instruction (WI)		
Doc No.	**Doc Name**	**Version**
WI-01	Warehouse Instruction	
WI-02	Incoming Goods Inspection Instruction	
WI-03	Product Identification and Segregation Instruction	
WI-04	Product Disposal Instruction	
IV. Form		
Doc No.	**Doc Name**	**Version**
Form 01	Quotation Record	
Form 02	Quotation	
Form 03	Tender Record	
Form 04	Purchase Order	
Form 05	Invoice Record	
Form 06	Invoice	
Form 07	Stock Record	
Form 08	Delivery Note	
Form 09	Warehouse Cleaning Record	
Form 10	Warehouse Temperature Record	
Form 11	Specific Competence Requirement List for the Employee of Third-party Supplier	

Form 12	External Training Record	
Form 13	Third-party Logistic Supplier Monitor Record	
Form 14	Third-party Logistic Supplier Re-evaluation Record	
Form 15	Product Maintenance Form	
Form 16	New Staff Training Record	
Form 17	Specific Competence Requirement List	
Form 18	Employee Training Record	
Form 19	Approved Supplier List	
Form 20	Supplier Evaluation Form	
Form 21	Supplier Re-evaluation Form	
Form 22	Customer Satisfactory Survey	
Form 23	Customer Complaint Feedback Form	
Form 24	Corrective and Preventive Action Record	
Form 25	Product Recall Form	
Form 26	Nonconforming Product Report	
Form 27	Risk Management Report	
Form 28	Internal Audit Checklist	
Form 29	Adverse Incident Report	
Form 30	Equipment Calibration Record	
Form 31	Document Distribution List	
Form 32	Regulatory Update Form	
Form 33	Record Disposal Form	
Other Documents (Document Names For Reference Only)		
Internal Record		
Doc No.	**Doc Name**	**Version**
N/A	Management Review Meeting Minutes	
N/A	Quality Assessment Result Issued by the Manufacturer	
N/A	Revised Order Email Sample	
N/A	Revised Delivery Note Email Sample	
N/A	Advisory Notice Sample	
N/A	Customer List of Advisory Notice Recipients	
N/A	Related Documents Submitted to Regulatory Authority	
N/A	Invitation Email Sample for the Customer Satisfactory Survey	
N/A	“Monthly Stock Record” of Logistic supplier	
N/A	“Stock Receipt” of Logistic supplier	
N/A	“Warehouse Floor Plan” of Logistic supplier	
N/A	“Purchase Order” of customer	
Local Regulatory Documents		
Doc No.	**Doc Name**	**Version**
MDCO [GN-01]	Overview of the Medical Device Administrative Control System	
MDCO [GN-07]	Guidance Notes for Listing of Importers of Medical Devices	
MDCO [GN-03]	Guidance Notes for Adverse Incident Reporting by Local Responsible Persons	
MDCO [COP-01]	Code of Practice for Local Responsible Persons	

1.7 Format of COPs (Cover)

ABC Medical Device Distribution Company

Doc Name	**XXXX Procedures**
Doc Number	**COP- X**
Version	**X**

Document Endorsement	
Prepared by: _____	Date: _____
Review by: _____(Department Manager)	Date: _____
Approved by: _____(Top Management)	Date: _____

Revision History		
Version	Description of Changes	Effective Date
		DD/MM/YYYY

Corporate Stamp

1.8 Format of COPs (Content)

1. Purpose
<<The purpose and the function of this COP>>

2. Scope
<<The product(s) and services(s) applicable to this COP>>

3. Reference
<<List of documents related to this COP>>

4. Definition
<<Define and explain specific terms in this COP>>

5. Responsibility
<<List of all responsibility of related personnel of this COP>>

6. Qualification and Training
<<The qualification and training requirement for the personnel to implement this COP>>

7. Procedure
<<Detail description of the operation procedures>>

8. Record
<<List of all related records>>

1.9 Format of Work Instruction

ABC Medical Device Distribution Company
XXXX Work Instruction
Document Code: WI-XX-YY

Applied Department(s)				
Administration Department ☐	Accounts Department ☐	Sales and Marketing Department ☐	Quality Department ☐	Logistics Department ☐
Purpose				
Scope				
Prepared by		**Approved by**		
(Department Manager) Date：		(Top Management) Date：		

Step 1:

Picture description of the procedures (if necessary)	Words description of the procedures

Step 2:

Picture description of the procedures (if necessary)	Words description of the procedures

1.10 Format of Form

(Take “Quotation Record” as an example)

ABC Medical Device Distribution Company
Quotation Record
Document Code: Form XX-YY

Issued Date	Customer Name	Quotation Reference Code	Quotation Description	Prepared by (Signature)	Approved by (Signature)

Medical Device Good Distribution Practice
Case Book

Chapter 3. Sample of Quality Manual

Applicable to	Route 1	Route 2	Route 3
		✓	✓

1.11 Sample of Quality Manual

3.1.1. Quality Manual of MDGDP shall include the following elements

- Corporate Background
- Organization chart
- Exempted Clauses
- Scope of the MDGDP
- Key Departments and their responsibilities
- Distribution process flow, procedures and their related work instructions
- Quality Policy and Quality Objectives
- Assignment of Management Representatives
- Overall description of the corporate Quality Management System and how it fulfill MDGDP requirements
- List of Corporate Operation Practices (COP), Work Instructions (WI) and Forms

Applicable to	Route 1	Route 2	Route 3
		✓	✓

3.1.2. Sample - Quality Manual

3.1.2.1 Cover
- Version of Quality Manual (May use 1,2,3 or A,B,C symbols to express the version)
- Signatory of Prepared Personnel and Date
- Signatory of Endorsed Personnel and Date
- Signatory of Approved Personnel and Date
- Indication of Controlled Document

3.1.2.2 Table of Content

3.1.2.3 Summary of Previous Version
- Document Amendment History
- Summary of Amendment
- Effective Date of Each Version of Quality Manual

3.1.2.4 Number of Printed Quality Manual – Both Original and Copy

3.1.2.5 Corporate Introduction
- Corporate Name, Contact and Address
- Description of Business Nature (including Any Subcontracted Process)
- Classification of Medical Devices

3.1.2.6 Exempted Clauses from MDGDP
- List of any Clauses may be Exempted from the ISO standard or Local Regulation

3.1.2.7 Organization Chart
- Name of Each Department
- Interrelationship between each Departments
- Key Personnel Names and Positions

3.1.2.8 Scope of MDGDP
- List of Products and Operations Conform with MDGDP

3.1.2.9 Business Process Conform with MDGDP

3.1.2.10 Quality Objectives and Quality Policy
- Quality objective shall be measureable, (e.g. number of complaints shall not exceed a certain number, the number of nonconforming product shall remain lower than a certain target, warehouse management shall remain at an appropriate range, etc.)

3.1.2.11 Distribution Operations and Process Flow, and the Corresponding Work Instruction

3.1.2.12 Specific Description of MDGDP Requirements are Fulfilled
- Brief description on how each clause of MDGDP is conformed

3.1.2.13 Assigning Management Representative
- Management Representative appointment, its role and responsibilities

3.1.2.14 Elaboration of the Responsibilities of Each Department and the Corresponding Key Personnel
- List of Corporate Operation Practice, Work Instruction and Form List of all Procedures, their reference numbers, titles, corresponding clauses in MDGDP

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Quality Manual – Cover

ABC Medical Device Distribution Company

Quality Manual

Version: E

Prepared by: _____ Date: _____

Endorsed by: _____ Date: _____
(Department Manager OR
Management Representative OR
Other Management Personnel)

Approved by: _____ Date: _____
(Top Management OR
other Senior Management Personnel)

Quality Manual shall be treated as controlled document.
Quality Manual shall be treated as effective only if it is stamped with "Controlled Document" in red

Corporate Chop

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Quality Manual – Table of Content

Chapter 0.X : **Content**
0.1 Version Control of Quality Manual
0.2 Distribution of Quality Manual Control Copy
0.3 Corporate Introduction
0.4 Quality Management System
0.5 Exempted Clauses from MDGDP
0.6 Organization Chart

1.0 **Scope of MDGDP**
1.1 Applicable Scope of MDGDP
1.2 Scope monitored MDGDP

2.0 **Quality Policy**

3.0 **Quality Objectives**

4.0 **Quality Management System Process Flow**

5.0 **Management Responsibilities**
5.1 Management Commitment
5.2 Customer Focus
5.3 Quality Policy
5.4 Establishment
5.5 Responsibility, Permission and Communication
5.6 Management Review

6.0 **Resource Management**
6.1 Resource Supply
6.2 Human Resource
6.3 Basic Facilities
6.4 Working environment

7.0 **Product/Service Realization**
7.1 Product Realization Plan
7.2 Procedures related to customer
7.3 Design and Development
7.4 Purchase
7.5Manufacture and Service

8.0 **Measurement, Analysis and Improvement**
8.1 General Rules
8.2 Monitor and Surveying
8.3 Control of nonconforming product
8.4 Information Analysis
8.5 Improvement

9.0 **Reference Document Index**
9.1 Index of Reference Document
9.2 Corporate Operation Practice List
9.3 Work Instruction List
9.4 Form List

Chapter 3. Sample of Quality Manual

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Quality Manual – Version Control of Quality Manual

Chapter 0.1: Version Control of Quality Manual

Revision History		
Version	Revision Description	Effective Date
A	First Issue	DD/MM/YYYY
B	Revised Chapter XX, YY and ZZ	DD/MM/YYYY
C	Added Chapter XX; Revised YY and ZZ	DD/MM/YYYY
D	Deleted XX	DD/MM/YYYY
E	Revised Chapter XX, YY and ZZ	DD/MM/YYYY

XX Department Manager shall maintain the documents.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Quality Manual – Quality Manual Publications (Original and Copy) & Corporate Introduction

Chapter 0.2: Distribution of Quality Manual Control Copy

Quality Manual Format	Distributed to
Internal Original Copy 1 Copy	XX Department Maintained
Internal Copy 1 Copy	XX Department Maintained

Chapter 0.3: Corporate Background

Corporate Address: Telephone No.: Facsimile No.: Email Address

- *Date of Establishment*
- *Business Nature*
- *Products and Services*
- *Classification of Medical Devices*
- *Distribution Market*
- *Corporate Process Flow*
- *Third Party Supplier Involvement*
- *Obtained Certificate*

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Quality Manual –Quality Management System & Exempted Clauses from MDGDP

Chapter 0.4: MDGDP Framework

The MDGDP built in ABC Company is based on the structure of ISO 9001:2008 or ISO13485:2003 and the regulatory requirements.

Chapter 0.5: Exempted Clauses from MDGDP

The following clauses in MDGDP are not applicable to ABC Company:

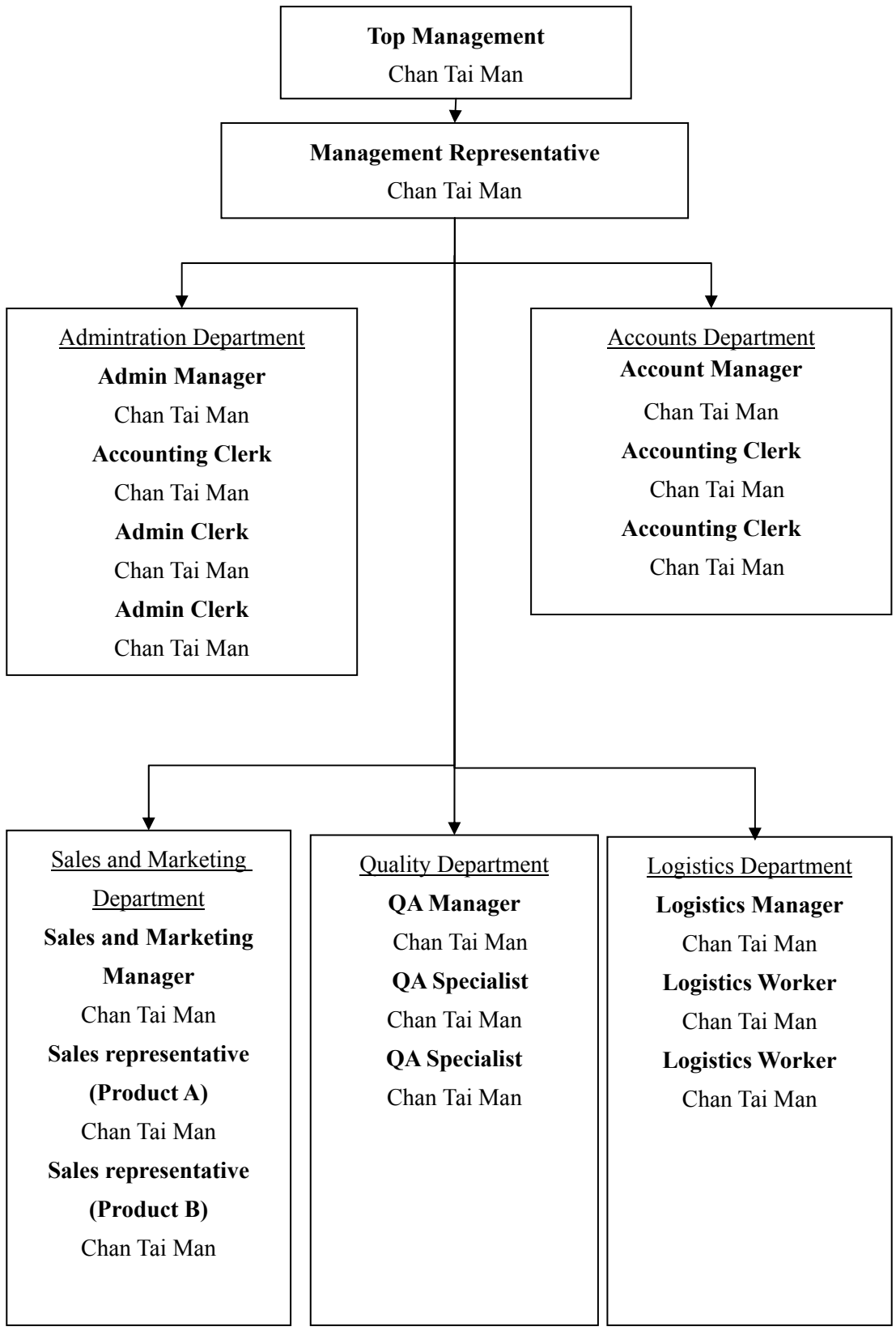
(The following Exempted Clauses are for reference only. The actual clauses to be exempted are subject to the actual business nature and the assessment by Conformity Assessment Body.)

	Exempted Clauses	Exemption Description
1	ISO 13485 Clause 7.3 Design and Development	ABC Company does not involve in the medical device design and development process, it only involves in distribution process.
2	ISO 13485 Clause 7.5.1.2.2 Installation Activities	The products being distributed by ABC Company do not involve any hardware or software installation.
3	ISO 13485 Clause 7.5.1.2.3 Servicing Activities	The products being distributed by ABC Company do not involve any servicing or maintenance activities, in case any nonconforming products found after sales, they would be offered with replacement.
4	ISO 13485 Clause 7.5.3.2.2 Particular Requirements for Active Implantable Medical Devices and Implantable Medical Devices	ABC Company does not distribute any active implantable or implantable medical devices, therefore no related records are generated.
5	ISO 13485 Clause 8.2.4.2 Particular Requirements for Active Implantable Medical Devices and Implantable Medical Devices	ABC Company does not distribute any active implantable or implantable medical devices, therefore no personnel are involved in performing any related inspection or testing.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Quality Manual – Organization Chart

Chapter 0.6: Organization Chart



Applicable to	Route 1	Route 2	Route 3
		✓	✓

Quality Manual –Scope of MDGDP

Chapter 1.0: Scope of MDGDP
Chapter 1.1: Applicable Scope of MDGDP

This Quality Manual is applicable to the distribution of medical device A, medical device B, medical device C and medical device D.

List of Medical Devices under MDGDP	
Name of Medical Devices	**Classification**
Brand and Category of Device	Medical Device A
Brand and Category of Device	Medical Device A
Brand and Category of Device	Medical Device A
Brand and Category of Device	Medical Device A
Brand and Category of Device	Medical Device B
Brand and Category of Device	Medical Device B
Brand and Category of Device	Medical Device C
Brand and Category of Device	Medical Device C
Brand and Category of Device	Medical Device C
Brand and Category of Device	Medical Device C
Brand and Category of Device	Medical Device C
Brand and Category of Device	Medical Device C
Brand and Category of Device	Medical Device C
Brand and Category of Device	Medical Device C
Brand and Category of Device	Medical Device D

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Quality Manual – Scope, Quality Policy and Objective of Quality Management System

Chapter 1.2: Scope monitored by MDGDP

This Quality Manual was established based on the requirements of MDGDP by:

- Demonstrating the corporate ability to fulfill customer and regulatory requirements through the system implementation
- Maintaining the effectiveness of the quality management system, and distribute safe and effective medical device
- Ensuring customer requirements are fulfilled and they are satisfied

Chapter 2.0: Quality Policy

Quality Policy shall be approved by a specific management personnel. Quality Policy shall be realized through various trainings and regular communication with staff member, in particular it shall also be displayed in office common area as a reminder.

ABC Medical Device Distribution Co., Ltd.

Medical Device Good Distribution Practice (MDGDP)

Quality Policy

Our Corporate shall devote our best effort to maintain the effectiveness via the following means:

(1) Ensure that products are delivered to our customers with the best quality,

(2) Ensure timely delivery of the products,

(3) Strictly comply with the requirements of MDGDP and related local regulations,

(4) Ensure that customers satisfy with our products and services.

Chapter 3.0: Quality Objectives

3.1 Review Principle
Quality Objectives shall be reviewed during management review meeting.

3.2 Quality Objectives
Quality Objectives shall be measureable (e.g. number of complaints shall not exceed a certain number, the number of nonconforming product shall remain lower than a certain target, warehouse management shall remain at an appropriate range, etc.) and be defined by the corporate.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Quality Manual – Quality Management System Process Flow, and Corresponding Procedures

Chapter 4.0: Quality Management System Process Flow (The below chart is prepared based on ISO 13485: 2003)

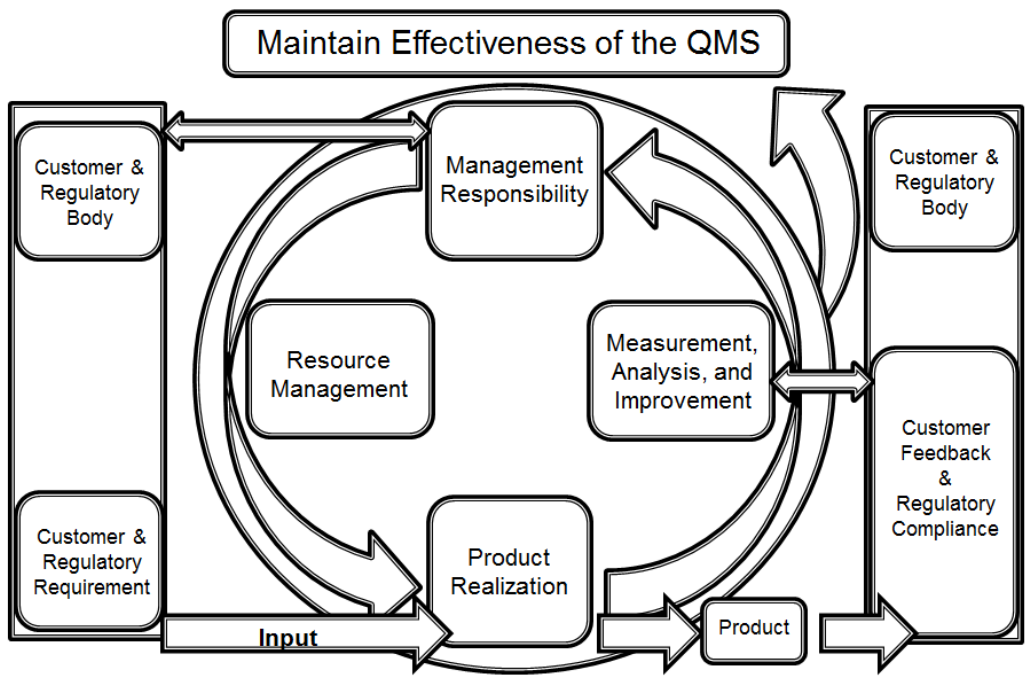


Fig 1： Corporate Process Flow Chart
(Listed from left to right)

Elements of Process + Corresponding Procedures (COPs):

1. Customer (COP - 1, 2, 3)
   Public and private hospitals, clinics, rehabilitation center, elderly center, drug store, chain store.
2. Requirements (COP - 4, 5, 6)
   Purchasing orders, quotations, tenders, telephone order
3. Manage Responsibility (COP - 7, 8, 9, 10)
   Continuous improvement (applicable to ISO 9001), maintain quality management system effectiveness (applicable to ISO13485)
4. Resource Management (COP - 11, 12, 13, 14, 15)
   Human Resource, infrastructure, warehouse, logistics
5. Products and Services Provision (COP - 16, 17, 18, 19, 20)
   Warehouse management, customer requirements determination and confirmation, customer order handling
6. Product (COP - 21, 22, 23)
   Medical device, aftersales services, device installation and maintenance, device user manual
7. Feedback and Complaint (COP - 24, 25)
   Customer feedback and complaint investigation
8. Continuous Improvement of QMS (COP - 26, 27, 28, 29)
   Management review meeting, customer feedback and complaint investigation, corrective and preventive action, product recall, advisory notice handling

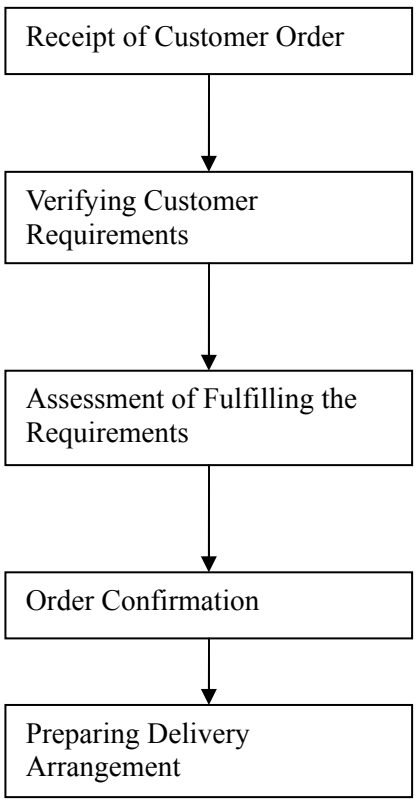


Fig 2: Product and Services Realization Processes

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Quality Manual – Detailed Description of the Processes Implemented for Fulfilling MDGDP Requirements

Chapter 5.0: Management Responsibility
Chapter 5.1: Management Commitment

(Corporate responsible person) Establishes the Quality Management System (QMS) and maintains its effectiveness through the following activities, and to provide evidence of compliance.

5.1.1 Through various trainings, internal meeting, etc., to communicate with staff members and to ensure their awareness of the importance of customer and regulatory requirements.
- Establish appropriate awareness to the importance of the compliance to local medical device regulation. To fulfill the customer requirements shall be the foundation of QMS requirements.
- Ensure each staff member agree and understand that their awareness and product quality are interrelated.

5.1.2 Establish and approve Quality Policy and Quality Objectives.
5.1.3 Management review shall be held in a planned time interval.
5.1.4 Ensure that resources are available for the implementation of QMS.

Chapter 5.2: Customer Focus

Top Management shall be responsible to ensure the effectiveness of the QMS for fulfilling customers' requirements.

5.2.1 Determine customers' needs and expectations: Through collecting market information, forecasting and communicating with customers.
5.2.2 Translate the customer needs and expectations to requirements: These requirements shall include the requirements on product, procedures and quality management system.
5.2.3 Satisfy the requirements by effectively operating the quality management system.

Chapter 5.3： Quality Policy

The Quality Policy shall be established and approved by the Top Management and issued with this Quality Manual.

5.3.1 Quality Policy is the main component of the corporate policy to ensure the effectiveness and satisfaction of products and quality system.
5.3.2 Quality Policy provides the structure for the establishment and review of the Quality Objectives.
5.3.3 Top Management, Management Representative and all Department Manager shall promote the Quality Policy through various meetings, trainings or other methods to ensure all employees of the corporate understand and implement the Quality Policy.
5.3.4 Top Management shall review the sustainability and appropriateness of the Quality Policy in each Management Review Meeting. To ensure the Quality Policy reflects the updated corporate policy and direction of development. Quality Policy shall also be amended if necessary.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Chapter 5.4： Planning

5.4.1 Quality Objectives

The corporate shall establish the Quality Objectives and they shall be measurable and harmonized with the Quality Policy.

5.4.2 Quality Management System

5.4.2.1 Suitable Time for System Establishment

- When the Quality Management System is changed, the system shall be revised to fulfill the standard requirements.
- When insufficiency is detected in the current Quality Management System, the system shall be improved.

5.4.2.2 Contents

- The Quality Objectives (including the amendment of the system) and corresponding procedures shall be included to ensure and govern the import, export and activities of the procedures.
- Identification of the needs of resources allocation and related resources for system amendment shall be included in order to achieve the Quality Objectives.
- The regulation, procedures and improvement of the Quality Objectives shall be discussed in regular revision
- The procedures and schedule for the system amendment shall be included to ensure the completeness of the system.

According the results of the review, any short-fail from achieving the Quality Objectives shall be evaluated to ensure its effectiveness and to increase efficiency.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Quality Manual - Responsibility of Major Department and Personnel

Chapter 5.5： Responsibility, Permission and Communication

5.5.1 Responsibility and Permission

- Top Management shall list the responsibility and permission of all major department and personnel in the Quality Manual.
    - The Top Management shall approve relative clauses in the Quality Manual or announce the responsibility of the related personnel in the meeting when any changes of responsibility are needed/
- Top Management shall determine the organization structure.
- The responsibility and permission of all major personnel/departments can be described as follow:

5.5.2 Top Management

He/She is the top decision maker and in charge of the policy, operation, marketing, and to set the objectives of the corporate. He/She shall verify the relationship between key personnel who involved in management, implementation or inspection of the quality system. He/ She shall ensure the independency and permission of all employees, and to ensure that the quality of product fulfills the corporate standard and customer requirements. Finally, Top Management also has the following duties:

- Approve tender documents, quotation and purchase documents.
- Approve internal documents under MDGDP.
- Make important decision.

5.5.3 Administration Department

- To prepare the plan and provide sufficient resources to the distribution and management procedures.
- To receive customer enquiry
- To purchase products.
- To manage documents related to administration.
- To conduct internal audit.
- To collect disinfection certificates and ensure all distributed products enclose with effective disinfection certificate.
- To arrange employees training.
- To monitor internal communication.
- To arrange business review meeting.

5.5.4 Marketing Department

- To receive customer order and identify the needs of the customer.
- To update and maintain the stock record.
- To conduct visual inspection if any suspected nonconforming products are discovered.
- To contact manufacturer in order to arrange detail quality report for the nonconforming product.
- To collect and analyze customer satisfaction and present the results in the Business Review Meeting.
- To collect and investigate customer feedback and complaint, and to present the results in the Business Review Meeting.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

5.5.5 Accounts Department

- To issue invoice and manage the corporate account.
- To collect the sales revenue.
- To prepare the Management Evaluation Record.

5.5.6 Logistics Department

The Logistics Department is responsible to arrange the shipment and transport of products and to ensure that Third-party Logistic Supplier deliver products according to customer requirements. Logistics Department Manager shall also monitor the logistics operation, warehouse, equipment and product inspection procedures of the Third-party Logistic Supplier to ensure that all procedures fulfill the MDGDP and the requirement of the Quality Policy and Quality Objectives.

The following are the description of responsibility of the Logistics Department Manager:

- To prepare Delivery Note for Third-party Logistic Supplier.
- To notify the Third-party Logistic Supplier with the delivery details, including the time and destination.
- To contact the Third-party Logistic Supplier for the amendment of delivery procedures.
- To arrange the incoming of goods, including the shipping and stocking in.
- To monitor the inspection of the warehouses in order to ensure that they fulfill the requirements of MDGDP, local regulation and the Quality Policy and Quality Objectives of the corporate.
- To conduct regular inspection in the warehouse and ensure that (1) the warehouses have sufficient equipment to control the environment (2) the warehouse products are labeled and segregated (3) all distributed products are inspected (4) the stock records are clearly maintained.
- To maintain related logistic records.
- If there are serious changes for the stock or the environment which may affect the quality of the product, Top Management shall be notified immediately.

5.5.7 Third-party Logistic Supplier

The Third-party Logistic Supplier may have its own warehouse, transportation vehicle and logistic personnel. The suppliers are chosen according to the results of the supplier evaluation procedures.
Third-party Logistic Supplier shall follow the requirements of MDGDP, local regulations, Quality Policy and Quality Objectives to provide (1) Product storage (2) Product delivery and receipt (3) Incoming and outgoing product inspection (4) Daily maintenance of product (5) Control of warehouse environment (6) Update and maintenance of stock record.
Third-party Logistic Supplier shall also assure that the above services are completed. If the logistic supplier does not meet the above requirements, the corporate shall be notified immediately.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

The following are the description of responsibility of the Third-party Logistic Supplier:

- **Product storage service**

  - To provide warehouse storage service for the corporate product.
  - All products shall be stored in safe and controlled environment as according to the requirement.

- **Product delivery and receipt service**

  - Logistic supplier shall provide custom clearance service after receiving products delivered by the shipping company from the suppliers.
  - Provide logistic service (including transportation team). Follow the required delivery date to deliver product to specific customer without delay. To collect returned product from customer or from other specific locations.

- **Incoming and outgoing product inspection**

  - All products shall be inspected before entering the warehouse; personnel responsible for the inspection shall be trained by the corporate. All products shall pass the inspection. The employees from the logistic supplier shall sign the documents before delivering the products to the customer.
  - Nonconforming product shall not be distributed to the customer.
  - All the sterile products shall be enclosed with the approved disinfection certificate before delivering to the customer.

- **Daily maintenance of the products.**

  - Logistic supplier shall pay attention to the product qualification.
  - To label and segregate nonconforming product, returned product, customer property and sample.
  - To repackage the product according to the requirement.

- **Control of warehouse environment.**

  - To record and control temperature and humidity of the warehouse.
  - To record and control the cleanliness of the warehouse.
  - Pay attention to the warehouse environment in order to ensure there are no pests or rodents.
  - To ensure sufficient fire prevention tools at the warehouse, and the fulfilment of local regulatory, and to arrange inspection.

- **Update and maintenance of stock record**

  - To record the quantity, lot number, inspection certificates and other important information.
  - To maintain the mentioned stock record for at least seven years (softcopy or hardcopy)
  - To provide documents including the Temperature Record and Cleanliness Record as requested by the corporate.

Applicable to	Route 1	Route 2	Route 3
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Quality Manual – Assign Management Representative

5.5.8 Management Representative

Management Representative shall be assigned by the Top Management. They shall have full control of the Quality Management System and responsible to plan and approve the policy so as to ensure that MDGDP is maintained and enforced. They shall also report the system performance and improvement.

Chapter 5.6：Management Review

5.6.1 General rules

The Top Management shall conduct at least one regular evaluation meeting per year to ensure that the Quality System is effective. (Reference: COP-2 Management Review Procedures)

5.6.2 Review input

Management Review shall be based on (1) Results of audits including internal audit and third-party audit, (2) Customer feedback, (3) Process performance and product conformity, (4) Status of corrective and preventive actions, (5) Follow-up actions from previous management reviews, (6) Changes that could affect the quality management system, (7) Recommendations for improvement and (8) New or revised regulatory requirements.

5.6.3 Review output

Related personnel shall carry out actions based on (1) Improvements needed to maintain the effectiveness of the quality management system and its processes, (2) Improvements of product and service related to customer requirements and (3) resource needs.

Chapter 6.0： Resource Management
Chapter 6.1： Provision of Resources

The corporate shall provide resources to implement the Quality Management System and maintain its effectiveness; and to meet the regulation and customer requirements. Administration Department Manager shall facilitate the resources, for example, inspection and testing equipment and software.

Chapter 6.2： Human Resources

6.2.1 General Rules

Personnel responsible for management, operation and internal audit shall be trained and qualified with specific expertise. Job related to the quality of product and service shall be assigned to competent candidate.

6.2.2 Competence, awareness and training

The corporate shall evaluate the ability of personnel involved in MDGDP by conducting accreditation. The corporate shall also provide training or other support to staff members to meet the qualification requirements. The effectiveness of such policy shall also be evaluated. Related employees shall be equipped with the

Applicable to	Route 1	Route 2	Route 3
		✓	✓

knowledge related to their work and contribute to the achievement of Quality Objectives. Records related to education, training, technical skills and experience shall be maintained.

Remark: Specific country or district may also require the corporate to establish document procedures for the identification of training needs.

Chapter 6.3： Infrastructure

The corporate shall determine, provide and maintain the infrastructure which affect product quality. If the maintenance activity may affect product quality, the corporate shall establish documented procedures to see the requirement for such maintenance activities (e.g. to define the maintenance frequency) and keep the maintenance record.

Chapter 6.4： Work environment

The corporate shall keep the area involved in distribution processes clean and tidy. The corporate shall also ensure the workplace can support the fulfillment of any product requirements.

The following requirements shall be applicable:

a) If the contact between employees and product or workplace will lead to negative effect on product quality, the corporate shall establish documented procedures to monitor the health, cleanliness and clothing of employees.
b) If the workplace environment will lead to negative effect on the product quality, the corporate shall establish operation documents to monitor the workplace environment.
c) The corporate shall also ensure that temporary employees in specific workplace shall be trained or worked under the supervision of trained employees.

Chapter 7.0： Product Realization

Chapter 7.1： Planning of Product Realization

a) When new products are launched or there are substantial changes, related resources, procedures and environment shall be reviewed to ensure the quality of products being distributed is maintained.
b) The corporate shall define and record the requirements on product quality/ service quality. All documents shall be maintained in the Quality System.
c) Administration Department shall prepare necessary plans for specific conditions that are not governed by the documents of the Quality Management System.
d) The corporate shall establish and maintain documents for risk management during the process of product realization.

Chapter 7.2： Customer-related Processes

7.2.1 Determination of requirements related to the product

Top Management or the Sales and Marketing Department Manager shall review the purchase orders to ensure their fulfillment of customer, regulations and other requirements.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

7.2.2 Review of requirements related to the product

Product requirement shall be clearly defined and documented. The distributed service and product shall satisfy customer's requirements. They shall be delivered on time and according to specified quantity and quality in customers' orders. The amendment of the purchase order shall be monitored by Top Management or the Marketing Department Manager. Related departments shall handle any amendment requested by the customer. Any amendment initiated by the corporate shall be notified to the customer. The Administration Manager shall maintain the purchase record. If no documents are established, the corporate shall confirm the amendment with the customer and notify related personnel.

7.2.3 Customer communication

The corporate shall collect product information from the customer and notify the customer with any progress of the contract or purchase order, including the amendment procedures. The corporate shall also handle customer feedback. The corporate shall issue "Advisory Notice" according to the corresponding COPs to ensure effective customer communication.

Chapter 7.3： Design and Development

The corporate does not participate in any product design and development process.

Chapter 7.4： Purchasing

7.4.1 Purchasing process

The corporate shall establish documented procedures to ensure the purchased products fulfill the requirements.
The corporate shall verify the purchased products. The evaluation of suppliers and purchased products shall be based on the impact of the purchased products.
The suppliers and subcontractors shall have the capability to provide products or services according to the requirements of the customer and the corporate.
The evaluation and re-evaluation records shall be maintained.

7.4.2 Purchasing Information

The corporate shall evaluate the purchase information before releasing them to the supplier.
The purchase information shall include the requirements on the product to be purchased, acceptance requirement, inspection procedures and equipment, requirements on the qualification of employee and requirements on Quality Management System. Before communicating with the supplier, the corporate shall confirm the purchase order from the customer. According to the requirements on traceability, the corporate shall maintain the related purchase information.

7.4.3 Verification of purchased product

The corporate shall inspect the purchased product in order to ensure

Applicable to	Route 1	Route 2	Route 3
		✓	✓

their satisfaction to the customer requirements as listed in the purchase order.
If the corporate proposes to conduct inspection at the supplier's site, the inspection and product arrangement shall be listed on the purchase order and all records shall be maintained.

Chapter 7.5： Manufacture and Service

7.5.1 Control of production and service provision

7.5.1.1 General Requirements

The corporate shall ensure that all procedures are governed by the standard requirements to maintain the product quality, for example: Confirm the product characteristics; Document the work instruction; Ensure the qualified equipment operate effectively; Ensure that appropriate inspection are conducted; Monitor the process parameters and product characteristic; Implement the delivery and post-delivery procedures; Implement the label and operation procedures. The corporate shall establish and maintain record for each batch of medical devices in order to provide supportive documents which fulfill the requirements of records for the extent of product traceability as stated in ISO13485:2003 Section 7.5.3.2. The distributed quantity and the number of approved sales shall be listed out and all records shall be reviewed and approved.

7.5.1.2 Control of production and service provision - specific requirements

7.5.1.2.1 Cleanliness of product and contamination control

Under the following situation, the organization shall establish documents governing the product cleanliness:
a) When the products are required to be cleaned by the organization before disinfection and/or before use; or
b) When the products are provided without disinfection, however needed to be cleaned before disinfection and/or before use; or
c) When the product are provided without disinfection, however must be cleaned during usage; or
d) During the manufacturing process, some materials shall be removed from the product.

If the products shall be cleaned base on a) or b), they do not have to fulfill the requirements of 6.4a) and 6.4b).

7.5.1.2.2 Installation activities

The products of the corporate do not involve machinery and software installation.

7.5.1.2.3 Servicing activities

With the services that have specific requirements, the corporate shall establish operation documents, work instructions, reference materials and measuring procedures. All documents shall govern the activity related to service providing and the evaluation of the satisfaction of service if necessary. All activity record shall be maintained.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

7.5.1.3 Particular requirements for sterile medical devices

The organization shall maintain the disinfection record of all procedures. The disinfection record could be traced back to the each batches of medical device.

7.5.2 Validation of processes for production and service provision

The results of any procedures cannot pass the inspection of the later procedures, the corporate shall provide special control on these procedures. For example, setup protocols for the evaluation and approval procedures; verify the qualification of equipment and employee, adopt special methods and procedures; maintain record; reconfirm the procedures.

7.5.3 Identification and Traceability

When appropriate, the corporate shall adopt suitable methods to identify the products. If there are any requirements on traceability, the corporate shall implement relative Quality Plan.

7.5.4 Customer Property

The customer properties of the corporate are the information of the customer. The corporate had established operation document (COP_9 Customer Property Handling Procedures) to manage the customer property.

7.5.5 Preservation of Product

The corporate shall provide sufficient protective policy during the product distributing procedures, after the product final approval, after the inspection and before delivering to the customer. Operation documents or work instruction shall be established. The protective actions include labeling, transportation, packaging and storage.

Chapter 7.6：Control of monitoring and measuring devices

The corporate shall establish documents to ensure the measuring and testing equipment (thermometer and hygrometer) are maintained in the acceptable range.

Control methods include:

a) The corporate shall provide maintenance for the equipment base on the country/international calibration standards. If no such standards, documents shall be established to govern the procedures.
b) Adopt appropriate action to ensure the equipment are calibrated correctly.
c) Inspected, surveyed or tested equipment shall be labeled with their progress.
d) The corporate shall carry out regular check for the measuring and surveying equipment, the equipment that can be measured shall be delivered to the external metrology institute, while the remaining equipment shall be inspected according to the internal technical documents.
e) Appropriate method shall be adopted for the transportation, maintenance, inspection and surveying of the equipment.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

f) If the equipment is abnormal or expired, the effectiveness of the previous surveying shall be improved.
g) If the computational software is used for monitor and surveying, the capability of the software shall be confirmed before use.
h) Calibration and verification record shall be maintained.

Chapter 8.0： Measurement, Analysis and Improvement
Chapter 8.1： General

The corporate shall plan, monitor, analyze and improve the policy to ensure that the current product and quality management system is appropriate and effective.

Remark: Country or local regulation companies shall establish statistical techniques for the control of documentation procedures (Reference COP-3 Regulatory Control Procedures). Administration Department Manager shall confirm the statistical techniques used for operation monitor and analysis in order to evaluate the effectiveness of the quality system and the product.

Chapter 8.2：Monitoring and Measurement

8.2.1 Feedback

Customer feedback and Customer Satisfaction

8.2.1.1 Chief Executive Office and the Sales and Marketing Department Manager shall adopt appropriate method and policy to monitor the customer satisfaction of the corporate through available ways.

8.2.1.2 The corporate shall establish documents for the feedback system (Reference: COP-14 Customer Feedback and Complaint Handling Procedures) in order to provide early alert on the quality issue and enforce the preventive and corrective action (Reference: COP-17 Corrective and Preventive Action Procedures)

8.2.1.3 The corporate shall establish documents for the customer satisfactory feedback system (Reference: COP-14 Customer Feedback and Complaint Handling Procedures) in order to determine whether the product and service provided are satisfied by the customer and enforce the preventive and corrective action for any dissatisfaction (Reference: COP-17 Corrective and Preventive Action Procedures)

8.2.1.4 Administration Manager shall tidy the returned survey and other feedback information in order to investigate the procedures that govern the products and service in order to satisfy the customer. Improvement recommendation shall also be transferred to related department for further corrective, preventive and improvement actions. If the country and local regulations required the corporate to obtain experience from the procedures after distribution of the products, the audit of these procedures shall be included into the feedback system.

8.2.2 Internal Audit

The corporate shall conduct synthesized and systematic internal audit to ensure the effectiveness of the quality system and verify the progress of quality management.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Lead Internal Auditor is responsible to arrange internal audit to verify whether the progress of quality management fulfill the documents governing the quality system. The audit plan shall be prepared base on the progress.
If Internal Auditor discovers any nonconformity, he/she shall issue audit report to the related department and request further action. The Administration Manger shall follow-up and evaluation the effectiveness of the actions.
The responsibility of planning and implementing audit, presenting results and maintaining audit record shall be documented and regulated. (Reference: COP-5 Internal Audit Procedures).

8.2.3 Monitoring and Measurement of Processes

Top Management shall adopt appropriate method to monitor the quality management system and conduct inspection if necessary.
The corporate shall use appropriate statistical techniques to analyze the results of the procedure. If the targets are not achieved, corrective and preventive actions shall be taken to ensure the quality of the products.

8.2.4 Monitoring and Measurement of Product

The Third-party Logistic Supplier shall verify the qualification of products before distribution, records shall also be maintained.

Chapter 8.3： Control of nonconforming product

All the nonconforming products of the corporate shall be clearly labeled and segregated to avoid unexpected usage.

The requirements on permission and responsibility of the control of nonconforming product and nonconformity handling shall be included in the established documents (Reference COP-16 Control of Nonconforming Products and Services Procedures).

The Sales and Marketing Department shall handle the nonconformity base on the inspection results. The nonconforming products shall be segregated and labeled. The handling method shall be approved by Top Management; methods can be repackaging, use as samples or dispose.

The corporate shall record the characteristics of the nonconformity and the follow-up procedures.
If the customers discover nonconformity after using the device, the corporate shall handle these cases according to the impact and potential effect of the nonconformity.

Chapter 8.4： Analysis of Data

In order to prove the effectiveness and appropriateness of the quality management system, the corporate shall establish documented procedures to ensure that appropriate statistical analysis is adopted to analyze the following information.

8.4.1 Feedback
8.4.2 Conformity to product requirements
8.4.3 Characteristics and trends of processes and products including opportunities for preventive action, and

Applicable to	Route 1	Route 2	Route 3
		✓	✓

8.4.4 Suppliers

The analysis results shall be recorded and maintained. The improvement of the quality management system shall also be evaluated.

Chapter 8.5： Improvement

8.5.1 General

8.5.1.1 The corporate shall identify and implement any necessary amendments base on the Quality Policy, Quality Objective, evaluation results, data analysis, preventive and corrective actions and management review. This is to ensure the effectiveness and sustainability of the quality management system.

8.5.1.2 The corporate shall establish procedures governing the issue and implementation of Advisory Notice. Also, implement the procedures if necessary.

8.5.1.3 The corporate shall maintain all investigation record of the customer complaints. If the complaint is not within the scope of corporate operations, then the related information shall be forward to the involved corporate. If there is no preventive or corrective action for the customer complaints, the reason shall be approved and recorded.

8.5.1.4 If the country or local regulations claim that adverse events which fulfill the standard shall be reported, the corporate shall establish operation documents for the procedures of notification to the Administration Manager.

8.5.2 Corrective Action

The corporate shall establish suitable procedures to investigate and solve the actual or potential nonconformity in order to prevent recurrence.

The established documents shall include the requirements of the following items (Reference: Corrective and Preventive Action Procedures):

- Evaluation of nonconformity (including customer complaints)
- Formal investigation of the cause of nonconformity
- Synthesized analysis of the potential cause and evaluation on the reoccurrence of nonconformity
- Confirmation and implementation of policy, including the update of documents
- Formal evaluation of corrective action to verify and analyze its effectiveness
- Record and enforce the results of corrective action

The Quality Department shall handle customer complaints and confirm the receipt of complaints from the customer. If the complaint had been verified, the Administration Department shall propose corrective actions and the Top Management shall approve the proposal and assign it to related departments. He/she shall also monitor and evaluation the action before closing the case.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

8.5.3 Preventive Action

The corporate shall confirm the preventive policy to eliminate any cause of nonconformity, therefore preventing the occurrence of nonconformity.

The corporate shall also establish documents to govern the following requirements (Reference: Corrective and Preventive Action Procedures):

- Collect appropriate information, then investigate, analyze and eliminate the cause of nonconformity
- Confirm the procedures of the potential nonconformity
- Propose preventive action for the potential nonconformity
- Formal evaluation of preventive action to verify and analyze its effectiveness
- Record and enforce the results of preventive action

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Quality Manual - List of Corporate Operation Practice, Work Instruction and Form

Chapter 9.0： Reference Document Index

Chapter 9.1： Index of Reference Document

To be more convenient, all documents related to this manual are listed in this section. The latest version of the documents shall be updated and distributed to related user by the Administration Manager.

Chapter 9.2： Corporate Operation Practice List

Doc No	Doc Name	Corresponding MDGDP requirements
QM	Quality Manual	
COP-1	Document Control Procedures	
COP-2	Management Review Procedures	
COP-3	Regulatory Requirements Procedures	
COP-4	Staff Development Procedures	
COP-5	Internal Audit Procedures	
COP-6	Aftersales Servicing Procedures	
COP-7	Product Identification and Traceability Procedures	
COP-8	Customer Property Handling Procedures	
COP-9	Infrastructure and Work Environment Management Procedures	
COP-10	Receipt, Verification and Acceptance of Incoming Goods Procedures	
COP-11	Storage and Stock Monitoring Procedures	
COP-12	Customer Order Handling Procedures	
COP-13	Products Delivery Procedures	
COP-14	Customer Satisfaction, Feedback and Complaint Handling Procedures	
COP-15	Sterile Products Procedures	
COP-16	Control of Nonconforming Products and Services Procedures	
COP-17	Corrective and Preventive Action Procedures	
COP-18	Advisory Notice Handling Procedures	
COP-19	Products Recall Procedures	
COP-20	Risk Management Procedures	
COP-21	Adverse Incident Reporting Procedures	
COP-22	Supplier Evaluation Procedures	
COP-23	Purchasing Procedures	
COP-24	Calibration of Measuring Equipment Procedures	

Chapter 9.3：Work Instruction List

Doc No.	Doc Name	Corresponding COP
WI-01	Warehouse Instruction	COP-X
WI-02	Incoming Goods Inspection Instruction	COP-X
WI-03	Product Identification and Segregation Instruction	COP-X
WI-04	Product Disposal Instruction	COP-X

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Chapter 9.4：Form List

Internal Form (Controlled document format)		
Doc No.	**Doc Name**	**Corresponding COP**
Form 01	Quotation Record	COP-X
Form 02	Quotation	COP-X
Form 03	Tender Record	COP-X
Form 04	Purchase Order	COP-X
Form 05	Invoice Record	COP-X
Form 06	Invoice	COP-X
Form 07	Stock Record	COP-X
Form 08	Delivery Note	COP-X
Form 09	Warehouse Cleaning Record	COP-X
Form 10	Warehouse Temperature Record	COP-X
Form 11	Specific Competence Requirement List for External Employee	COP-X
Form 12	External Training Record	COP-X
Form 13	Third-party Logistic Supplier Monitor Record	COP-X
Form 14	Third-party Logistic Supplier Re-evaluation Record	COP-X
Form 15	Product Maintenance Form	COP-X
Form 16	New Staff Training Record	COP-X
Form 17	Specific Competence Requirement List	COP-X
Form 18	Employee Training Record	COP-X
Form 19	Approved Supplier List	COP-X
Form 20	Supplier Evaluation Form	COP-X
Form 21	Supplier Re-evaluation Form	COP-X
Form 22	Customer Satisfactory Survey	COP-X
Form 23	Customer Complaint Feedback Form	COP-X
Form 24	Corrective and Preventive Action Record	COP-X
Form 25	Product Recall Form	COP-X
Form 26	Nonconforming Product Report	COP-X
Form 27	Risk Management Report	COP-X
Form 28	Internal Audit Checklist	COP-X
Form 29	Adverse Incident Report	COP-X
Form 30	Equipment Calibration Record	COP-X
Form 31	Document Distribution List	COP-X
Form 32	Regulatory Update Form	COP-X
Form 33	Record Disposal Form	COP-X

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Internal Record (No table format)		
Doc No.	**Doc Name**	**Corresponding COP**
N/A	Management Review Meeting Minutes	COP-X
N/A	Quality assessment result issued by the manufacturer	COP-X
N/A	Revised Order Email Sample	COP-X
N/A	Revised Delivery Note Email Sample	COP-X
N/A	Advisory Notice	COP-X
N/A	Customer List of Advisory Notice Recipients	COP-X
N/A	Related Documents Submitted to Regulatory Authority	COP-X
N/A	Invitation Email Sample for the Customer Satisfactory Survey	COP-X
N/A	“Monthly Stock Record” of Logistic supplier	COP-X
N/A	“Stock Receipt” of Logistic supplier	COP-X
N/A	“Warehouse Floor Plan” of Logistic supplier	COP-X
N/A	“Purchase Order” of customer	COP-X

Local Regulatory Documents	
Title	**Corresponding COP**
MDCO [GN-01] Overview of the Medical Device Administrative Control System	COP-X
MDCO [GN-07] Guidance Notes for Listing of Importers of Medical Devices	COP-X
MDCO [GN-03] Guidance Notes for Adverse Incident Reporting by Local Responsible Persons	COP-X
MDCO [COP-01] Code of Practice for Local Responsible Persons	COP-X

Chapter 4.
Sample of Corporate Operation Practice

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.12 Document Control Procedures

1. Purpose

To govern the processes of drafting, authorizing, distributing and revising of documents.

2. Scope

This procedure is applicable to the following corporate documents: Quality Manuals, Corporate Operation Practice, Work Instructions, Product Files. (for example, all local and international standards, external documents, etc.)

3. Reference

N/A

4. Definition

4.1 QM: Quality Manual
4.2 COP: Corporate Operation Practice
4.3 WI: Work Instruction
4.4 MR: Management Representative
4.5 Controlled documents: including the original and the duplicated copy of the latest edition of Quality Manual, Corporate Operation Practice and Work Instruction.
4.6 Uncontrolled documents: including the original, duplicated and loaned copy of the old edition of Quality Manual, Corporate Operation Practice Corporate Operation Practice and Work Instruction.
4.7 External documents: documents related to the product provided by the third party, including the disinfection certificates of the product and description files.

5. Responsibility

Department/ Person	Responsibility
All employee	- To draft and amend the Quality Manual, Corporate Operation Practice and Work Instruction
Department Manager	- To review the drafted documents
Top Management	- To approve the related documents
Administration Manager	- To release the latest documents and maintain the old documents - To fill in the Document Distribution List

6. Qualification and training

N/A

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

7. Procedure

7.1 Control of document

7.1.1 Identification

7.1.1.1 The latest edition of the original controlled documents must be kept by the Administration Manager.

7.1.1.2 All controlled documents are effective after the completion of the following processes (A) Signed by the initiating person, endorsed by the department head & GM (B) Chopped with corporate chop (C) Chopped with red “Controlled Document” chop

7.2 Initial issue and authorization of document

7.2.1 All employees in the corporate are eligible to draft the controlled documents if necessary.

7.2.2 The coding method of the controlled documents is as followed:

7.2.2.1 The coding method of the Corporate Operation Practice

COP-X

which X is the reference number

7.2.2.2 The coding method of the Work Instruction

WI-YY-ZZ

which YY is the reference number ZZ is the version number (first version shall be 01)

7.2.2.3 The coding method of form sheet

Form YY-ZZ

which YY is the reference number ZZ is the version number (first version shall be 01)

7.2.3 Employees responsible for drafting shall deliver the completed documents to the Top Management and the Top management for review and approval. The documents shall then be signed. The Administration Manager shall chop the corporate chop and print a “Controlled Document” red stamp on the signed document. This process assures document adequacy, correctness and conformity to quality policies.

7.2.4 The Administration Manager is responsible for the storage of the original and duplicated copy of all documents.

7.3 Inspection of document

7.3.1 Original copies: Store properly at specific position by Administration Manager.

7.3.2 Duplicated copies: Employees can inspect the copy of the document at any time. The copy shall be copied from the original document by Administration Manager and chopped with a red “COPY” chop.

7.3.3 The corporate encourages employees to review the documents during office hour and inside office area.

7.3.4 The original and duplicated copy shall not be brought out of the office area.

7.4 Document Distribution

7.4.1 Original copies: After the Administration Manager completed the Document Distribution List, he/she can copy the requested document and chop the copy with the “Distributed” stamp (Named as Loaned copy).

7.4.2 Every division can request the loaned copy from the Administration Department if necessary. Basically, every department will receive the loaned copy of the following documents, the Quality Manual, Corporate Operation Practice and Work Instruction related to the respective departments, released by the Administration Department. Every request shall complete with the Document Distribution List. If the documents are updated or deleted, the

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

Administration Department shall recycle all the old documents and release the latest version, the Document Distribution List shall also be filled in.

7.4.3 The corporate will lend related Work Instruction to third-party logisitc supplier.

7.4.4 If the third-party logisitc supplier returned the loaned copy, the Administration Manager shall complete the Document Distribution List. The returned loaned copy shall then be destroyed.

7.5 File Update and Withdrawn

7.5.1 Documents can be modified if the content of it does not comply with the corporate's actual operations, or the corporate operation has been changed.

7.5.2 The modification of documents can be done by any employees in the corporate, modified draft shall be delivered to the Administration Manager and Top Management for review and approval, the documents shall then be signed. After that, the signed documents shall be delivered to the Administration Manager to chop the corporate chop and print with a "Controlled Document" red stamp. Now, the document would be effective.

7.5.3 Administration Manager shall replace the old documents (original and duplicated copy) with the latest documents (original and duplicated copy).

7.5.4 Administration Manager shall follow the Document Distribution List to retrieve the old loaned copy and complete the Document Distribution List.

7.5.5 The old original documents shall be chopped with "Obsoleted file" stamp and store at a specific place. The duplicated copy of the old documents can be destroyed.

7.6 Control of External Document

7.6.1 Collection

7.6.1.1 Administration Manager is responsible for collecting and storing all external documents related to the corporate's products (including the disinfection certificates and description files).

7.6.2 Update

7.6.2.1 When there is a new version document released, the new document shall be stored instead of the old version.

7.7 Storage of Obsoleted Document

7.7.1 All obsoleted documents shall be kept at least (1) the lifetime of the medical device defined by the manufacturer, (2) but not less than the retention period of any resulting record, or (3) as specified by relevant regulatory requirements.

7.8 Control of Form

7.8.1 Identification

7.8.1.1 Form shall be coded as according to section 7.2.2 of this procedures.

7.8.1.2 All controlled forms are effective after the completion of the following processes (A) Signed by the initiating person, endorsed by the department head & GM (B) Chopped with red "Controlled Document" chop

7.8.2 Drafting and Endorsement

7.8.2.1 Every employee shall be eligible to draft a new form if necessary/

7.8.2.2 When the form is drafted, the employee who draft the form shall sign on the original copy, together with the signing date.

7.8.2.3 Afterwards, the original copy shall been endorsed and approved by department heads and Top Management respectively.

7.8.2.4 The original copy is effective after the Administration Manager chops the "Controlled Document" red-colored stamp onto the front page of the original copy,

7.8.2.5 Duplicated copy is photocopied from the original copy. It is effective after the Administration Manger chop the "Copy" red-colored stamp

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

onto the front page of the photocopied document.

7.8.3 Storage, Protection and Retrieval

7.8.3.1 All the form shall be stored and protected by the Administration Manager.

7.8.4 Update

7.8.4.1 Controlled documents shall be updated if (1) the document content does not conformed with the corporate operation, or (2) Corporate operation occurs changes.

7.8.4.2 Document update can be carried out by any employee, the drafted document shall follow the approval process as shown in section 7.8.2 of this procedures.

7.8.4.3 Old original copy shall chop with "Obsoleted Document" stamp, and be stored in a designated area. Old duplicated copy shall be disposed by administration manager.

7.1 Control of Record

7.1.1 Identification

7.1.1.1 Records are defined as the completed forms. The form list and their latest format can refer to the "Reference Document Index" in Chapter 9 of the Quality Manual.

7.1.2 Storage, Protection and Retrieval

7.1.2.1 According to the property of the record, the following table lists the storage department of different records. The records shall be stored in a specific folder. If any inspection is needed, employees shall request the records from the Department Manager and seek his/her approval. Records shall not be amended. Any revision of record shall be reviewed, approved and signed again.

Department for Storage of Different Records		
Doc No.	**Doc Name**	**Storage Department**
Form 01	Quotation Record	Administration Department
Form 02	Quotation	Administration Department
Form 03	Tender Record	Administration Department
Form 04	Purchase Order	Administration Department
Form 05	Invoice Record	Administration Department
Form 06	Invoice	Administration Department
Form 07	Stock Record	Administration Department
Form 08	Delivery Note	Administration Department
Form 09	Warehouse Cleaning Record	Logistics Department
Form 10	Warehouse Temperature Record	Administration Department
Form 11	Specific Competence Requirement List for Third-party Employee	Administration Department
Form 12	External Training Record	Administration Department
Form 13	Third-party Logistic Supplier Monitor Record	Administration Department
Form 14	Third-party Logistic Supplier Re-evaluation Record	Administration Department
Form 15	Product Maintenance Form	Administration Department
Form 16	New Staff Training Record	Administration Department
Form 17	Specific Competence Requirement List	Administration Department
Form 18	Employee Training Record	Administration Department
Form 19	Approved Supplier List	Administration Department
Form 20	Supplier Evaluation Form	Administration Department
Form 21	Supplier Re-evaluation Form	Administration Department
Form 22	Customer Satisfactory Survey	Administration Department
Form 23	Customer Complaint Feedback Form	Administration Department
Form 24	Corrective and Preventive Action Record	Administration Department
Form 25	Product Recall Form	Administration Department

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

Form 26	Nonconforming Product Report	Administration Department
Form 27	Risk Management Report	Administration Department
Form 28	Internal Audit Checklist	Administration Department
Form 29	Adverse Incident Report	Administration Department
Form 30	Equipment Calibration Record	Administration Department
Form 31	Document Distribution List	Administration Department
Form 32	Regulatory Update Form	Administration Department
Form 33	Record Disposal Form	Administration Department
N/A	Management Review Meeting Minutes	Administration Department
N/A	Quality assessment result issued by the manufacturer	Administration Department
N/A	Revised Order Email Sample	Administration Department
N/A	Revised Delivery Note Email Sample	Administration Department
N/A	Advisory Notice	Administration Department
N/A	Customer List of Advisory Notice Recipients	Administration Department
N/A	Related Documents Submitted to Regulatory Authority	Administration Department
N/A	Invitation Email Sample for the Customer Satisfactory Survey	Administration Department
N/A	“Monthly Stock Record” issued by Logistic supplier	Logistics Department
N/A	“Stock Receipt” issued by Logistic supplier	Logistics Department
N/A	“Warehouse Floor Plan” issued by Logistic supplier	Logistics Department
N/A	“Purchase Order” of customer	Administration Department

7.1.3 Record Maintenance Period

7.1.3.1 All documents shall be kept at least for the following three period (1) Life-span of the medical device defined by the manufacturer (2) within two years since the distribution of products (3) period required by local regulations.

7.1.4 Record Disposal Control

7.1.4.1 All disposed records shall be delivered to the Administration Department.

7.1.4.2 The Administration Manager shall dispose the record once a year, by collecting all expired records and completing the “Record Disposal Form”.

7.1.4.3 The Top Management shall approve the “Record Disposal Form”.

7.1.4.4 If the records to be disposed include any customer information, shredder shall be used.

8. Record

Document Distribution List (Form 31)
Record Disposal Form (Form 33)

Applicable to	Route 1	Route 2	Route 3
		✓	✓

1.13 Management Review Procedures

1. Purpose

To govern the establishment and instruction to assign responsibilities for the management review.

2. Scope

Applicable to all employees of the corporate.

3. Reference

COP-5 Internal Audit Procedures
COP-3 Regulatory Control Procedure
COP-14 Customer Feedback and Complaints Handling Procedures
COP-17 Corrective and Preventive Action Procedures

4. Definition

N/A

5. Responsibility

Department/ Person	Responsibility
Top Management	- To manage the Management Review Meeting - To implement improvement policy
Department Manager	- To attend Management Review Meeting
Administration Manager	- To announce the meeting date, time and venue - To schedule the Management Review Meeting - To release meeting agenda and prepare meeting documents - To present in the meeting
Sales and Marketing Department Manager	- To present in the review meeting
Accounts Department Manager	- To maintain records of meeting and email them to participants
All employee	- To take actions as refer to the meeting outcome

6. Qualification and training

N/A

7. Procedures

7.1 Frequency and scheduling

7.1.1 The Management Review Meeting shall be held at least once a year.

7.1.2 Administration Manager is responsible to announce the meeting date, time and venue.

7.1.3 Top Management would be the chairman of the meeting. All Department Manager shall participate in the meeting.

7.2 Preparation

7.2.1 Administration Manager is responsible to schedule the Management Review Meeting. The purpose of the meeting is to assure the sustainability, sufficiency and effectiveness of the ISO 13485 Quality Management System.

7.2.2 Administration Manager is responsible to release the meeting agenda and to prepare related documents.

7.3 Agenda

7.3.1 Employees is required to present the following items in the meeting

7.3.1.1 Top Management approval of the last meeting record;

Applicable to	Route 1	Route 2	Route 3
		✓	✓

7.3.1.2 Administration Manager presents the result of internal audit; (refer to COP-5 Internal Audit Procedures)
7.3.1.3 Sales and Marketing Department Manager shall present the summary of the Customer Satisfactory Survey and summarize the customer feedback and complaints as applicable; (as defined in COP-14 Customer Feedback and Complaint Handling Procedures)
7.3.1.4 Administration Manager shall report the procedures performance and product conformance;
7.3.1.5 Administration Manager shall present all corrective and preventive actions; (as defined in COP-17 Corrective and Preventive Action Procedures)
7.1.3.6 Administration Manager shall report the status of actions items from previous meeting. Items that have not completed shall be reported with justification and shall be recorded in the meeting minutes; (refer to previous meeting minutes)
7.1.3.7 Administration Manager shall report any change of process(es) and procedure(s) that could affect the quality management system;
7.3.1.8 Participated staff shall be welcomed to discuss relating issues, and identify areas where improvement may be required;
7.3.1.9 Administration Manager shall report new or amended regulations. (as defined in COP-3 Regulatory Control Procedures)

7.3.2 Top Management may present improvement policy base on the following items
7.3.2.1 Improvement on Quality Policy and Quality Objective, in order to assure that they meet the standard and achieve sustainable improvement;
7.3.2.2 Improvement on quality management system and its effectiveness;
7.3.2.3 Improvement on product as required by customers;
7.3.2.4 Improvement on resource management, for example respond to the demand on new equipment and new staff.

7.4 Review Output
7.1.4 Accounts Department Manager is responsible to maintain meeting record and Top Management is responsible to review them.
7.4.2 The meeting minutes shall be emailed to all participants.
7.4.3 All employees is responsible to take actions as refer to the meeting outcome

8. Record

Management Review Meeting Minutes

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.14 Regulatory Requirements Procedures

1. Purpose
To govern the processes of distributing, maintaining and updating the local regulatory documents.

2. Scope
Applicable to all business and service related to local distribution of medical products.

3. Reference
COP-1 Document Control Procedures
COP-18 Advisory Notice Handling Procedures
COP-19 Product Recall Procedures
COP-21 Adverse Incident Reporting Procedures
ISO13485:2003 Medical device-Quality management system
MDCO [GN-01] Overview of the Medical Device Administrative Control System
MDCO [GN-07] Guidance Notes for Listing of Importers of Medical Devices
MDCO [COP-01] Code of Practice for Local Responsible Person
MDCO [COP-03] Guidance Notes for Adverse Incident Reporting by Local Responsible Persons

4. Definition
4.1 Local regulatory documents: including the local and international standard (for example ISO13485), external documents related to the product (for example Product Manual)
4.2 MDCO：Medical Device Control Office, Department of Health, The Government of Hong Kong Special Administrative Region (Website：www.mdco.gov.hk)
4.3 LRP: Local Representative Person

5. Responsibility

Department/ Person	Responsibility
Department Manager	- To review the draft of related documents
Top Management	- To approve related documents - To review and monitor the impact of the latest local regulatory documents on the quality system - To assign LRP
Administration Manager	- To collect all local regulatory documents related to corporate business - To monitor MDCO website - To request the latest documents from the publishing organization every year - To work on the listing application - To maintain the documents and records

6. Qualification and Training
N/A

7. Procedures
7.1 Control of local regulatory documents
7.1.1 Collection
7.1.1.1 Administration Manager is responsible to collect, copy and store all local regulatory documents related to corporate business.
7.1.1.2 The original copy shall be chopped with “Controlled Document” chop and the copy shall be chopped with “COPY” chop.
7.1.1.3 Same as the controlled documents, corporate employees can review the copy of the local regulatory documents.
7.1.1.4 Administration Manager shall frequently review MDCO website* and be

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

alert with the update on adverse event and the product recall announcement.
*MDCO website：http://www.mdco.gov.hk/tc_chi/safety/safety.html

7.1.1.5 If any product of the corporate is related to the adverse event or the product recall announcement, actions shall be done according to the procedures of the following documents.
Reference documents:
COP-1 Document Control Procedures
COP-18Advisory Notice Handling Procedures
COP- 19 Product Recall Procedures
COP- 21 Adverse Incident Reporting Procedures

7.1.1.6 All employees shall follow COP-1 Document Control Procedures Section 7.3 regarding the procedures of documents inspection in order to borrow the documents for inspection.

7.1.2 Update

7.1.2.1 Administration Manager shall assure that the current local regulatory documents in the corporate are the latest version. He/she shall also review the website* for any regulatory updates and then update the Regulatory Update Form monthly.
* Enquiry on latest version of ISO9001 and ISO13485: http://www.iso.org/
* Enquiry on latest version of MDCO-Department of Health documents: http://www.mdco.gov.hk/tc_chi/mdacs/mdacs_gn/mdacs_gn.html

7.1.2.2 If any documents are updated, the Administration Manager shall inform the Top Management to evaluate the impact of the latest documents on the corporate.

7.1.2.3 The latest documents shall be kept while the old version shall chop with "Invalid Document" chop and store at a specific place. The copy and the loaned copy of the old version can be destroyed.

7.1.2.4 Administration Manager shall fill the "Regulatory Update Form" and the form shall be approved and signed by the Top Management.

7.1.2.5 The Administration Manager shall keep the "Regulatory Update Form".

7.2 Listing of Medical Device

7.2.1 Top Management shall decide whether any existing medical device(s) being distributed shall be listed on MDCO.

7.2.2 All newly launched medical device(s) that have specific function different to the existing product shall be listed on MDCO. However, if the newly launched medical device(s) have same function as existing product, Top Management shall decide whether it shall be listed on MDCO.

7.2.3 Administration Manager is responsible to implement and follow the application procedures and update the Top Management on the application progress.

7.2.4 LRP shall be assigned by the Top Management.
Reference documents:
MDCO [GN-01] Overview of the Medical Device Administrative Control System
MDCO [COP-01] Code of Practice for Local Responsible Person
MDCO [GN-07] Guidance Notes for Listing of Importers of Medical Devices

8. Records

Regulatory Update Form (Form 32)

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.15 Staff Development Procedures

1. Purpose
To govern the processes of trainings provided to employees.

2. Scope
Applicable to all trainings provided to the employees.

3. Reference
N/A

4. Definition
Training is defined as
- New Staff Training: including training on corporate's Quality Management System, Quality Policy, Quality Objectives and the medical product being distributed by the corporate.
- Safety Training: including training on the safe work practices, use of personal protective equipment and emergency procedures.
-Job Related Training: particular staff training based on respective job needs.

5. Responsibility

Person	Responsibility
Top Management	- To evaluate the effectiveness of training - To sign and approve " Employee Training Record" - To sign and approve "Specific Competence Requirement List" - To sign and approve "New Staff Training Record"
Administration Manager	- To define the specific competence requirement of staff and record them on the "Specific Competence Requirement List" - To create a new record file for each new staff - To arrange New Staff Training and Safety Training - To maintain " Employee Training Record" - To maintain "New Staff Training Record" - To monitor the professional qualification of staff and assure they are not expired - To keep record - To provide product inspection training to employees who are responsible for product import and export - To maintain "External Training Form"
All employee	- To maintain " Employee Training Record" - To present the outcome of training course - To submit training documents to Administration Manager
Accounts Department	- To arrange reimbursement of training fee
Logistic supplier	- To notify the corporate if there is any change on human resources for product inspection in order to provide training to all related staff

6. Qualification and Training
N/A

7. Procedure
7.1 Specific Competence Requirement List

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

7.1.1 Administration Manager shall define the specific competence requirement of staff whose are responsible for work that required specific qualification and expertise and record them on the "Specific Competence Requirement List". The Top Management shall approve the completed list.

7.2 New Staff Training:

7.2.1 Administration Manager shall create a new record file for each new staff, qualification of the staff is required in the record, including the copy of professional licenses or certificates which are related to the job or required by local regulations.

7.2.2 Administration Manager shall arrange New Staff Training and Safety Training for new employees within two weeks from the report duty date.

7.2.3 Administration Manager shall complete the first section of the "New Staff Training Record" and deliver it to the Top Management.

7.2.4 Administration Manager shall evaluate the learning outcome of the staff.

7.2.5 Top Management shall complete section two of the "New Staff Training Record" and provide the assessment result. If the staff fail in the assessment, second training is required. The Administration Manager shall keep the completed record.

7.3 Other Job-related Training

7.3.1 Identify training needs

7.3.1.1 All employees can request training from the Top Management. With the approval of the Top Management, employees shall complete the "Employee Training Record" and the Top Management shall sign the form and deliver it to the Administration Manager.

7.3.1.2 Head of the corresponding employees or Top Management can request training on staff. With the approval of the Top Management, employees shall complete the "Employee Training Record" and the Top Management shall sign the form and deliver it to the Administration Manager.

7.3.2 Effectiveness evaluation

7.3.2.1 Employee shall first pay for the training fee and request reimbursement from the corporate after completion of the training.

7.3.2.2 After completion of training, evaluation shall be carried out to access whether a particular training has achieved its objective and the employee is sufficiently competent and/or skilled to perform the new job for which he or she was trained. The effectiveness can be determined from the examination or assessment results. If no results can be referred, the employee shall give a presentation to Top Management for evaluation.

7.3.2.3 Training employee shall request the "Employee Training Record" from the Administration Manager and complete the remaining sections.

7.3.2.4 Training employee shall submit the following documents to the Administration Manager.

- Attendance proof (for example copy of training certificate, copy of training application form or attendance list)
- Receipt of training course
- "Employee Training Record" signed by Top Management
- Examination or assessment results of training (if available)

7.3.2.5 Administration Manager shall notify the Accounts Department for reimbursement.

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

7.3.3 Effectiveness of qualification

7.3.3.1 If professional qualification is required for the employee, Administration Manager shall keep the copy of the certificates and assure that they are not expired.

7.3.4 External Training

7.3.4.1 Administration Manager shall provide product inspection training to employees who are responsible for product import and export.

7.3.4.2 Logistic supplier shall inform the corporate if there is any change on employees for product inspection in order to provide training to all related staff.

7.3.4.3 Administration Manager shall fill in the training record on the "External Training Form".

8. Record

Employee Training Record (Form 18)
New Staff Training Record (Form 16)
External Training Record (Form 12)
Specific Competence Requirement List (Form 17)

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.16 Internal Audit Procedures

1. Purpose
To provide for a system, instructions to assign responsibilities for conducting internal quality audit.

2. Scope
Applicable to all activities comprising the ISO13485 Quality Management System.

3. Reference
COP-17 Corrective and Preventive Action Procedures
COP-2 Management Review Procedures

4. Definition
N/A

5. Responsibility

Items	Department/ Person
Internal Audit Team	Top Management
Internal Audit Plan - Internal Audit Schedule - Internal Audit Checklist	Lead Internal Auditor
Internal Audit Team	Lead Internal Auditor
Internal Audit	Lead Internal Auditor, Internal Auditor(s)
To complete Internal Audit Checklist	Lead Internal Auditor, Internal Auditor(s)
To conduct corrective and preventive action	Lead Internal Auditor, Internal Auditor(s)
To review corrective and preventive action	Lead Internal Auditor, Internal Auditor(s)
Internal Audit Result	Lead Internal Auditor

6. Qualification and Training
N/A

7. Procedures

7.1 Internal audit standard

7.1.1 Perform internal audit procedures once a year, but if the quality management system undergo any changes that affect the quality of product(s) or service(s), Top Management may request internal audit for specific group. To assure the independence of internal quality system, Internal Auditor shall not conduct internal audit on their work.

7.2 Internal audit plan

7.2.1 Lead Internal Auditor shall plan and schedule internal audit plan and assign work to Internal Auditor(s) every year. The internal audit schedule shall be updated once a year. Frequency of internal audit can be increased if there are serious internal/external incidents or customer complaints.

7.3 Internal audit team

7.3.1 Internal audit team shall complete, review and maintain the “Internal Audit Checklist”. Lead Internal Auditor and Internal Auditor(s) shall be assigned or changed by Top Management.

Person	Number
Lead Internal Auditor	1 person
Internal Auditor(s)	1 person or above

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

7.4 Conducting internal audit

7.4.1 Internal Auditors shall have a meeting with the Department Manager being audited before the internal audit. The purposes are the following:

7.4.1.1 To present the internal audit plan and the arrangement of Internal Auditors.

7.4.1.2 To schedule the closing meeting after the internal audit.

7.4.2 Internal Auditors shall carry out internal audit following the bullets on the “Internal Audit Checklist”. If necessary, the Internal Auditors may adjust the scope of the “Internal Audit Checklist”, it can be expanded to assure the comprehensiveness of the internal audit.

7.4.3 Internal Auditors shall carry out sample check on the documents and records and record the nonconforming item(s), record may include the description of nonconforming item(s) and the related equipment or emloyee.

7.4.4 After the internal audit, Internal Auditors shall conduct a closing meeting with the Department Manager being audited, Internal Auditors shall present audit findings, nonconforming item(s) and conclusions in the meeting.

7.5 Internal audit report

7.5.1 After internal audit, Internal Auditors shall summarize all the nonconforming item(s) and complete section one of the “Corrective and Preventive Action Record”. Top Management shall approve the completed record.

Reference: COP-17 Corrective and Preventive Action Procedures

7.6 Conducting Corrective and Preventive Action

7.6.1 Internal Auditors shall inform the recommended action on the “Corrective and Preventive Action Record” to the Department Manager being audited and request the implementation of corrective actions.

7.7 Reviewing Corrective and Preventive Action

7.7.1 Responsible Internal Auditors shall review the effectiveness of the corrective and preventive actions and record the findings on section two of the “Corrective and Preventive Action Record”.

7.8 Internal Audit Result

7.8.1 Lead Internal Auditor shall present the related corrective and preventive action to Top Management in the Management Review Meeting every year.

Reference: COP-2 Management Review Procedures

8. Record

Internal Audit Checklist (Form 28)
Corrective and Preventive Action Record (Form 24)

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.17 Aftersales Service Procedures

1. Purpose
To govern the processes of maintenance and troubleshooting service.

2. Scope
Applicable to the maintenance and troubleshooting services of all medical products distributed locally by the corporate.

3. Reference
COP-14 Customer Feedback and Complaints Handling Procedures
COP-16 Control of Nonconforming Products and Services Procedures

4. Definition
After-sales service: including the customer service hotline and email, product inspection service provided by the corporate and the recycling and replacement services of nonconforming products. (Repairing service is except from the after-sales service because of the product properties)

5. Responsibility

Person	Responsibility
Sales and Marketing Department Manager	- To handle customer enquiry - To reply the follow-up action to the customer - To conduct visual inspection to the suspected product - To teach the customer proper use of the product - To reply the result to the customer and record them in the " Customer Complaint Feedback Form"

6. Qualification and Training
Sales and Marketing Department Manager is responsible to identify the nonconforming products. They shall have medical service experience in public or private medical organization, have well understandings on product manufacturing, product disinfection and product packaging procedures and have the ability to identify the differences in product materials and raw materials of different brands.

7. Procedures
7.1 Product troubleshooting
7.1.1 Customer enquiry
7.1.1.1 Customer may enquire product information through phone, fax or email to the corporate.
7.1.1.2 Sales and Marketing Department Manager shall response to the customer enquiry.
7.1.1.3 Sales and Marketing Department Manager shall reply the customer within one week if the enquiry cannot be answered immediately.
7.1.2 Product Inspection
7.1.2.1 Sales and Marketing Department Manager shall conduct visual inspection to the suspected product. If necessary, the product can be delivered to the manufacturer for quality assessment and the manufacturer shall reply the assessment results through email.
7.1.2.2 Visual inspection shall include
(1) Inspection on package damage level
(2) Inspection on product expiry date
(3) Inspection on texture and quality of raw material
(4) Inspection on the level of cleanliness
7.1.2.3 If the case involves improper product use, Sales and

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

Marketing Department Manager shall teach the customer the method of proper product use.

7.1.2.4 After the inspection, Sales and Marketing Department Manager shall present the assessment results to the customer and record them onto the "Customer Complaint Feedback Form".

7.1.2.5 If the enquiry is related to customer feedback and complaints handling procedures, Sales and Marketing Department Manager shall notify the Top Management and maintain record according to the "COP-14 Customer Feedback and Complaints Handling Procedures".

7.1.3 Product Recycling

7.1.3.1 The corporate shall recycle all the nonconforming products and assure that the nonconforming products would not be misused on any patients.

Reference: COP-16 Control of Nonconforming Products and Services Procedures

8. Record

Customer Complaint Feedback Form (Form 23)
Quality assessment result issued by the manufacturer

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.18 Product Identification and Traceability Procedures

1. Purpose
To govern the product identification and tracking procedures.

2. Scope
2.1 This procedure is applicable to all locally distributed medical product and service.
2.2 The corporate may outsource warehousing services to Third-party Logistic Supplier, so this procedure is also applicable to standardize the identification and tracking procedures. The corporate is responsible to ensure that the logistic supplier implements this procedure.

3. Reference
COP-15 Sterile Product Procedures
COP-9 Customer Property Handling Procedures
COP-16 Control of Nonconforming Products and Services Procedures
WI-03 Product Identification and Segregation Instruction

4. Definition
N/A

5. Responsibility

Person	Responsibility
Administration Manager	- To encode all medical product with an Item code
Logistics Department Manager	- To fill in the "Stock Record" after importing the products into the warehouse - To fill in the "Stock Record" after the products are exported from the warehouse
Third-party Logistic Supplier	- To distribute the product received earlier before the later one

6. Qualification and Training
N/A

7. Procedures
7.1 Information on product package
7.1.1 Every package of the products shall print with
- Corporate's name and logo
- Product name
- Lot number
- Item code
- Expiry date
- Corporate contact method

7.2 Product coding
7.2.1 Item code
7.2.1.1 All products shall have an Item code.
7.2.1.2 Administration Manager shall encode all medical products with an Item code and assure that different products have different Item codes.
7.2.1.3 Item code is composed of numbers, or combination of numbers and alphabets.
7.2.1.4 Item code is not sequence coding, all sterile product shall have Item code start with "8".
Reference: COP-15 Sterile Product Procedures

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

7.2.2 Lot Number

7.2.2.1 All products shall have a Lot number.

7.2.2.2 All products shall have a Lot number issued by the manufacturer.

7.2.3 Scrap product label

7.2.3.1 All scrap products shall be labeled with a “Scrap” tag.

7.2.4 Expired product label

7.2.4.1 All expired products shall be labeled with an “Expired” tag.

7.2.5 Customer property label

7.2.5.1 All customers’ properties shall be labeled with a “Customer Property” tag.

7.2.6 Returned product label

7.2.6.1 All returned products from the customer shall be labeled with a “Returned Product” tag.

7.2.7 Sample product label

7.2.7.1 All sample products shall be labeled with a “Sample” tag.

Reference:
COP-8 Customer Property Handling Procedures
COP-16 Control of Nonconforming Products and Services Procedures
WI-03 Product Identification and Segregation Instruction

7.3 Product Tracking

7.3.1 Logistics Department Manager shall fill in the “Stock Record”, record the incoming date, name, quantity and Lot number of the products.

7.3.2 Item code shall be printed on the product package and the Delivery note. Corporate can track the distributed product according to the “Stock Record” and the Delivery note.

7.3.3 Logistic supplier shall distribute the product base on the First-in-First-out principle.

7.3.4 Logistics Department Manager shall fill in the “Stock Record” after exporting the product from the warehouse; the record shall include the exporting date, name, export quantity and Lot number.

8. Record

Stock Record (Form 07)

Applicable to	Route 1	Route 2	Route 3
		✓	✓

1.19 Customer Property Handling Procedures

1. Purpose
To govern the processes of handling and preservation of customers' property.

2. Scope
2.1 Applicable to handling and preserving customers' properties for the process of sales and distribution of all locally distributed medical products.
2.2 The corporate may outsource warehousing services to Third-party Logistic Supplier, so this procedure is also applicable to standardize the identification and tracking procedures. The corporate is responsible to ensure that the logistic supplier implements this procedure.

3. Reference
N/A

4. Definition
Customer property(ies)
The ownership of any goods belongs to the customer. The goods include all properties, products, equipment, confidential documents and customer healthcare records which are stored in the corporate or the logistic supplier.

5. Responsibility

Person	Responsibility
Logistic supplier	- To inspect the customer(s)' property(ies) - To print the related products with "Customer Property" labels
Logistics Department Manager	- To inspect the customer(s)' property(ies) - To contact the customer when their products have suspected problem - To record the result in the "Nonconforming Product Report"

6. Qualification and Training
N/A

7. Procedures
7.1 Receipt of customers' properties
7.1.1 Upon receiving any customer(s)' property(ies), The Logistics Department Manager or the logistic supplier shall inspect the property according to the customer request.
7.1.2 If the result is nonconforming, the Logistics Department Manager shall notify the customer and the Top Management to discuss the follow up actions.

7.2 Container(s) and storage
7.2.1 Qualified customer(s)' property(ies) shall be stored in the warehouse of the logistic supplier. The property(ies) shall be printed with the "Customer Property" labels, customers' name and contact method if necessary.
7.2.2 The storage of product shall base on the product properties or customer requirements to prevent any adverse event.
7.2.3 If there is any adverse event related to the customer(s)' property(ies), the logistic supplier shall notify the corporate and the Logistics

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Department Manager shall report to the customer(s).

7.2.4 The customer(s)'property(ies) shall be handled with the agreed method after discussing with the customer(s).

7.2.5 Logistics Department Manager shall record the result in the "Nonconforming Product Report".

7.3 Control of customer record

7.3.1 The corporate shall sign an agreement with the customer according to the local regulation regarding the intellectual property (for example patented technology, non-patented key technology and commercial secret) of the customer.

8. Record

Nonconforming Product Report (Form 26)

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.20 Infrastructure and Work Environment Management Procedures

1. Purpose
To govern the process of maintenance and monitoring the infrastructure and work environment needed to achieve conformity to the product requirements.

2. Scope
Applicable to all locally distributed medical products and services.

3. Reference
COP-16 Control of Nonconforming Products and Services Procedures
COP-17 Corrective and Preventive Action Procedures
COP-24 Calibration of Measuring Equipment Procedures
WI-01 Warehouse Instruction
WI-02 Incoming Goods Instruction
WI-03 Product Identification and Segregation Instruction

4. Definition
N/A

5. Responsibility

Person	Responsibility
Logistic supplier	- To notify Logistics Department Manager if the temperature or humidity are not within appropriate range - To perform corrective action (for example open air-conditioner, arrange humidifier) - To fax the completed “Warehouse Cleaning Record” and “Warehouse Temperature Record” of previous month to Logistics Department Manager - To maintain the operation of all environment control equipment (including humidifier, fan and air-conditioner) - To arrange inspection and maintain the qualification documents - To ensure that there is no pest and rodent infestation in the warehouse. If found, shall inform the Logistics Department Manager and take immediate measures.
Top Management	- To propose corrective measures if the temperature or humidity is not within appropriate range for twelve hours - To approve and sign the “Third-party Logistic Supplier Monitor Record”
Administration Manager	- To implement COP-17 Corrective and Preventive Action Procedures if the temperature or humidity is not within appropriate range for twelve hours - To back-up the computer record every month, the external hard disk of the back-up shall be stored out of the office - To assure all measuring equipment (including thermometer and hygrometer) are in effective calibration period
Logistics Department Manager	- To review the “Warehouse Cleaning Record” and “Warehouse Temperature Record” and sign the record if there is no problem - To perform site inspections at least twice a month (routine inspection) - To perform spot check at any time - To record the inspection results on the “Third-party Logistic Supplier Monitor Record” and the Top Management shall sign the record for approval

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

6. Qualification and Training

N/A

7. Procedures

7.1 Manage equipment and working environment

7.1.1 Warehouse

The third-party logisitc supplier shall monitor the warehouse according to the following requirements of the corporate:

7.1.1.1 Logistic supplier shall strictly obey the Work Instruction of the corporate.

Reference:
COP-16 Control of Nonconforming Products and Services Procedures
WI-01 Warehouse Instruction
WI-02 Incoming Goods Instruction
WI-03 Product Identification and Segregation Instruction

7.1.1.2 Employees of logistic supplier shall be cautious during transportation of product to assure the cleanliness of the product.

7.1.1.3 Logistic supplier shall assure all incoming product undergo inspection and shall maintain inspection record.

7.1.1.4 Logistic supplier shall clean the warehouse and complete the "Warehouse Cleaning Record".

7.1.1.5 Logistic supplier shall assure all products are stored under the standard temperature and humidity and complete the "Warehouse Cleaning Record". Normally, the sterile products shall be stored in the environment with temperature 7°C -33 °C and humidity 53% - 87%. The expiry date shall be displayed on product package, normally with effective period of five years. Non-sterile products shall be stored at cool, ventilated and clean environment.

7.1.1.6 Logistic supplier shall assure all environment control equipment (including humidifier, fan and air-conditioner) operate normally and to replace them if they are malfunctioned.

7.1.1.7 Logistic supplier and Logistics Department Manager shall monitor the daily temperature and humidity level of the observatory. If the observatory level exceeds the standard temperature or humidity set by the manufacturer for storage of products, the logistic supplier shall pay special attention to the warehouse condition.

7.1.1.8 If the warehouse condition is unsatisfied, the logistic supplier shall notify the Logistics Department Manager immediately and perform corrective actions.

7.1.1.9 The Administration Manager shall make sure that all calibrated devices (including thermometer and hygrometer) are in effective calibration period. If the devices expired the calibration period, they shall be handled according to COP-24 Calibration of Measuring Equipment Procedures.

7.1.1.10 Fire prevention tools of the warehouse shall obey local regulatory and shall be inspected by government Fire Service Department regularly. The logistic supplier shall arrange fire service inspection and maintain effective Fire Inspection Record.

7.1.1.11 The logistic supplier shall maintain all the records related to the corporate (either hardcopy or softcopy) for at least seven years. These records included the Product Inspection Record, Warehouse Cleaning Record, Warehouse Temperature Record, Product Storage and Maintenance Record and Fire Inspection Record.

7.1.1.12 The logistic supplier shall ensure that employees responsible of

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

warehouse maintenance understands the above requirements.

7.1.2 Office

7.1.2.1 The office shall maintain clean and tidy.

7.1.2.2 The equipment (hardware and software) related to office operations and product quality shall maintain functioning. Equipments include the computer for accounting and the communication tools with the customers.

7.1.3 Computer Back-up

7.1.3.1 Back-up record can effectively prevent the loss of data due to damage of corporate's equipment.

7.1.3.2 Administration Manager shall back-up all the computer record every month and the external hard disk of the back-up shall be stored out of office.

7.2 Maintenance of equipment

7.2.1 The hygrometer and thermometer shall have effective calibration certificates to ensure correct measurements.

7.2.2 Administration Manager shall arrange employees to handle the problem of the equipment.

7.3 Inspection of nonconforming products

7.3.1 Monthly regular inspection

7.3.1.1 The Logistics Department Manager shall inspect the logistic supplier at least twice a month for the following items:

(1) Selective inspection of the storage amount of 3 batches of products

(2) All Product Storage and Maintenance Record

(3) Inspection of the incoming goods according to the First-in First-out Principle

(4) Product placement

(5) Selective inspection of the expiry date of 3 batches of products

(6) Unidentified nonconforming product

(7) Labeling and segregation of all nonconforming product(s) /customers' property(ies)/ sample and recall product.

(8) Calibration and operation of warehouse facilities

(9) Completeness of fire facilities

(10) Cleanliness and temperature and humidity control of the actual environment

(11) Warehouse Cleaning Record and Warehouse Temperature Record

(12) Functionality of the temperature and humidity control facilities

(13) Pest and rodent control

(14) Conduct oral assessment for the employees of the third-party logisitc supplier on topics related to daily inspection procedures.

7.3.1.2 Administration Manager shall record the results on the "Third-party Logistic Supplier Monitor Record" and the Top Management shall approve and sign the record.

7.3.1.3 The Logistics Department Manager and the logistic supplier shall perform corrective actions if there is any unsatisfied situation and the Top Management shall determine the implementation of COP-17 Corrective and Preventive Action Procedures

7.3.1.4 The Logistics Department Manager and the logistic supplier shall label and segregate the nonconforming product if they are identified. The COP-16 Control of Nonconforming

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

Products and Services Procedures shall also be implemented.

7.3.1.5 If in the section two of "Third-party Logistic Supplier Monitor Record", the Third-party Logistic Supplier is rated as "Not Approved", Logistics Department Manager shall carry out re-evaluation on the logistic supplier and determine whether the corporate shall stop the contract of the logistic supplier.

7.3.2 Daily Inspection

7.3.2.1 The logistic supplier shall inspect the quality of each incoming and distributed products.

7.3.3 Spot Check

7.3.3.1 Logistics Department Manager can perform spot check at any time. The inspection content can be the same as the content of monthly regular inspection, any deletion and addition of items are allowed.

7.3.3.2 Logistics Department Manager shall record the results on the "Third-party Logistic Supplier Monitor Record" and the Top Management shall sign the record.

7.3.3.3 The procedures of "Monthly regular inspection" can be applied to any unsatisfied situation and unidentified nonconforming products.

7.4 Record Inspection

7.4.1 The logistic supplier shall fax the completed "Warehouse Cleaning Record" and "Warehouse Temperature Record" of previous mouth to Logistics Department Manager.

7.4.2 Logistics Department Manager shall check the inspection record and sign the record for approval.

8. Record

Third-party Logistic Supplier Monitor Record (Form 13)
Warehouse Cleaning Record (Form 09)
Warehouse Temperature Record (Form 10)

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.21 Receipt, Verification and Acceptance of Incoming Goods Procedures

1. Purpose
To govern the processes of receiving, verifying and accepting purchased goods.

2. Scope
2.1 Applicable to all locally distributed medical products and services.
2.2 The corporate had outsourced the warehouse service to a third-party logistic supplier, so this procedure is also applicable to monitor the receipt, verification and acceptance procedures of the incoming products. The corporate is responsible to ensure that the third-party logistic supplier implements this procedure.

3. Reference
COP-8 Customer Property Handling Procedures
COP-16 Control of Nonconforming Products and Services Procedures
COP-15 Corrective and Preventive Action Procedures

4. Definition
N/A

5. Responsibility

Person	Responsibility
Administration Manager	- To review the disinfection record issued by the manufacturer - To update the "Stock Record"
Logistics Department Manager	- To notify the logistic supplier the supplied date, item code, name, specification, lot number, quantity and package of the products which are issued by the manufacturer - To perform site inspections at least twice a month (routine inspection) - To perform spot check at any time - To record the inspection results on the "Third-party Logistic Supplier Monitor Record" and the Top Management shall sign the record for approval
Logistic supplier	- To check if the products' quantity, name, package and expiry date(if provided) are correct when they arrive the warehouse - To email the "Stock Receipt" to Logistics Department Manager within three days after the receiving date - To apply the First-in First-out Principle as the warehouse management model, the product received earlier will be distributed first. - To check the quantity, name and lot number of the distributed product and to notify the corporate if they are incorrect. - Warehouse employees shall ensure that the expiry date of the distributed product meet the customer standard. The expired products shall be labeled and segregated. The corporate shall be notified for corrective actions.

6. Qualification and Training
The logistic supplier shall inspect the incoming goods and the employees shall have basic knowledge of the product.

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

7. Procedures

7.1 Inspection on purchased products

7.1.1 Logistics Department Manager shall notify the logistic supplier with the product information. Information shall include the supplied date, item code, name, specification, lot number, quantity and package which are provided by the manufacturer after purchasing the products from the manufacturer or supplier.

7.1.2 The Logistics Department Manager shall get the bill of lading from the shipping company and deliver it to the logistic supplier in order to arrange the transportation and placement of products.

7.1.3 Logistics Department Manager shall notify the logistic supplier if the delivery date has been changed.

7.1.4 Shipping company shall immediately notify the corporate if any incidents occur during the transportation of the products and Top Management shall determine the handling method.

7.1.5 Upon the arrival of the product, the logistic supplier shall check if the products' quantity, name, package and expiry date (if provided) are corrected. The logistic supplier shall immediately notify the corporate for any incorrect information.

7.1.6 Logistic supplier shall ensure the cleanliness of the product package and complete all inspection before storing the product. And to email the "Stock Receipt" to Logistics Department Manager within three days after the receiving date.

7.1.7 Every batches of product with different lot number shall have supportive disinfection records, for example Certified Quality Report (CQR) or disinfection certificate. Absorbent gauze shall provide isolated Physical and Chemical Test Report on Absorbent Gauze.

7.1.8 The logistic supplier shall not distribute products without the above documents.

7.1.9 Administration Manager shall review the documents to ensure that each batches of product has all effective documents before the Logistics Department Manager notify the logistic supplier to distribute the products.

7.1.10 Logistic supplier shall apply the First-in First-out Principle as the warehouse management model, the product received earlier will be distributed first.

7.1.11 Administration Manager shall update the "Stock Record".

7.2 Inspection of distribute products

7.2.1 Logistic supplier shall check if the products' quantity, name, package and expiry date (if provided) are correct when they are ready to be distributed. The logistic supplier shall immediately notify the corporate for any incorrect information.

7.2.2 The logistic supplier shall ensure that the expiry date of the distributed product meet the customer standard. The expired products shall be labeled and segregated and the corporate shall be notified for corrective actions.

7.2.3 All expired products, nonconforming products and products without disinfection certificate cannot be distributed to the customers.

7.2.4 Logistic supplier shall distribute the products after the cleanliness inspection of the package.

7.3 Inspection of nonconforming products

7.3.1 Monthly regular inspection

7.3.1.1 The Logistics Department Manager shall inspect the logistic supplier at least twice a month for the following items:

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

(1) Selective inspection on the storage amount of 3 batches of products
(2) All Product Storage and Maintenance Record
(3) Selective inspection of 3 batches of products to ensure that the distribution record matches the stock record
(4) Product placement
(5) Selective inspection of the expiry date of 3 batches of products
(6) Unidentified nonconforming product
(7) Labeling and segregation of all nonconforming product(s) /customers' property(ies)/ sample and recall product.
(8) Calibration and operation of warehouse facilities
(9) Completeness of fire facilities
(10) Cleanliness and temperature and humidity control of the actual environment
(11) Warehouse Cleaning Record and Warehouse Temperature Record
(12) Functionality of the temperature and humidity control facilities
(13) Pest and rodent control
(14) Conduct oral assessment for the employees of the third-party logisitc supplier on topics related to daily inspection procedures.

7.3.1.2 Administration Manager shall record the results on the "Third-party Logistic Supplier Monitor Record" and the Top Management shall approve and sign the record.

7.3.1.3 The Logistics Department Manager and the logistic supplier shall perform corrective actions if there is any unsatisfied situation and the Top Management shall determine the implementation of COP-17 Corrective and Preventive Action Procedures.

7.3.1.4 The Logistics Department Manager and the logistic supplier shall label and segregate the nonconforming product if they are identified. The COP-16 Control of Nonconforming Products and Services Procedures shall also be implemented.

7.3.1.5 If in the section two of "Third-party Logistic Supplier Monitor Record", the Third-party Logistic Supplier is rated as "Not Approved", Logistics Department Manager shall carry out re-evaluation on the logistic supplier and determine whether the corporate shall stop the contract of the logistic supplier.

7.3.2 Daily Inspection

7.3.2.1 The logistic supplier shall inspect the quality of each incoming and distributed products.

7.3.3 Spot Check

7.3.3.1 Logistics Department Manager can perform spot check at any time. The inspection content can be the same as the content of monthly regular inspection, any deletion or addition of items is allowed.

7.3.3.2 Logistics Department Manager shall record the results on the "Third-party Logistic Supplier Monitor Record" and the Top Management shall sign the record.

7.3.3.3 The procedures of "Monthly regular inspection" can be applied to any unsatisfied situation and unidentified nonconforming products.

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

7.4 Inspection of recall products

7.4.1 Refer to COP-16 Control of Nonconforming Products and Services Procedures

7.5 Inspection of customers' property(ies)

7.5.1 Refer to COP-8 Customer Property Handling Procedures

8. Record

Third-party Logistic Supplier Monitor Record (Form 13)
Stock Record (Form 07)
Logistic supplier Stock Receipt
Manufacturer Disinfection Certificate
Manufacturer Physical and Chemical Test Report on Absorbent Gauze
Manufacturer Packing List

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.22 Storage and Stock Monitoring Procedures

1. Purpose
To govern the processes and the use of warehouse and storage areas, inventory system and periodic monitoring of stock.

2. Scope
Applicable to all locally distributed medical products and services.

3. Reference
COP-10 Receipt, Verification and Acceptance of Incoming Goods Procedures
COP-16 Control of Nonconforming Products and Services Procedures

4. Definition
N/A

5. Responsibility

Person	Responsibility
Administration Manager	- To update the "Stock Record"
Logistics Department Manager	- To compare the "Monthly Stock Record" and the "Stock Record" to investigate any differences in the records - To sign the "Stock Record"
Logistic supplier	- To update the "Monthly Stock Record"

6. Qualification and Training
N/A

7. Procedures

7.1 Stock Record

7.1.1 All distributed medical device shall be stored in the warehouse of the logistic supplier.

7.1.2 The corporate and the logistic supplier shall keep the stock record separately, the record of corporate shall title with "Stock Record" while the record of logistic supplier shall title with "Monthly Stock Record".

7.1.3 Administration Manager shall update the "Stock Record" while the logistic supplier shall update the "Monthly Stock Record".

7.2 Monthly Stock Verification

7.2.1 Every month, the logistic supplier shall email the "Monthly Stock Record" of the previous month to the corporate. Logistics Department Manager shall compare the "Monthly Stock Record" and the "Stock Record" to investigate any differences in the records.

7.2.2 If there is any differences, Logistics Department Manager shall notify the logistic supplier to count and verify the quantity of product and correct the record according to the verification.

7.2.3 The Logistics Department Manager shall sign the "Stock Record" if the records are correct.

7.3 Incoming Stock Record

7.3.1 Purchased Stock

7.3.1.1 Logistic supplier shall check the purchased product before storing them in the warehouse and email the "Stock Receipt" to Logistics Department Manager within three days after the receiving date.

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

7.3.1.2 Administration Manager shall update the "Stock Record" according to the "Stock Receipt"
Reference:
COP-10 Receipt, Verification and Acceptance of Incoming Goods Procedures

7.3.2 Return Stock

7.3.2.1 Logistic supplier shall place all returned products in the "Return Stock Area".

7.3.2.2 Returned products may be customers' property(ies) or non-conforming products, logistic supplier shall issue "Stock Receipt" after receiving these types of product.

7.3.2.3 Administration Manager shall update the "Stock Record" according to the "Stock Receipt"

7.4 Export Product

7.4.1 Product Delivery

7.4.1.1 Logistic supplier shall fax the signed/stamped delivery note to the corporate within three working days after the delivery date. Logistics Department Manager shall review the delivery note.

7.4.1.2 Administration Manager shall update the "Stock Record" according to the "Delivery note" if there is no problem in the procedures.
Reference: COP-13 Products Delivery Procedures

7.5 Storage and segregation of nonconforming product

7.5.1 Logistic supplier shall store the nonconforming product in the "Nonconforming Stock Area".

7.5.2 Nonconforming product shall be handled according to the procedures listed in the "Nonconforming Product Report", including re-packaging, sampling and dispose.

7.5.3 Administration Manager shall update the "Stock Record" after completing all the procedures.
Reference: COP-16 Control of Nonconforming Products and Services Procedures

8. Record

Stock Record (Form 07)
Logistic supplier Monthly Stock Record
Logistic supplier Stock Receipt
Logistic supplier Stock Location Floor Plan

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.23 Customer Order Handling Procedures

1. Purpose
To govern the processes of receiving and handling customer order prior the process of delivery.

2. Scope
Applicable to all locally distributed medical products and services.

3. Reference
COP-13 Products Delivery Procedures
COP-23 Purchasing Procedures

4. Definition
N/A

5. Responsibility

Person	Responsibility
Top Management	- To receive all contents of email, fax and phone call from the customer - To review the customer satisfaction - To prepare and release the quotation - To sign and stamp the purchase order - To monitor the tender notice issued online - To prepare and submit tender documents - To contact the customer - To notify the alterations requested by the customer to the Department Manger
Sales and Marketing Department Manager	- To receive all contents of email, fax and phone call from the customer - To contact the customer
Administration Manager	- To maintain the records
Logistics Department Manager	- To ensure the supply of products in the warehouse and monitor the delivery date

6. Qualification and Training
N/A

7. Procedures

7.1 Identification of customer needs

7.1.1 Top Management and the Sales and Marketing Department Manager shall identify the customer needs and present the request in the following ways:

7.1.1.1 Customer needs that listed on the tender, purchase order, email or fax, including the request on the product quality, product functionality, payment service, supporting service (for example transportation) and price;

7.1.1.2 Customer expectations and needs based on the defined uses and intended uses. These needs are not listed out by the customer but they are potential requirements from them;

7.1.1.3 Needs base on the local compulsory standard and regulations;

7.1.1.4 Additional needs defined by the corporate.

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

7.2 Quotation

7.2.1 Release

7.2.1.1 Customer can request quotation through email, fax or phone call to the corporate.

7.2.1.2 Top Management and the Sales and Marketing Department Manager shall receive all contents of email, fax and phone call from the customer (including the quotation and purchase order).

7.2.1.3 Top Management or the Sales and Marketing Department Manager shall review the customer satisfaction (for example on the delivery date and product requirements) and together with the Logistics Department Manager shall (1) ensure the continuous supply of products in the warehouse (purchase product if out of stock) (2) monitor the delivery date.

Reference: COP-23 Purchasing Procedures

7.2.1.4 Top Management or the Sales and Marketing Department Manager shall release quotations to the customer (through email or fax) if the customers are satisfied with the products.

7.2.1.5 Top Management or the Sales and Marketing Department Manager shall fill in the "Quotation Record".

7.2.1.6 Customer shall reply the quotation and confirm the order through email or fax.

7.2.2 Revise Quotation

7.2.2.1 If customers request any changes after the release of quotation, Top Management or the Sales and Marketing Department Manager shall reconfirm the request of the customer and determine whether the quotation needs any amendment.

7.2.2.2 Revised quotation will be labeled according to its version; First revised version will be printed with "Revised 1" while the second revised version will be printed with "Revised 2", and so on.

7.3 Purchase order

7.3.1 Receipt

7.3.1.1 Top Management or the Sales and Marketing Department Manager shall review the customer satisfaction (for example on the delivery date and product requirements) and together with the Logistics Department Manager shall ensure the continuous supply of products in the warehouse (purchase product if out of stock) and monitor the delivery date.

Reference: COP-23 Purchasing Procedures

7.3.1.2 Top Management or the Sales and Marketing Department Manager shall contact the customer if they are unsatisfied and request amendment on the order.

7.3.1.3 Top Management or the Sales and Marketing Department Manager shall stamp on the purchase order for confirmation and fax the purchase order to the customer if the customers are satisfied with the products.

7.3.1.4 Administration Manager shall maintain the stamped purchase order.

7.3.2 Revise purchase order

7.3.2.1 If the stamped purchase order (1) have different delivery date with the actual delivery (2) have any amendments, the Logistics Department Manager shall confirm the revised purchase order with the customer by phone and the Top Management or the Sales and Marketing Department

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

Manager shall confirm the customer satisfaction on the order at the same time. The date, time and conversation of the phone call shall be recorded on the "Phone Record".

7.3.2.2 If it is impossible to contact by phone, Logistics Department Manager shall fax the revised purchase order to the customer according to the "Revised Order Email Sample".

7.3.2.3 Logistics Department Manager shall take action according the revised order.

7.3.3 Tender

7.3.3.1 Top Management shall monitor the tender notice issued online. Top Management shall also prepare and submit tender documents after reviewing the customer needs.

7.3.3.2 Top Management shall fill in the "Tender Record".

7.4 Product delivery

7.4.1 Deliver the product base on COP-13 Products Delivery Procedures after confirmation of the order.

8. Record

Quotation (Form 02)
Quotation Record (Form 01)
Tender Record (Form 03)
Revised Order Email Sample
Phone Record

Applicable to	Route 1	Route 2	Route 3
		✓	✓

1.24 Products Delivery Procedures

1. Purpose
To govern the process of delivering all products

2. Scope
Applicable to all locally distributed medical products and services.

3. Reference
N/A

4. Definition
QuickBooks: an accounting software package used by the corporate to prepare and release Invoice.

5. Responsibility

Person	Responsibility
Logistics Department Manager	- To prepare Delivery note - To email the Delivery note to logistic supplier - To check the received Delivery note
Logistic supplier	- To deliver the product to the customer base on the specific date and time on the Delivery note
Accounts Department Manager	- To prepare Invoice - To check whether the quantity and sum of money match between the true and fax copy of Delivery note - To calculate the expense on transportation of the logistic supplier - To paid the logistic supplier

6. Qualification and Training
N/A

7. Procedures

7.1 Confirmation of Delivery

7.1.1 Logistics Department Manager shall prepare the Delivery note after receiving the customer order. The Delivery note shall include the customer contact information, delivery date and time, product quantity and product description.

7.1.2 Logistics Department Manager shall email the Delivery note to logistic supplier and contact the logistic supplier by phone to confirm the receipt.

7.1.3 Logistics Department Manager shall call the customer to reconfirm the delivery date and time. If there is no change, the logistic supplier shall deliver the product according to the Delivery note.

7.1.4 Customer shall sign or stamp the Delivery note for confirmation of receiving the products.

7.2 Revise Delivery note

7.2.1 If there is any amendment on the delivery date (either early or delayed delivery) or any unsuccessful delivery due to the customer's warehouse, Logistics Department Manager shall contact the customer and confirm the revised contents. The date, time and conversation of the phone call shall be recorded on the "Phone Record".

7.2.2 Logistics Department Manager shall notify the logistic supplier with the revised contents and request delivery.

7.2.3 If it is impossible to contact by phone, Logistics Department Manager shall fax the revised purchase order to the customer according to the

Applicable to	Route 1	Route 2	Route 3
		✓	✓

"Revised Delivery Note Email Sample".

7.2.4 Logistics Department Manager shall fill in the actual delivery date on the received Delivery note.

7.3 Checkout

7.3.1 Logistic supplier shall fax the signed or stamped Delivery note to the corporate within three working days after the delivery date.

7.3.2 Logistics Department Manager shall check the received Delivery note, to ensure that:

- the Delivery note coordinates with the purchase order of the customers.
- the exporting records on the "Stock Record" are correct.
- all sterile products enclose with disinfection certificates (Products without disinfection certificates shall not be distributed).

Reference: COP-15 Sterile Product Procedures

7.3.3 Accounts Department Manager shall use QuickBooks to prepare Invoice. The Invoice shall be stamped and mailed to the customer.

7.3.4 Customer shall paid by either bank transfer, check or other format according to the amount on the Invoice.

7.3.5 Logistic supplier shall collect all signed Delivery note every month and mail them to the corporate.

7.3.6 Accounts Department Manager shall check whether the quantity and sum of money match between the true and fax copy of Delivery note. If the true copies are not completed, he/she shall request the logistic supplier to submit the missing notes. The Accounts Department Manager shall keep the true copy of the completed Delivery note and dispose the fax copy.

7.3.7 Accounts Department Manager shall calculate and report the expense on transportation of the logistic supplier to the Top Management. Then the corporate shall pay the logistic supplier.

8. Record

Delivery Note (Form 08)
Invoice (Form 06)
Invoice Record (Form 05)

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.25 Customer Satisfaction, Feedback and Complaint Handling Procedures

1. Purpose
To govern the processes of receiving and investigating customer feedback and complaints.

2. Scope
Applicable to all customer feedback and complaint received by the corporate regarding the products and services. Products and services included all locally distributed medical products and services under the ISO13485.

3. Reference
COP-2 Management Review Procedures
COP-17 Corrective and Preventive Action Procedures

4. Definition
4.1 Customer feedback and complaint
4.1.1 Comments from the customer regarding the products and services, the feedback could be offer through phone, fax or email.

5. Responsibility

Person	Responsibility
Top Management	- To determine the complaint handling method and whether the implementation of corrective and preventive actions is necessary
Sales and Marketing Department Manager	- To conduct Customer Satisfactory Survey once a year - To email or mail the "Customer Satisfactory Survey" to the customer - To analyze and present the results of the survey to the Top Management in the Management Review Meeting - To contact the customer if the survey result is lower than 20 marks and request the customer to fill in the "Customer Complaint Feedback Form" - To fill in the "Customer Complaint Feedback Form" after receiving customer feedback or complaint - To submit the "Customer Complaint Feedback Form" to the Top Management - To investigate the feedback within one month after the receipt and to report the results to the customer. The results shall also be recorded in the "Customer Complaint Feedback Form" - To report the "Customer Complaint Feedback Form" handling results

6. Qualification and Training
N/A

7. Procedures
7.1 Customer Satisfactory Survey
7.1.1 Sales and Marketing Department Manager shall conduct Customer Satisfactory Survey every year. The scope of survey included the product and service quality, price, delivery service, and improvement area.
7.1.2 Sales and Marketing Department Manager shall email or fax the

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

"Customer Satisfactory Survey" to eight random customers.

7.1.3 Sales and Marketing Department Manager shall contact the customer by fax or phone if there is no feedback from the customer after two weeks of the release of survey.

7.1.4 Sales and Marketing Department Manager shall analyze the collected feedback. The total mark of section one and two of the survey is 45 marks. If the total result is lower than 20 marks or any comments are offered in the improvement section, Sales and Marketing Department Manager shall request that customer to fill in the "Customer Complaint Feedback Form". Then, determine whether the implementation of corrective and preventive actions is necessary.

7.1.5 Sales and Marketing Department Manager shall report results of the "Customer Satisfactory Survey" to the Top Management in the yearly Management Review Meeting.

COP-2 Management Review Procedures

7.2 Handling customer feedback and complaint

7.2.1 Sales and Marketing Department Manager shall fill in the "Customer Complaint Feedback Form" after receiving customer feedback or complaint, the customer information, complaint date and feedback content shall be recorded.

7.2.2 Sales and Marketing Department Manager shall investigate the complaint, verify whether the complaint is true and record the investigation result and cause of the incident.

7.2.3 Sales and Marketing Department Manager shall submit the "Customer Complaint Feedback Form" to Top Management and the Top Management shall determine the complaint handling method and whether the implementation of corrective and preventive actions is necessary.

7.2.4 Sales and Marketing Department Manager shall complete the investigation within one month after receiving the complaint and to report the results to the customer, the results shall also be recorded in the "Customer Complaint Feedback Form".

7.2.5 If the investigation cannot be completed within one month, the Sales and Marketing Department Manager shall report the reason to the Top Management.

7.2.6 Sales and Marketing Department Manager shall report the results of the "Customer Complaint Feedback Form" in the yearly Management Review Meeting.

Reference: COP-2 Management Review Procedures

7.3 Corrective and Preventive Action

7.3.1 Sales and Marketing Department Manager shall discuss with Top Management to determine whether it is necessary to implement the corrective and preventive action

7.3.1.1 Results on the "Customer Satisfactory Survey" is lower than the standard

7.3.1.2 Received customer oral, letter or email complaints and the complaints had verified to be true

7.3.1.3 Discovery of problem of the Management system by employee

Reference: COP-17 Corrective and Preventive Action Procedures

8. Record

Customer Satisfactory Survey (Form 22)
Customer Complaint Feedback Form (Form 23)

Applicable to	Route 1	Route 2	Route 3
			✓

1.26 Sterile Product Procedures

1. Purpose
To govern the process related to sterile products.

2. Scope
Applicable to all locally distributed medical products and services.

3. Reference
COP-7 Product Labeling and Tracking Procedures
COP-10 Receipt, Verification and Acceptance of Incoming Goods Procedures
COP-13 Products Delivery Procedures
COP-9 Infrastructure and Work Environment Management Procedures
WI-01 Warehouse Instruction

4. Definition
N/A

5. Responsibility

Person	Responsibility
Logistic supplier Employees	- To participate in the training course provided by the corporate to enhance the basic knowledge of the products
Administration Manager	- To receive disinfection records - To record the disinfection records on the "Stock Record".
Logistics Department Manager	- To ensure all distributed products have disinfection certificates.
Logistic supplier	- Cannot distribute any product without a disinfection certificates.

6. Qualification and Training
N/A

7. Procedures
7.1 Distributing requirement of sterile products
7.1.1 All sterile products shall have an Item code started with "8".
Reference: COP-7 Product Labeling and Tracking Procedures
7.1.2 Employees of the logistic supplier shall participate in the training course provided by the corporate to enhance the basic knowledge of the products.
7.1.3 Every batch of sterile products shall enclose with disinfection records issued by the manufacturer, for example Certified Quality Report (CQR) or disinfection certificate. Absorbent gauze shall provide isolated Physical and Chemical Test Report on Absorbent Gauze.
7.1.4 The logistic supplier shall not distribute the batches of product if they do not have the above documents.
7.1.5 Administration Manager shall review the disinfection records to ensure that (1) the Item codes on the documents are correct (2) the documents are effective. Then, the Logistics Department Manager may notify the logistic supplier to distribute the products.
Reference: COP-10 Receipt, Verification and Acceptance of Incoming Goods Procedures
7.1.6 At the same time, the Administration Manager shall record the disinfection records on the "Stock Record".

Applicable to	Route 1	Route 2	Route 3
			✓

7.1.7 The Logistics Department Manager shall not distribute the batches of product if it does not have the above documents.
7.1.8 Logistics Department Manager shall ensure all distributed products have disinfection certificates by reviewing the "Delivery note" faxed from the logistic supplier.
Reference: COP-13 Products Delivery Procedures

7.2 Expiry date of sterile products
7.2.1 Manufacturer shall print the expiry date of different batches of products on the Packing List.
7.2.2 Logistics Department Manager shall maintain related record after receiving the Packing List.
7.2.3 Logistics Department Manager shall ensure the effectiveness of the Lot number of all products according to the "Stock Record", which means that the expiry date has not exceeded.
7.2.4 If the warehouse products are expired, Logistics Department Manager shall notify the logistic supplier for labeling and segregation.
7.2.5 Logistic supplier shall check the expiry date on the product package before distributing the products. This is to ensure that the products satisfy customer expectations.

7.3 Maintenance of sterile products
7.3.1 The manufacturer shall set up standard for the environment of warehouse in which the sterile products are stored.
7.3.2 Logistic supplier shall control the environment according to the COP-9 Infrastructure and Work Environment Management Procedures and WI-01 Warehouse Instruction.

8. Record
Stock Record (Form 07)
Disinfection records

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.27 Control of Nonconforming Product and Service Procedures

1. Purpose

To systemize the control of nonconforming product procedures, from nonconformance identification to the controls of specifications. Products included the distributed products and products store in the warehouse.

2. Scope

2.1 Applicable to all locally distributed medical products and services.

2.2 The corporate had outsourced the warehouse service to the logistic supplier, so this procedure is also applicable to monitor the handling procedures of nonconforming products. The corporate is responsible to ensure that the logistic supplier implements this procedure.

3. Reference

COP-17 Corrective and Preventive Action Procedures
COP- 19 Product Recall Procedures
COP-18 Advisory Notice Handling Procedures
COP- 21 Adverse Incident Reporting Procedures
WI-02 Product Repackaging Instruction
WI-04 Product Disposal Instruction

4. Definition

4.1 Nonconforming product : Can be divided into expired products or scrap products

4.1.1 Expired products are products that have exceed the expiry date.

4.1.2 Scrap products are products that do not meet the quality standard, including the damaged products in the warehouse and that returned by the customer.

5. Responsibility

Person	Responsibility
Top Management	- To determine the handling method of expired products and nonconforming product
Sales and Marketing Department Manager	- To record the "Nonconforming Product Report" - To investigate the suspected nonconforming products - To report the investigation results to Top Management
Logistics Department Manager	- To inform the lgistic company with the handling method of nonconforming products
Logistic supplier	- If identified any nonconforming products, relocate the related product in segregation area and label them as "Scrap" - To contact Logistics Department Manager to report the quantity of nonconforming products and whether they were distributed to the market - To place the customer returned product in the segregation area and label them as "Returned Product"

6. Qualification and Training

Sales and Marketing Department Manager is responsible to identify the nonconforming products. They shall have medical service experience in public or private medical organization, have well understandings on product manufacturing,

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

product disinfection and product packaging procedures and have the ability to identify the difference in product materials and raw materials of different brands.

7. Procedures

7.1 Segregation of nonconforming products

7.1.1 Logistic supplier shall assign segregation area for the nonconforming products.

7.1.2 The segregation area can be used to store qualified products if it has extra spaces. However, the qualified and the nonconforming products shall be separated with the nonconforming products labeled with “Expired” or “Scrap” tag.

7.2 Handling expired products

7.2.1 Top Management shall determine the handling method and the Sales and Marketing Department Manager shall record it in the “Nonconforming Product Report”.

7.2.2 Expired products can only be returned to the manufacturer or disposeed; they shall not be distributed to the customers.

7.3 Handling nonconforming products

7.3.1 If identified any nonconforming products, logistic supplier shall relocate the related product in segregation area and label them as “Scrap”.

7.3.2 Logistic supplier shall contact the Logistics Department Manager to report the quantity of nonconforming products and whether they were distributed to the market. If related products are distributed to the market, Logistics Department Manager shall inform Top Management. Top Management shall determine whether product shall be recycled or returned and any warnings shall be issued base on the local regulations.

Reference:
COP- 19 Product Recall Procedures
COP- 18 Advisory Notice Handling Procedures
COP- 21 Adverse Incident Reporting Procedures

7.3.3 Top Management shall determine the handling method, and conduct inspection on the nonconforming products in person.

7.3.4 Administration Manager shall delete the nonconforming product in the “Stock Record”.

7.3.5 If the nonconformity involves the manufacturing process, Administration Manager shall monitor the situation with the manufacturer. If necessary, the nonconforming product samples shall be delivered to the manufacturer for quality test and the results shall be reported.

7.3.6 After the investigation, Sales and Marketing Department Manager shall fill in the “Nonconforming Product Report” and notify the Logistics Department Manager with the handling method.

7.3.7 Logistics Department Manager shall notify the logistic supplier with the method. Handling method can be the following:

7.3.7.1 **Repackaging:** Logistic supplier shall repackage the products according to WI-02 Product Repackaging Instruction.

7.3.7.2 **Sample:** Sales and Marketing Department Manager shall inspect the product and ensure that the nonconforming product will not affect product quality and patients safety. The nonconforming product can therefore be distributed as sample with “Sample” tag on the package.

7.3.7.3 **Scrap:** Logistics Department Manager shall receive the

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

scrap product from the logistic supplier warehouse. Upon arrival to the office, the Logistics Department Manager shall remove the corporate name and logo from the product package and destroyed the package.

Reference: WI-04 Product Disposal Instruction

7.3.8 After handling the nonconforming products, Sales and Marketing Department Manager shall amend the "Stock Record".

7.3.9 Top Management shall whether it is necessary to implement the COP-17 Corrective and Preventive Action Procedures.

7.4 Handling Returned Products

7.4.1 Customer may notify the corporate with any suspected nonconforming products.

7.4.2 Sales and Marketing Department Manager shall conduct investigation and report to the Top Management. Top Management shall determine the handling method.

7.4.3 If the customer has not opened the package of the returned product and the package is visually undamaged, it can be regarded as approved product.

7.4.4 If the package is opened, Sales and Marketing Department Manager shall inspect it and determine the handling method.

7.4.5 (Large quantity return) Logistic supplier shall arrange the product restocking procedures, the returned product shall be placed in segregation area and labeled as "Returned Product".

7.4.6 (Small quantity return) The corporate shall arrange the transportation of the returned product to the office.

7.4.7 Sales and Marketing Department Manager shall handle the nonconforming product identified in the investigation according to section 7.3.3-7.3.6.

7.5 Handling nonconforming service

7.5.1 Customer notify the corporate with the nonconforming services.

7.5.2 Sales and Marketing Department Manager shall investigate and verify the case. He/She shall also report to the Top Management and the Top Management shall determine the handling method.

7.5.3 If the returned product has not been opened yet and with no package damage, it can be treat as conforming product.

7.5.4 If the product is opened, the Sales and Marketing Department Manager shall inspect and determine how to handle it.

7.5.5 (Large quantity return) Logistic supplier shall arrange the product restocking procedures, the returned product shall be placed in segregation area and labeled as "Returned Product".

7.5.6 (Small quantity return) The corporate shall arrange the transportation of the returned product to the office.

7.5.7 Sales and Marketing Department Managershall handle the nonconforming product identified in the investigation according to section 7.3.3-7.3.6.

8. Record

Nonconforming Product Report (Form 26)
Stock Record (Form 07)

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.28 Corrective and Preventive Action Procedures

1. Purpose
To govern the process of initialing, requesting, implementing, and reviewing the effectiveness of corrective and preventive actions. To ensure the Quality Management System can effectively identify and correct the operations that do not follow the local regulations.

2. Scope
Applicable to all procedures of the Quality Management System of the corporate.

3. Reference
COP-2 Management Review Procedures
COP-9 Infrastructure and Work Environment Management Procedures
COP-14 Customer Feedback and Complaints Handling Procedures

4. Definition
Corrective action: Corporate adopts action to eliminate the cause of nonconformity and prevent nonconformity.
Preventive action: Corporate approves action to eliminate potential cause of nonconformity and prevent nonconformity. Potential nonconformity means the nonconformity that has not happened but may happen in the future.

5. Responsibility

Person	Responsibility
Top Management	- To determine the implementation of corrective and preventive actions - To approve the contents of "Corrective and Preventive Action Record"
Administration Manager	- To arrange employees to inspect the suspected nonconformity and find out the cause - To propose corrective action base on the nonconformity - To propose preventive action base on the potential nonconformity - To arrange employees for the corrective and preventive actions - To revise the corrective action if the previous actions are not effective - After the implementation of corrective actions (1) review the effectiveness of action and (2) follow up the action results to ensure that (1) the nonconformity had been handled and (2) to ensure no similar nonconformity occur in the future - To present the results of corrective and preventive action to the Administration Manager in the next Management Review Meeting - To fill in the "Corrective and Preventive Action Record" - To maintain records

6. Qualification and Training
N/A

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

7. Procedures

7.1 Corrective Actions

7.1.1 If the following situation happened, employees shall report to the Top Management and Top Management shall determine the implementation of corrective actions

7.1.1.1 Discover operations that do not follow regulations in the internal audit or third party audit.

7.1.1.2 Discover nonconforming procedures in the daily operations.

7.1.1.3 The marks on the Customer Satisfactory Survey are lower than standard (Reference: COP-14 Customer Feedback and Complaints Handling Procedures).

7.1.1.4 Receive customer oral, letter or email complaint and the complaints had been verified to be true.

7.1.1.5 Employees discover problems of the Management system.

7.1.1.6 Similar nonconformity repeatedly happened with no improvements.

7.1.1.7 Corrective or improvement actions are proposed in the Management Review Meeting.

7.1.1.8 The Quality Policy and Quality Objective are not achieved.

7.1.1.9 The warehouse of the logistic supplier failed to maintain temperature and humidity within the standard over 48 hours (Reference: COP-9 Infrastructure and Work Environment Management Procedures).

7.1.1.10 Nonconformity is identified during the regular inspection and spot check of the warehouse of logistic supplier (Reference: COP-9 Infrastructure and Work Environment Management Procedures).

7.1.1.11 Other reason.

7.1.2 Administration Manager shall arrange employees to inspect the suspected nonconformity, to find out (1) the cause of the nonconformity (2) the corrective action. Administration Manager shall report the cause and the proposed preventive action in the “Corrective and Preventive Action Record”.

7.1.3 Preventive and corrective actions shall be conducted if customer complaints are confirmed. Any reason for not conducting the actions shall be listed on the “Customer Complaint Feedback Form” and the Top Management shall approve the record.

7.1.4 Administration manager shall propose corrective action base on the nonconformity and list them in the “Corrective and Preventive Action Record”.

7.1.5 Top Management shall approve the “Corrective and Preventive Action Record” and the Administration Manager shall arrange employees to carry out the corrective actions.

7.1.6 Administration Manager shall revise the corrective action if the previous actions are not effective, until the expected results are achieved.

7.1.7 After the implementation of corrective actions, Administration Manager shall (1) review the effectiveness of action and (2) follow up the action results to ensure that (1) the nonconformity had been handled and (2) to ensure no similar nonconformity occur in the future.

7.1.8 Record the results in the “Corrective and Preventive Action Record” and approve the record by the Top Management.

7.1.9 Present the results of corrective action to the Administration Manager in the next Management Review Meeting

Reference: COP-2 Management Review Procedures

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

7.2 Preventive Actions

7.2.1 If the following situation happened, employees shall report to the Top Management and Top Management shall determine the implementation of preventive actions

7.2.1.1 Analyze the situation when implementing corrective actions and deliver any method to prevent nonconformity.

7.2.1.2 Nonconforming products are discovered in other brand which the products have similar potential nonconformity as the corporate's products.

7.2.1.3 Employees discover problem of the corporate operation and potential nonconformity.

7.2.1.4 Other Reason.

7.2.2 Administration Manager shall arrange employees to inspect the suspected nonconformity, to find out (1) the cause of the potential nonconformity (2) the preventive action. Administration Manager shall report the cause and the proposed preventive action in the Corrective and Preventive Action Record.

7.2.3 Top Management shall approve the "Corrective and Preventive Action Record" and the Administration Manager shall arrange employees to carry out the preventive actions.

7.2.4 Administration Manager shall revise the preventive action if the previous actions are not effective, until the expected results are achieved.

7.2.5 After the implementation of preventive actions, Administration Manager shall (1) review the effectiveness of action and (2) follow up the results to ensure that (1) the potential nonconformity had been handled.

7.2.6 Record the results in the "Corrective and Preventive Action Record" and approve the record by the Top Management.

7.2.7 Present the results of preventive action to the Administration Manager in the next Management Review Meeting.

Reference: COP-2 Management Review Procedures

8. Record

Corrective and Preventive Action Record (Form 24)

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.29 Advisory Notice Handling Procedures

1. Purpose
To govern the procedures of issuing the Advisory Notice.

2. Scope
Applicable to all locally distributed medical products and services.

3. Reference
COP-21 Adverse Incident Reporting Procedures

4. Definition
Advisory Notice:
One of the communication channels between the corporate and the customers, other channels included customer feedback, customer satisfactory survey, phone, email and fax. The communication with the regulatory authority is controlled by the COP-21 Adverse Incident Reporting Procedures.

5. Responsibility

Person	Responsibility
Top Management	- To determine the release of the "Advisory Notice" - To confirm the contents of "Advisory Notice" - To issue the "Advisory Notice" through email or mail to the customer
Sales and Marketing Department Manager	- To compose the "Advisory Notice" - To release the "Advisory Notice" through email or mail to the customer - To record the customer list of the mailed "Advisory Notice"

6. Qualification and Training
N/A

7. Procedures
7.1 Identify needs of Advisory Notice
7.1.1 Top Management shall determine whether it is necessary to issue the "Advisory Notice" to the customer at any time under the following situations:
a) Supplementary guidelines on using the medical device
b) Alternation of medical device
c) Return of medical device to the corporate or manufacturer
d) Disposal of medical device
e) Recycle of medical device
f) Amendment of local regulations
7.1.2 Top Management shall pay attention to (1) the received customer feedback and complaint (2) the emergence of nonconforming product and determine the necessity of issuing the "Advisory Notice".

7.2 Issue Advisory Notice
7.2.1 Sales and Marketing Department Manager shall compose the "Advisory Notice" and Top Management shall confirm the contents of "Advisory Notice". Sales and Marketing Department Manager and Top Management shall issue the "Advisory Notice" through email or mail to the customer.
7.2.2 "Advisory Notice" normally contain the following contents:
a) Name, Lot number, specification and quantity of product with problem

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

b) Reason for issuing the Advisory Notice
c) Potential hazards
d) Follow up procedures

7.2.3 Sales and Marketing Department Manager shall confirm the address, name and contact number of the product recipient according to the distributing record in order to issue the "Advisory Notice". Immediate notification through the "Advisory Notice" is expected and the Customer List of Advisory Notice Recipients shall be maintained.

7.2.4 The procedures of notifying the regulatory authority are controlled by COP-21 Adverse Incident Reporting Procedures.

8. Record

Advisory Notice
Customer List of Advisory Notice Recipients

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.30 Product Recall Procedures

1 Purpose
To govern the product recall procedures.

2. Scope
Applicable to all locally distributed medical products and services.

3. Reference
Medical Device Control Office COP-01 Code of Practice Local Responsible Persons- Section 3.7

4. Definition
Local Representative Person (LRP)

5. Responsibility

Person	Responsibility
Top Management	- To determine whether a product is needed to be recalled (If the product recall is compulsory, immediate action is required)
Logistics Department Manager	- To evaluate the quantity and impact of the distributed nonconforming products by reviewing the "Stock Record" with the Lot number of the related products. - To notify the logistic supplier to label the nonconforming product as "Scrap" and segregate them. All nonconforming products returned by the customer shall be labeled as "Returned Product" and shall be segregated.
Administration Manager	- To contact the LRP - To initiate actions according to the LRP - To assist the product presentation of LRP - To fill in the "Product Recall Form"

6. Qualification and Training
N/A

7. Procedures
7.1 Product recall can be due to following situations:
7.1.1 Suppliers or the corporate discover problem of the products
7.1.2 Customer complaint on nonconforming product
7.1.3 Product safety notification and the recall is determined by the corporate
7.1.4 Compulsory recall

7.2 Product alerts, modifications and recalls procedures
7.2.1 If any employees discover that the distributed product have potential hazards and need to be recall, they shall notify the Top Management and the Top Management shall determine whether the product is needed to be recalled (If the product recall is compulsory, immediate action is required). Potential hazards can be classified as:
7.2.1.1 The distributed products have serious defects or damages which may cause death or injury to the users.
7.2.1.2 The distributed products have potential risk that is undetected and this risk may cause death or injury to the users.
7.2.1.3 The distributed product do not meeting the standard even if this may not cause immediate impact on users.

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

7.2.1.4 Other reason that may threaten the life of users.

7.2.2 Logistics Department Manager shall evaluate the quantity and impact of the distributed nonconforming products by reviewing the "Stock Record" with the Lot number of the related products.

7.2.3 Logistics Department Manager shall label the nonconforming products that have not been distributed with "Scrap" tag and segregate them. All nonconforming products returned by the customer shall be labeled as "Returned Product" and shall be segregated.

7.2.4 Administration Manager shall contact the LRP of the product and present the plan for product recall.

7.2.5 Administration Manager shall initiate actions according to the LRP.

7.2.6 Administration Manager shall provide all information to the LRP to assist the product presentation of LRP.

7.2.7 Administration Manager shall fill in the "Product Recall Form" and Top Management shall sign for approval.

7.2.8 Administration Manager shall fill in the "Product Recall Form" after the nonconforming product had been disposed or returned to the manufacturers.

7.3 Department of Health- Products alerts, modifications and recalls procedures (extracted from COP-01 section 3.7 issued by the Department of Health)

7.3.1 Upon the issuance of alerts, modification notices and recalls by the manufacturer or overseas authorities, the LRP shall inform MDCO of related details and actions to be taken in Hong Kong as soon as possible, not later than 10 calendar days after their issuance. The LRP shall follow up the actions and shall submit progress reports to MDCO as requested until the case is concluded. It is preferred that prior arrangements be made such that within four hours of the issuance of an alert, recall or modification notice by the manufacturer, the same be also e-mailed direct to MDCO.

8. Record

Product Recall Form (Form 25)
Related Documents Submitted to Regulatory Authority

Applicable to	Route 1	Route 2	Route 3
			✓

1.31 Risk Management Procedures

1. Purpose
To govern the procedures of risk management of corporate's products.

2. Scope
Applicable to all locally distributed medical products and services in the scope of the ISO13485.

3. Reference
ISO14971 International Standard of Risk Management

4. Definition
N/A

5. Responsibility

Items	Department/ Person
To establish risk management plan	Risk Management Team leaderer
To establish and lead the Risk Management Team	Risk Management Team leaderer
To identify the intended purpose and identification of characteristics relating to the safety of the medical device	Risk Management Team Member
To conduct initiate risk evaluation	Risk Management Team Member
To identify, enforce, record and evaluate risk control procedures (Reviewed by Risk Management Team leader)	Risk Management Team Member
To evaluate residue risk (Reviewed by Risk Management Team leader)	Risk Management Team Member
To prepare the Risk Management Report (Reviewed by Risk Management Team leader)	Risk Management Team Member
To conduct distribution information control	Risk Management Team Member

6. Qualification and Training
N/A

7. Procedures
7.1 Risk Management Requirements
- 7.1.1 The risk of all type of products shall be evaluated and controlled prior to the distribution to customers, the evaluation include the risk management evaluation and risk management control.
- 7.1.2 The risk of all distributing products shall also be managed and documented in Risk Management Report.
- 7.1.3 Where the products which share similar intended purposes, their risks may be managed and documented in one "Risk Management Report". For the products with different intended purposes, design and specification, it shall be documented on a separated "Risk Management Report" with the explanation of risk difference.

7.2 Risk Management Team Establishment
- 7.2.1 Risk Management Report shall be prepared by the Risk Management Team. The team is responsible to analyze product risk and the team consisted of the following personnel:

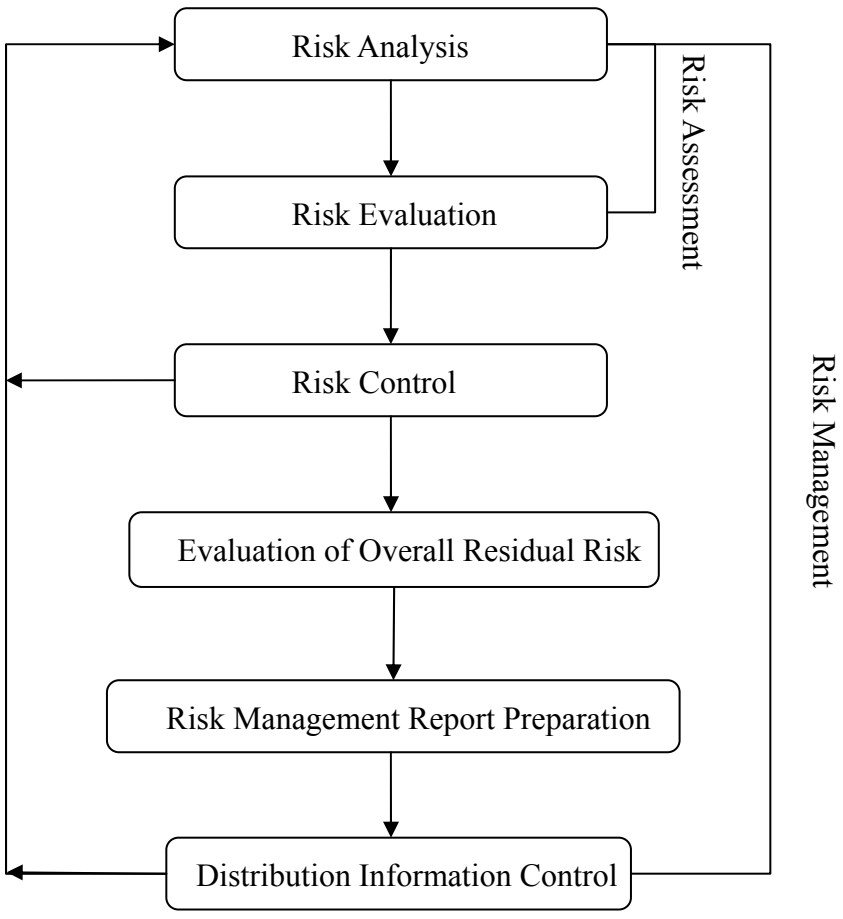
Applicable to	Route 1	Route 2	Route 3
			✓

Risk Management Team Members	Department/ Person
Risk Management Team leader	Top Management
Risk Management Team Member	Administration Manager
Risk Management Team Member	Accounts Department Manager
Risk Management Team Member	Logistics Department Manager
Risk Management Team Member	Sales and Marketing Department Manager

7.3 Risk Management System

7.3.1 The elements and processes of risk management are listed as follow:

- Risk Analysis
- Risk Evaluation
- Risk Control
- Evaluation of Overall Residual Risk
- Distribution Information Control



7.4 Scope of Risk Management

Risk management shall consider and evaluate all risks occurred during the distribution process, including purchasing, storage, delivery and maintenance.

7.5 Risk Management evaluation requirements

7.5.1 Risk Management Team shall conduct initial risk evaluation base on the product design. If the risk is greater than the acceptable level, Risk Management Team shall establish action plan to lower the related risk. If the residue risk is still greater than the acceptable level, residue risk evaluation shall be conducted until the risk level is lower than the acceptable level. Another option is to conduct Risk Benefit

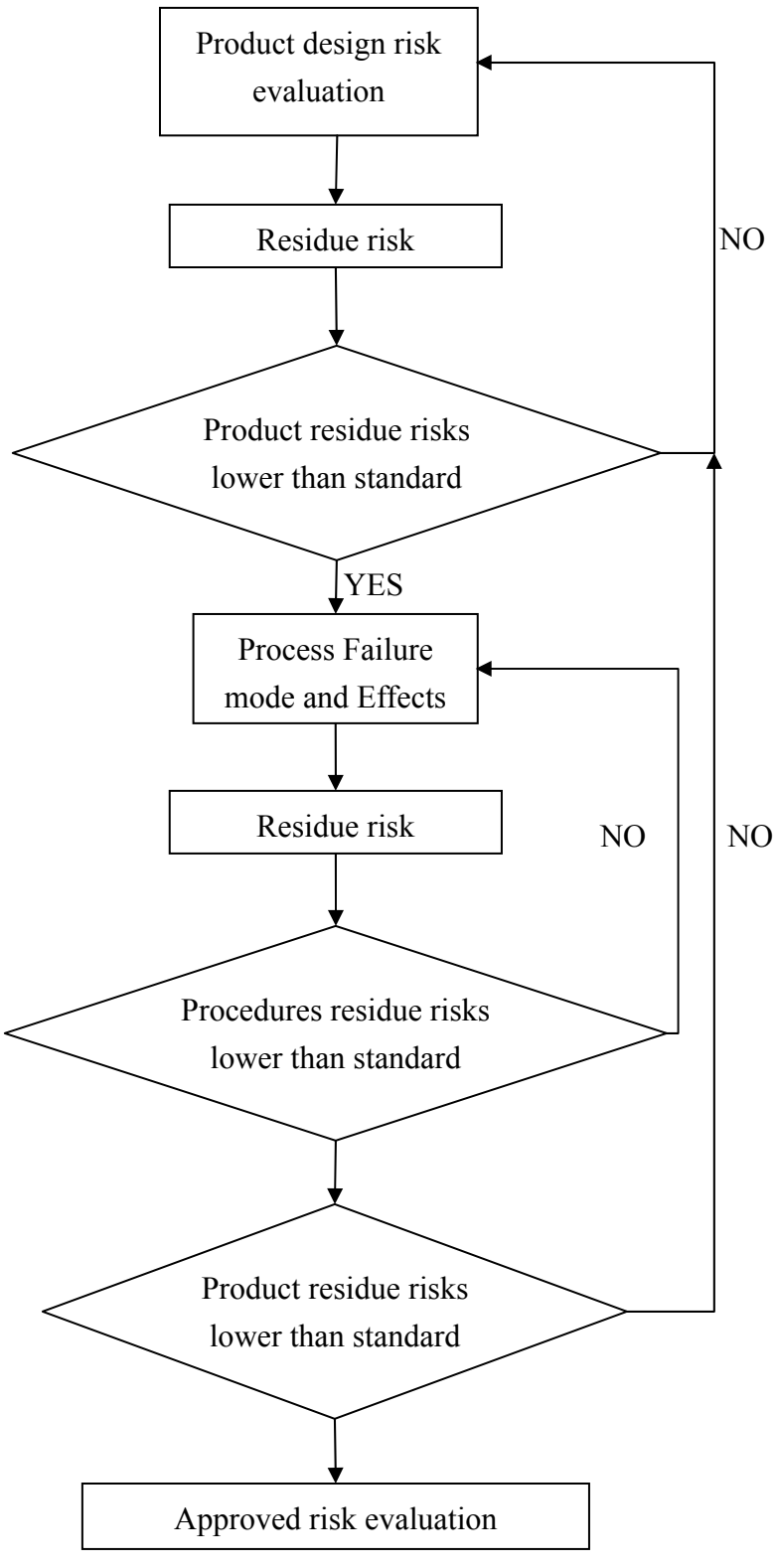
Applicable to	Route 1	Route 2	Route 3
			✓

Analysis in order to determine whether the effectiveness of corrective actions is greater than the related risk.

7.5.2 When a product passes the product design risk evaluation and the residue risk evaluation, the product shall be analyzed based on the Failure mode and effects analysis in order to evaluate the risk of product distribution. The result of the analysis shall be used t conduct the second residue risk evaluation. If the results of the second evaluation do not pass the acceptable level, another risk evaluation and residue risk evaluation shall be conducted until there is no residue risk.

Applicable to	Route 1	Route 2	Route 3
			✓

7.6 Risk Management Process



Applicable to	Route 1	Route 2	Route 3
			✓

7.7 Distribution Risk Evaluation

7.7.1 Criteria of Risk Evaluation:

Risk management shall be performed according to their severity, frequency and detectability and then form Risk Priority Number (RPN). The RPN shall be the multiple of the Severity (S), Occurrence (O) and Detectability (D). It shall be calculated by the following formula, where RPN shall be proportional to the risks level identified. The higher value of RPN represents a higher failure effect.

Risk Priority Number (RPN) = Severity(S) x Occurrence(O) x Detectability(D)

7.7.2 Description of Severity

Failure Effect	Description	Degree
Crucial without alert	— The potential failure may affect the safety of the product related employees and affect the distribution procedures. — Highly serious, without the alert, potential failure effect may affect the safety of medical device and/or may violate government regulations.	10
Crucial with alert	— The potential failure may affect the safety of the product related employees and affect the distribution procedures. — Highly serious, under the alert, potential failure effect may affect the safety of medical device or may violate government regulations.	9
Very Serious	— Distribution process is seriously disturbed. — All products needed to be disposed. — Medical device or components loss its basic function and effect. — Customer seriously dissatisfied.	8
Serious	— Distribution process is mildly disturbed. — Product needed to be classified and part of them (Less than 100%) need to be disposed. — Medical device or components function normally but with low effectiveness. — Customer dissatisfaction	7
Medium	— Distribution process is mildly disturbed. — Part of the products (Less than100%) shall be disposed without classification. — Medical device or components function normally but with low effectiveness. — User feels uncomfortable.	6
Low	— Distribution process is mildly disturbed. — 100% of products need to be repackaged. — Medical device or components do not meet the standard. — Customer mildly dissatisfied.	5
Very Low	— Distribution process is mildly disturbed. — Product needed to be classified and part of them (Less than 100%) need to be repackaged.. — Medical device or components do not meet the standard. — Majority of customer discovered nonconformity.	4
Light	— Distribution process is mildly disturbed. — Part of the products (Less than 100%) need to be repackaged. — Medical device or components do not meet the standard. — Half of the customer discovered nonconformity.	3
Very Light	— Distribution process is mildly disturbed. — Part of the products (Less than 100%) need to be repackaged. — Medical device or components do not meet the standard.	2
None	No effect	1

Applicable to	Route 1	Route 2	Route 3
			✓

7.7.3 Description of Occurrence

Failure Probability	Probability Occurrence	Cpk	Occurrence
Very High, unpreventable	≥1/2	<0.33	10
	1/3	≥0.33	9
High, occur repeatedly	1/8	≥0.51	8
	1/20	≥0.67	7
Medium, Sometimes occur	1/80	≥0.83	6
	1/400	≥1.00	5
	1/2000	≥1.17	4
Low, very few occur	1/15000	≥1.33	3
	1/150000	≥1.50	2

7.7.4 Description of Detection Level

Detect Probability	Level	Test Type A	B	C	Detect procedure	Detectability
Almost impossible	Cannot detected				No detection method	10
Very Rare	Almost impossible to detect				Indirect or random inspection	9
Rare	Difficult to detect				Naked-eye inspection	8
Very Low	Difficult to detect				Double naked-eye inspection	7
Low	Possible to detect				Chart inspection, for example SPC	6
Medium	Possible to detect				Detect failure by measuring equipment after distribution	5
Above Average	Always detect				Inspection before or during distribution	4
High	Always detect				Segmented inspection and verification method	3
Very high	Almost surely detect				Auto-termination device or mechanism under failure	2
Usually possible	Surely detect				Preventive action can be conducted during distribution procedures	1

* Test Type: (A) Prevention (B) Gaging (C) Human test

Note：If the Risk Priority Number is higher than 150, corrective actions must be performed.

7.8 Acceptability Criteria

7.8.1 The distribution activities shall fulfill the requirements of (1) safety guidelines set out by the manufacturer, (2) local regulatory requirements, and (3) no cause of hazards during normal usage.

7.9 Verification Activities

7.9.1 The evaluation on the effectiveness of risk management shall base on the internal guidelines of the verification activities, the implementation and effectiveness shall both be verified.

Items	Responsible by	Proof
Improve service	Sales and Marketing Department, Logistics Department	Customer Satisfactory Survey
Improve operation procedures	Administration Department, Accounts Department	Internal Audit Record Management Review Meeting Minutes

Applicable to	Route 1	Route 2	Route 3
			✓

7.10 Collection of Distribution Information

7.10.1 The member of Risk Management Team shall regularly take note on customer feedback and complaints, as well as the information released by MDCO to collect any information regarding to the updates of regulatory requirements and adverse event. The collection method shall be evaluated regularly. The responsibility of member is listed below:

Member	Responsibility
Sales and Marketing Department	Customer feedback and complaint as well as the information released by MDCO shall be monitored every day to collect any information regarding to the product and service compliance. The results shall be presented to the Top Management once a week. Immediate notification to the Top Management shall be taken if any hazardous information is discovered.

7.10.2 Risk Management Teams shall consider the information released by the following organizations as an input of risk evaluation

Country	Related Regulation	Source	Organization
Europe	IEC,EN,ISO etc.	http://ec.europa.eu/consumers/ sectors/medical-devices/index_en.htm	European Commission
Canada	CMDR,SOR98-282 etc.	http://www.hc-sc.gc.ca	Health Canada
Japan	Health and Medical Services Policy etc.	http://www.mhlw.go.jp/english/index.html	Ministry of Health, Labour and Welfare
US	ASTM,ANSI,AAMI etc.	http://www.fda.gov/default.htm	US Food and Drug Administration
China	Regulation on the Supervision and Administration of Medical Devices, Registration regulations	http://www.sfda.gov.cn	China Food and Drug Administration
Australia	IEC,EN,ISO etc.	http://www.health.gov.au	Department of Health and Ageing

7.10.3 Because the regulations of other counties are normally established according to the main medical market, so the collection of information in the above sources could reveal the standard of the new regulations. If any change of regulatory requirements affecting the safety and efficacy of the medical devices and causing risk to the users, corresponding advisory notice procedures shall be taken.

8. Record

Risk Management Report

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.32 Adverse Incident Reporting Procedures

1. Purpose
To govern the processes for adverse incident reporting according to the guidelines in Medical Device Control Office, Department of Health, The Government of the Hong Kong Special Administrative Region.

2. Scope
Applicable to all locally distributed medical products and services.

3. Reference
COP-3 Regulatory Control Procedures
Guidelines of Medical Device Control Office (GN-03) - Guidance Notes for Adverse Incident Reporting by Local Responsible Persons

4. Definition
N/A

5. Responsibility

Person	Responsibility
Sales and Marketing Department Manager	- To contact Local Responsible Person - To provide all information to Local Responsible Person - To fill in "Adverse Incident Report" - To maintain close contact with Local Responsible Person and to present the latest development to Top Management

6. Qualification and Training
N/A

7. Procedures
7.1 Requirements of Regulatory Authority
7.1.1 The reporting procedures shall be guided by the guidelines of local Heath organization: GN-03 - Guidance Notes for Adverse Incident Reporting by Local Responsible Persons.
7.1.2 If there is updated version of GN-03, this COP shall be updated if necessary.
Reference: COP-3 Regulatory Control Procedures

7.2 Reporting Procedures
7.2.1 Sales and Marketing Department Manager shall contact Local Responsible Person and the Local Responsible Person shall determine whether the adverse incidents have to be reported to the Regulatory Authority according to the guidelines GN-03 of the Medical Device Control Office.
7.2.2 If the incident shall be reported, Sales and Marketing Department Manager shall provide all information to Local Responsible Person and assist him/her to fill in the Medical Device Adverse Incident Report Form which attached in the GN-03 document.
7.2.3 Upon completion of the form, Local Responsible Person shall submit it with the related documents to the regulatory authority.
7.2.4 Sales and Marketing Department Manager shall fill in the "Adverse Incident Report".
7.2.5 Sales and Marketing Department Manager shall maintain close contact with Local Responsible Person and to present the latest development to Top Management.

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

7.3 Adverse incidents to be reported (extracted from GN-03 issued by the Department of Health)

7.3.1 Any incident that meets all of the following three basic reporting criteria is considered a reportable adverse incident and shall be reported to MDCO within the timeframe of respective incident.

7.3.1.1 The LRP becomes aware of information regarding an incident that has occurred with his listed device(s).

7.3.1.2 The LRP's device is associated with the incident. In assessing the link between the device and the incident, the LRP shall take into account:

- The opinion, based on available information, from a healthcare professional;
- Information concerning previous, similar incidents;
- Other information held by the LRP or the manufacturer.

7.3.1.3 The incident led to one of the following outcomes:

- Death of a patient, user or other person;
- Serious injury of a patient, user or other person;
- No death or serious injury occurred but the incident might lead to death or serious injury of a patient, user or other person if the incident recurs.

7.3.1.4 Use errors meeting any of the following criteria are also reportable:

- Use error that results in death or serious injury / serious public health concern.
- When the LRP or manufacturer notes a change in trend or a change in pattern of an issue that can potentially lead to death or serious injury or public health concern.
- When the LRP or manufacturer initiates corrective action to prevent death or serious injury or serious public health concern.

7.4 Incidents exempt from reporting (extracted from GN-03 issued by the Department of Health)

7.4.1 Whenever any of the following exemption rules is met, the adverse incident does not need to be reported.

7.4.1.1 Deficiency of a new device found by the user prior to its use

7.4.1.2 Adverse incident caused by patient conditions.

7.4.1.3 Use of a medical device beyond its service life

7.4.1.4 Protection against a fault functioned correctly and where no death or serious injury occurs

7.4.1.5 Remote likelihood of occurrence of death or serious injury

7.4.1.6 Expected and foreseeable side effects

7.4.1.7 Adverse incidents described in an advisory notice previously sent to users, and where no serious injury or death occurs

7.4.1.8 Adverse incidents caused by user errors other than those specified in section 7.2.1.5

7.4.1.9 Adverse incidents caused by abnormal use of medical devices

7.4.2 Notwithstanding the exemption criteria, all adverse incidents involving issues of serious public health concern shall be reported to MDCO.

7.4.3 Similarly, those incidents that are subject to an exemption (Section 7.3.1) become reportable if a change in trend (usually an increase in frequency) or pattern is identified. Please refer to GHTF document of

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

ref.: SG2/N36R7:2003 for guidance on trend reporting of adverse incidents.

7.5 Timeframes for Submitting Adverse Incident Reports (extracted from GN-03 issued by the Department of Health)

7.5.1 Adverse incidents that result in death or serious injury or of a serious public health concern must be reported by the LRP to MDCO as soon as possible, but not later than 10 elapsed calendar days after the LRP becomes aware of the incident.- 4

7.5.2 All other reportable adverse incidents must be reported by the LRP to MDCO as soon as possible, but not later than 30 elapsed calendar days after the LRP becomes aware of the incident.

7.5.3 The LRP must submit a report to MDCO with as much information as possible within the required timeframe. Incomplete information is not an excuse for not meeting this requirement.

8. Record

Adverse Incident Report (Form 29)

Medical Device Adverse Incident Report Form (Attached in the GN-03 documents issued by the Medical Device Control Office)

Applicable to	Route 1	Route 2	Route 3
		✓	✓

1.33 Supplier Evaluation Procedures

1. Purpose
To govern the process of evaluating and monitoring suppliers.

2. Scope
Applicable to the process of evaluation and monitor the performance of suppliers, which provide distribution and relating services of medical device to the corporate.

3. Reference
N/A

4. Definition
Third-party Logistic Supplier: the outsourced supplier which provide the corporate with medical device inspection, storage, distribution and recording services.

5. Responsibility

Person	Responsibility
Top Management	- To explore new suppliers according to the market needs - To evaluate the new supplier and review whether the suppliers meet the standard of the corporate and the customer - To evaluate the need of re-evaluation of supplier - To determine the deletion of specific supplier from the Approved Supplier List
Administration Manager	- To take action according to evaluation results - To update the "Approved Supplier List" - To email the Approved Supplier List to all employee
Sales and Marketing Department Manager	- To contact the suppliers for their corporate information, copy of Business Registration Certificate/similar documents and product certificates (if applicable) - To re-evaluate the suppliers on the "Approved Supplier List" every year
Logistics Department Manager	- To re-evaluate the Third-party Logistic Supplier on the "Approved Supplier List" every year - To fill in section one of the "Third-party Logistic Supplier Re-evaluation Record"

6. Qualification and Training
N/A

7. Procedures
7.1 Addition of new supplier
7.1.1 All medical device distributed by the corporate can only be purchased from the suppliers on the "Approved Supplier List".
7.1.2 Top Management shall explore new suppliers at any time.
7.1.3 Sales and Marketing Department Manager shall contact the suppliers for their corporate information, copy of Business Registration Certificate/similar documents and product certificates (if applicable). Then, fill in section one of the "Supplier Evaluation Form"
7.1.4 If necessary, Sales and Marketing Department Manager shall request product samples from the new suppliers to ensure they meet the standard of the corporate and the customer.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

7.1.5 Top Management shall evaluate the new supplier and review whether the suppliers meet the standard of the corporate and the customer and record the results on section two of the "Supplier Evaluation Form".
7.1.6 Administration Manager shall receive the following documents and take action according to evaluation results
a. Supplier Evaluation Form
b. Copy of Business Registration Certificate/similar documents
c. Product certificates (if applicable)
7.1.7 If evaluated as "Approved", the Administration Manager shall update the "Approved Supplier List".
7.1.8 If evaluated as "Unapproved", the Administration Manager shall maintain the record according to section 7.5.
7.1.9 Administration Manager shall notify all employees on the update of "Approved Supplier List"
7.1.10 All employees can borrow the latest "Approved Supplier List" from the Administration Manager.

7.2 Supplier re-evaluation
7.2.1 Initiate re-evaluation procedures
7.2.1.1 Sales and Marketing Department Manager shall re-evaluate the suppliers on the "Approved Supplier List" every year.
7.2.1.2 All employees shall report to the Top Management if the supplier is discovered to have the following situation. The Top Management shall evaluate the need of re-evaluation of the supplier.
a. Repeated occurrence of quality problems with no intention to improve
b. Repeated delay of the promised actions with no intention to improve
c. Extremely poor attitude with no intention to improve
d. Usually not response to the email and enquiry of the corporate
e. Other special reason
7.2.2 Process the re-evaluation procedures
7.2.2.1 Sales and Marketing Department Manager shall fill in section one of the "Supplier Re-evaluation Form".
7.2.2.2 Top Management shall determine the deletion of specific supplier from the "Approved Supplier List" and record the results in section two of the "Supplier Re-evaluation Form".
7.2.2.3 If evaluated as "Approved", the Administration Manager shall maintain record according to section 7.5.
7.2.2.4 If evaluated as "Unapproved", the Administration Manager shall update the "Approved Supplier List".
7.2.2.5 Administration Manager shall notify all employees on the update of "Approved Supplier List"
7.2.2.6 All employees can borrow the latest "Approved Supplier List" from the Administration Manager.

7.3 Re-evaluation of Third-party Logistic Supplier
7.3.1 Initiate re-evaluation procedures
7.3.1.1 Sales and Marketing Department Manager shall re-evaluate the external logistic companies on the "Approved Supplier List" every year.
7.3.1.2 All employees shall report to the Top Management if the logistic supplier is discovered to have the following situation. The Top Management shall evaluate the need of re-evaluation of the logistic supplier.
a. Repeated occurrence of quality problems with no intention

Applicable to	Route 1	Route 2	Route 3
		✓	✓

to improve

b. Repeated delay of the promised actions with no intention to improve

c. Extremely poor attitude with no intention to improve

d. Usually not response to the email and enquiry of the corporate

e. Other special reason

7.3.1.3 If the Top Management evaluated the logistic supplier as "Unapproved Performance" in section two of the "Third-party Logistic Supplier Monitor Record", Logistics Department Manager shall immediately implement the re-evaluation of logistic supplier and determine the use of logistic service of this corporate.

7.3.2 Process the re-evaluation procedures

7.3.2.1 All medical device distributed by the corporate can only be delivered by the logistic supplier on the "Approved Supplier List".

7.3.2.2 Sales and Marketing Department Manager shall fill in section one of the "Third-party Logistic Supplier Re-evaluation Record". In section one, Sales and Marketing Department Manager shall collect the "Third-party Logistic Supplier Monitor Record" of the past 12 months, analyze the data and answer the questions. If any items are major nonconformity, he/she shall briefly fill in the date, content and corrective results of the findings.

7.3.2.3 Top Management shall determine the deletion of specific supplier from the "Approved Supplier List" and record the results in section two of "Third-party Logistic Supplier Re-evaluation Record".

7.3.2.4 Normally under the following situation, the Logistic supplier shall be disqualified. However, the Top management can determine the qualification of logistic supplier under specific conditions, sufficient reasons are required:

a. Each questions in section one accumulate three times of noncompliance

b. Repeated noncompliance after corrective actions

c. Major nonconformity cause huge amount of nonconforming products

d. Noncompliance cannot be corrected

e. Occurrence of product recall, issuance of Advisory Notice and adverse event due to the noncompliance of logistic supplier.

7.3.2.5 If the logistic supplier is decided to be maintained on the "Approved Supplier List", Administration Manager shall maintain the record according to section 7.4.

7.3.2.6 If the logistic supplier is decided not to be maintained on the "Approved Supplier List" and the corporate had determined to cancel the service provided by that logistic supplier, Administration Manager shall delete the corporate from the "Approved Supplier List".

7.3.2.7 Administration Manager shall notify the employees on the update of "Approved Supplier List".

7.3.2.8 All employees can borrow the latest "Approved Supplier List" from the Administration Manager.

8. Record

Supplier Evaluation Form (Form 20)
Supplier Re-evaluation Form (Form 21)
Approved Supplier List (Form 19)

Applicable to	Route 1	Route 2	Route 3
		✓	✓

Chapter 4. Sample of Corporate Operation Practice
Supplier Evaluation Procedures

Third-party Logistic Supplier Monitor Record (Form 13)
Third-party Logistic Supplier Re-evaluation Record (Form 14)

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Applicable to	Route 1	Route 2	Route 3
		✓	✓

1.34 Purchasing Procedures

1. Purpose
To govern the purchasing procedures including process for the preparation of necessary purchasing information, establishment of purchasing documents and assignation of responsibility in order to ensure the purchased product satisfy the corporate and the customer.

2. Scope
Applicable to all locally distributed medical products and services.

3. Reference
COP-10 Receipt, Verification and Acceptance of Incoming Goods Procedures

4. Definition
N/A

5. Responsibility

Person	Responsibility
Top Management	- To confirm the purchase order
Sales and Marketing Department Manager	- To review the "Stock Record" - To fill in the Purchase Order - To issue the Purchase Order to Manufacturer - To follow up the Purchase Order

6. Qualification and Training
N/A

7. Procedures

7.1 Identify purchasing needs

7.1.1 Regular stock inspection: Sales and Marketing Department Manager shall review the "Stock Record" at least once per two weeks to determine the needs for purchasing.

7.1.2 Stock shortage: If any employees discover there is shortage of stock, he/she shall report to the Sales and Marketing Department Manager and the Sales and Marketing Department Manager shall determine the needs for purchasing.

7.2 General purchasing procedures

7.2.1 All products shall be purchased from suppliers on the "Approved Supplier List".

7.2.2 Sales and Marketing Department Manager shall fill in the "Purchase Order" with the product Item code, name, specifications, quantity, raw materials, package and delivery date.

7.2.3 Upon completion of Purchase Oder, Sales and Marketing Department Manager shall encode the Purchase Order with a Purchase Order Number and forward it to the Top Management for approval.

7.2.4 After confirming the purchase quantity, Sales and Marketing Department Manager shall email the Purchase Oder to the supplier and confirm the supplied products fulfill all requirements.

7.2.5 The supplier shall reply the purchase order and confirm the delivery date by email.

7.2.6 Sales and Marketing Department Manager shall follow up the purchase order by phone or email if there is no reply form the supplier.

7.2.7 The procedures of handling the incoming products can be referred to COP-10 Receipt, Verification and Acceptance of Incoming Goods Procedures.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

7.3 Revise Purchase Order

7.3.1 The corporate and the supplier can request changes to the Purchase Order.

7.3.2 The revise content shall be first approved by Top Management and then the Sales and Marketing Department Manager shall confirm the order with the supplier by phone. The latest purchasing information shall be recorded on the Purchase Order and labeled as the updated version.

8. Record

Purchase Order (Form 04)

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.35 Calibration of Measuring Equipment Procedures

1. Purpose
To govern the processes for identification, calibration, and maintenance of measuring and monitoring equipment.

2. Scope
Applicable to measuring and testing equipment used for verifying product conformance.

3. Reference
N/A

4. Definition
N/A

5. Responsibility

Person	Responsibility
Administration Manager	- To fill in and update the "Equipment Calibration Record" - To recall the equipment and forward them to corresponding calibrating organization

6. Qualification and Training
N/A

7. Procedures
7.1 Calibrating Procedures
7.1.1 If the measuring equipment has a deviation value, Administration Manager shall define the acceptable deviation value before purchasing the equipment and record it on the "Equipment Calibration Record".
7.1.2 After purchasing the equipment, the Administration Manager shall check whether the deviation value of the equipment is in the defined acceptable range and record it on the "Equipment Calibration Record".
7.1.3 The measuring equipment used by the corporate and the logistic supplier shall be calibrated regularly before and during use to ensure that they operate normally.
7.1.4 All measuring equipment that needs to be calibrated shall be labeled with the Re-calibration Date.
7.1.5 The frequency of calibration shall be based on the Re-calibration Date listed on the calibration record.
7.1.6 Administration Manager shall fill in and update the "Equipment Calibration Record", the list of equipment need to be calibrated and the re-calibration date of the equipment shall be included.
7.1.7 If the measuring equipment need to be re-calibrated, Administration Manager shall recall the equipment and forward them to corresponding calibrating organization
7.1.8 After calibration, Administration Manager shall check whether the deviation value of the equipment is in the defined acceptable range and record it on the "Equipment Calibration Record".
7.1.9 Administration Manager shall (1) label the equipment with the next Re-calibration Date (2) fill in shall the "Equipment Calibration Record" (3) Maintain the calibration certificates issued by the calibrating organization.

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

8. Record

Equipment Calibration Record (Form 30)
Calibration certificate issued by the calibrating organization

Chapter 5. Work Instruction Sample

Applicable to	Route 1	Route 2	Route 3
		✓	✓

1.36 Warehouse Instruction

Applied Department(s):									
Administration Department	☐	Account Department	☐	Sales and Marketing Department	☐	Quality Department	☐	Logistic Department	☐
Purpose	Guideline for cleaning and temperature and humidity control in warehouse								
Scope	Applicable to the warehouse of the logistic supplier that stores the corporate's product.								
Prepared by				**Approved by**					
(Department Manager) Date：				(Top Management) Date：					

1 Requirements on warehouse employee

1.1 Be careful when transporting the stock to ensure cleanliness of the products.

1.2 Ensure correct number of stock in warehouse.

1.3 Ensure all import and export products are inspected and have related certificates.

1.4 Ensure the stock arrangement follow the "First-in-First-out principle".

1.5 Ensure all products are placed in correct area.

1.6 Ensure all products are within effective date

1.7 Identify the undiscovered nonconforming products

1.8 Ensure nonconforming products/customer properties/ samples and returned products are labeled and segregated.

1.9 Ensure measuring equipment (for example thermometer and hygrometer) in the warehouse are calibrated, within the effective calibration period and operate normally

1.10 Ensure the completeness of the fire prevention tools. Conduct inspection in the warehouse regularly and maintain related certificates.

1.11 Ensure the cleanliness, temperature and humidity of the warehouse meet the standard level.

1.12 Ensure all cleanliness and temperature lists are recorded.

1.13 Ensure all environment control equipment (including hygrometer, fan and air-conditioner) in the warehouse operate normally, any damage shall lead to immediate replacement of the equipment.

1.14 The air-conditioned room for the sterile products shall equip with hygrometer and air-conditioner; storage area of non-sterile product shall be equipped with large fan.

1.15 Ensure there are no pests and rodents in the warehouse

1.16 Monitor the daily temperature and humidity level of the observatory. If the observatory level exceeds the standard temperature or humidity set by the manufacturer for storage of products, special attention shall be paid to the warehouse condition.

1.17 Understand the corporate requirements on the warehouse products and warehouse employee.

2 Reminders on employees clothing and work requirements

2.1 Wear clean and tidy clothing in the warehouse.

2.2 Wash hands thoroughly before work. Check the cleanliness of hands before touching any products and wash hands with soap if not clean.

2.3 Be careful when transporting the stock to ensure cleanliness of the products.

2.4 Eating and drinking is not allowed in the warehouse, food and drinks shall never be brought into the warehouse.

2.5 Ensure the sole of shoe are clean before entering the warehouse area, clean the shoe if they are dirty.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

3 Storage requirements

3.1 The products shall be stored according to the requirements of the manufacturer.

3.2 Normally, the sterile products shall be stored in the environment with temperature 7°C -33 °C and humidity 53% - 87%. The expiry date shall be displayed on product package, normally with effective period of five years.

3.3 Non-sterile products shall be stored at cool, ventilated and clean environment. The manufacturer may not enclose with a expiry date but the corporate shall make sure the product will be distributed as soon as possible.

4 Temperature and humidity control

4.1 Sterile products shall be stored in the environment with temperature 7°C -33 °C and humidity 53% - 87%.

4.2 Warehouse for the sterile product shall maintain temperature and humidity control and the levels shall be recorded according to the calibrated thermometer and hygrometer.

4.3 Employees shall record the temperature and humidity twice a day (except public holiday) to ensure the levels are normal and the data shall be recorded on the ““Warehouse Temperature Record”.

4.4 Warehouse employees shall check the temperature and humidity are normal every day before and after work.

4.5 The “Warehouse Temperature Record” of the previous month shall be faxed to the corporate within the first week of every month.

4.6 If the temperature and humidity date are abnormal, logistic supplier have the responsible to notify the Logistics Department Manager.

4.7 Warehouse Manager shall monitor the daily temperature and humidity level of the observatory. If the observatory level exceeds the standard temperature or humidity set by the manufacturer for storage of products, special attention shall be paid to the warehouse condition.

5 Handling abnormal temperature and humidity

5.1 If the temperature or the humidity exceeds the standard range, warehouse employees shall notify the manager and the manager shall notify the Logistics Department Manager.

5.2 Manager shall carry out corrective actions base on the situation.
(1) If the temperature is higher than standard, the fan or air-conditioner shall be opened; if the temperature is lowered than standard, the doors and window of the warehouse shall be closed and the product shall be relocated in warmer place.
(2) If the humidity is higher than standard, the air-conditioner and hygrometer shall be opened; if the humidity is lower than standard, the product shall be relocated to wetter area.

5.3 Employees shall closely monitor the thermometer and hygrometer to check whether the levels are back to normal.

5.4 If the levels are still abnormal after 12 hours, employees shall report to the manager again and the manager must report the incident to the Logistics Department Manager.

5.5 The employees shall ensure all environment control equipment (including hygrometer, fan and air-conditioner) in the warehouse operate normally, any damage shall lead to immediate replacement of the equipment.

6 Cleaning the warehouse

6.1 Warehouse employees shall clean the warehouse floor once a week. The insect traps shall be checked and cleaned. After completion, the

Applicable to	Route 1	Route 2	Route 3
		✓	✓

"Warehouse Cleaning Record" shall be updated.

6.2 The floor shall be cleaned by water or antiseptic.

6.3 If the floor is filthy due to any reason, the employees shall clean it up immediately.

6.4 The "Warehouse Cleaning Record" of the previous month shall be faxed to the corporate within the first week of every month.

7 Pests control

7.1 Appropriate amount of insects trap shall be placed in the warehouse.

7.2 Warehouse employees shall clean the warehouse floor once a week. The insect traps shall be checked and cleaned. After completion, the "Warehouse Cleaning Record" shall be updated.

7.3 If employees discover any pests in the insect traps, or discover pests or rodents in the warehouse, he/she shall report to the manager and the manager shall arrange pests control by the building management corporate.

7.4 If the pests appear for over one week, logistic supplier must notify the Logistics Department Manager to handle the situation.

8 Fire service facilities inspection

8.1 Fire service facilities of the warehouse must fulfill the local regulation and inspected by the Fire Services Department regularly. Logistic supplier shall arrange the inspection and maintain all effective certificates.

9 Maintenance of record

9.1 Manager shall maintain all the corporate record (either in paper or computer file format). All record shall be maintained for at least seven years. These records included the Product Inspection Record, Warehouse Cleaning Record, Warehouse Temperature Record, Product Storage and Maintenance Record and Fire Inspection Record.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

1.37 Incoming Goods Inspection Instruction

Applied Department(s):				
Administration Department ☐	Account Department ☐	Sales and Marketing Department ☐	Quality Department ☐	Logistic Department ☐

Purpose	Guideline for handling of exporting and incoming products.
Scope	Applicable to the warehouse of the logistic supplier that store the medical devices.

Prepared by	**Approved by**
(Department Manager) Date：	(Top Management) Date：

1. Requirements of exporting and incoming products
   1.1 The package of the product shall listed with correct brand name, dimension description, Lot number, manufacture date, expiry date (if provided), brand logo and corporate phone number.
   1.2 The package shall be intact with no serious damage.
   1.3 The product shall fulfill the customer requirements, for example the product is within the effective period.
   1.4 (Sterile products) Each batches of sterile product shall be approved by the corporate with related disinfection certificate before distributed to the customer.

2. Product inspection before importation
   2.1 After receiving importation notification from the manager, warehouse employees shall confirm the product quantity, Lot number and name with the manager.
   2.2 Warehouse employees shall follow the instruction to check the correctness of the product quantity, name, Lot number, package, expiry date (If provided by the manufacturer) (Details in the following figure). Any incorrectness of the information shall be reported to the manager.
   2.3 If all information are correct and the packages are clean and intact the warehouse employees shall place the products onto the stock rack.

3. Product inspection before exportation
   3.1 After receiving exportation notification from the manager, warehouse employees shall confirm the product quantity, Lot number and name with the manager.
   3.2 Warehouse employees shall follow the instruction to check the correctness of the product quantity, name, Lot number (Details in the following figure). Any incorrectness of the information shall be reported to the manager.
   3.3 Warehouse employees shall check whether the expiry date meet the requirements of the customer, expired products must be labeled, segregated, and reported to the corporate.
   3.4 All expired products, nonconforming products and products without disinfection certificate shall not be distributed to the customers.
   3.5 If the packages are clean and intact, the warehouse employees can therefore distribute the products.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

4. Note for distribution of sterile products
   4.1 The corporate requires all batches of products to enclose with a disinfection certificate. The corporate shall notify the logistic supplier to distribute the sterile products to the customers after receiving the disinfection records.
   4.2 The logistic supplier shall no distribute the products if the corporate has not received the disinfection certificate provided by the manufacturer.

Attached with the photo of the approved products (Front and Back)	This blank shall be filled with the inspection procedures of the product Including how to identify the following items on the product package: • Product Name • Product characteristic (Include dimension and size) • Distributor name and contact information • Manufacture Date • Expiry Date • Lot Number Besides, another main point would be the cleanliness and completeness of the product package.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

1.38 Product Identification and Segregation Instruction

Applied Department(s):				
Administration Department ☐	Account Department ☐	Sales and Marketing Department ☐	Quality Department ☐	Logistic Department ☐

Purpose	Guideline for the Third-party Logistic Supplier to perform the labeling and segregation procedures.
Scope	Applicable to the warehouse of the logistic supplier that stores the medical devices.

Prepared by	**Approved by**
(Department Manager) Date：	(Top Management) Date：

1. Definition
   1.1 “Nonconforming Products” included (1) Expired products and (2) Scrap products
   1.2 “Returned Products” are the suspected nonconforming products returned to the warehouse from the customer.
   1.3”Customers’ Properties” are the products that temporary stored in the warehouse and supplied by the customer.
   1.4 “Samples” are the sample products that are given to the customer for trial use.

2. Labeling and Segregation
   2.1 If any nonconforming products are discovered (for example expired, damaged package or drenched), or the logistic supplier manager received the nonconforming notice issued by the corporate, the related products shall be located and the quantity shall be identified.
   2.2 The affected products shall be segregated to the specific area of the warehouse (see the following figure) and labeled with corresponding labels:

Product type	Label
Expired Products	Expired
Scrap Products	Scrap
Customer Property	Customer Property
Returned Products	Returned
Sample Products	Sample

   2.3 Upon completion, the corporate shall determine the handling method of the nonconforming products

Attach with the floor plan of the warehouse and label the photo with the stock area and segregation area.	This blank shall be filled with the description of the type of products store in each area and the location of the segregation area.

Applicable to	Route 1	Route 2	Route 3
		✓	✓

1.39 Product Disposal Instruction

Applied Department(s):				
Administration Department ☐	Account Department ☐	Sales and Marketing Department ☐	Quality Department ☐	Logistic Department ☐

Purpose	Guideline for the product disposal procedures.
Scope	Applicable to all the medical devices sold by the corporate.

Prepared by	**Approved by**
(Department Manager) Date：	(Top Management) Date：

1. After receiving products that need to be disposed, the (1) Corporate name and (2) Corporate logo on the package shall be deleted using permanent marker.
2. Remove the package and obtain the whole product from the package.
3. Use separate garbage bags to store the products and their package.
4. Upon completion, dispose the garbage bags to landfill.
5. Notify the Sales and Marketing Department Manager to revise the “Stock Record”

Attach with the photo of product package (before disposal)	Attach with the photo of product package (after disposal)

Medical Device Good Distribution Practice
Case Book

Chapter 6. Form Sample

(Applicable to ISO 9001 and ISO 13485)

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.40 Quotation Record

Issued Date	Customer Name	Quotation Reference Code	Quotation Description	Prepared by (Signature)	Approved by (Signature)

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.41 Quotation

Thank you for interested in the products of our corporate, the following are the related quotations.

Customer Name, Address, Contact Person and Other Contact Method		**Issue Date**			
		Quotation Number			
		Expiry Date			
Product Number	**Product Description**	**Quantity**	**Unit Price**	**Discount**	**Price**
				Total	

Related Remarks

(1) The effective date of the quotation is within 30 days since the insurance date. Another quotation shall be requested after this date.
(2) If the customer have any enquiry on the quotation, please contact employees A of the ABC Medical Device Distribution Company (Tel:XXXXXXXX).
(3) Our corporate can deliver the product within X working days after the confirmation of purchase order.
(4) The price on this quotation already included the logistic fee.

ABC Medical Device Distribution Company

Approver signature and Corporate stamp

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.42 Tender Record

Issued Date	Customer Name	Tender Reference Code	Tender Description	Prepared by (Signature)	Approved by (Signature)

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.43 Purchase Order

Purchase Order Number:_____
Receipt Date:_____
Supplier Number:_____
Supplier Address:_____

Product Number	Product description	Quantity	Unit Price	Discount	Total Price
Remarks:			Total		

Corporate Stamp

Supplier Confirmation Stamp or Signature

_____ _____

1.44 Invoice Record

Issue Date	Invoice Number	Payment Settled?	Payment Date	Total Cost
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
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		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		
		☐Yes ☐No		

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.45 Invoice

Customer Name, Address, Contact person and other contact method		**Issue Date**			
		Invoice Number			
		Customer Number			
		Due Date			
Product Model	**Products Description**	**Quantity**	**Unit Price**	**Discount**	**Price**
				Total	

Related Remarks

(1) If there are any problems on the products, please contact ABC Medical Device Distribution Company (Phone, address, fax).
(2) The payment could be made through bank transfer or cheque. The bank account number is "XXXXXXXX", cheques shall be made payable to "ABC Medical Device Distribution Company".
(3) For all expired payment , a monthly X percent interest will be charged.

ABC Medical Device Distribution Company

Approver signature and Corporate stamp

1.46 Stock Record

Product Name:	Item Code:

Date of Receipt or distribution	Order Number	Lot Number	Received Quantity	Distributed Quantity	Remaining Stock	Prepared by	Reviewed by

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.47 Delivery Note

Customer Name, Address, Contact person and other contact method		**Delivery Date**			
		Delivery Number			
		Customer Number			
Product Model	**Description**	**Quantity**	**Unit Price**	**Discount**	**Price**
				Total	
Related Remarks					
(1) If there are any problems on the products, please contact ABC Medical Device Distribution Company (Phone, address, fax). (2) Our corporate responsible to all maintenance and repair service. Please show the copy of this Delivery Note and the maintenance certificate (If applicable) for any maintenance service.					
Customer confirmation the received devices are under good condition at the delivery. Customer signature and Corporate stamp		ABC Medical Device Distribution Company Approver signature and Corporate stamp			

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.48 Warehouse Cleaning Record

Remark 1: This form is used to record the cleanliness of the warehouse. After each regular cleaning, the cleaner shall complete the record.
Remark 2: If any abnormal situation is discovered, the cleaner shall notify the Logistics Department Manager to handle the situation and the case shall be recorded in this form.
Remark 3: Logistics Department Manager shall conduct inspection every month, sign the "Warehouse Cleaning Record" of the previous month and check whether the cleaner completes the form. Upon completion, the original copy shall be maintained by the Administration Department.

Record Month and Year： mm/yyyy				
Date	**Completed cleaning**	**Check Insect Trap**	**Cleaner Signature**	**If discovered any abnormal situation,, please describe the abnormity and the corresponding corrective actions**
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
For Internal Use Only				
Approved by: (Logistics Department Manager) Date:				

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.49 Warehouse Temperature Record

Remark 1: This form shall be used to record the warehouse temperature and humidity. Cleaner shall fill in related record after each inspection.
Remark 2: The standard for the temperature and humidity shall be referred to COP-11 Infrastructure and Work Environment Management Procedures.
Remark 3: Any abnormity of the warehouse temperature and humidity shall be reported to the Logistics Department Manager for corrective actions. The corrective actions shall also be included in this form.
Remark 4: Logistics Department Manager shall review and sign the "Warehouse Temperature Record" of the previous month, check whether the cleaner complete the form. Upon completion, the Administration Manager shall maintain the original form.

Record Month and Year： mm/yyyy					
Date		**Temperature**	**Humidity**	**Cleaner Signature**	**If discovered any abnormal temperature or humidity , please describe the abnormity and the corresponding corrective actions**
1	am				
	pm				
2	am				
	pm				
3	am				
	pm				
4	am				
	pm				
5	am				
	pm				
6	am				
	pm				
7	am				
	pm				
8	am				
	pm				
9	am				
	pm				
10	am				
	pm				
11	am				
	pm				
12	am				
	pm				
For Internal Use Only					
Approved by： Date: (Logistics Department Manager)					

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.50 Specific Competence Requirements of Third-party Employee

This record shall be filled by the administration Manager,
and approved and signed by the Top Management

Item	Position	Specific Competence Requirements	Prepared by	Approved by
1				
2				
3				
4				
5				
6				

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.51 External Training Record

This record shall be filled by the administration Manager,
and approved and signed by the Top Management

Section One: Basic Information

Training Staff Details		
Name:	Position:	
Training Item		
Training Date:	Training Time(Hour):	Training Venue:
Training Contents:		

Section Two: Training Effectiveness Evaluation

Evaluation Method	
☐ Oral evaluation ☐Other method (please specific): _____	
Evaluation Contents (Examination results and oral evaluation content):	
Evaluation Result	
☐**Pass**	☐**Fail** (The Sales and Marketing Department Manager shall determine whether re-training is required.)
Evaluated by: (Administration Manager)	Date:
Approved by: (Top Management)	Date:

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.52 Third-party Logistic Supplier Monitoring Record

Remark 1: The Logistics Department Manager shall conduct on-site inspection at the logistic supplier at least twice a month based on the following items (1) Random inspection of the storage amount of 3 batches of products (2) All Product Storage and Maintenance Record (3) Inspection on the incoming goods according to the First-in First-out Principle (4) Product placement (5) Selective inspection of the expiry date of 3 batches of products (6) Unidentified nonconforming product (7) Labeling and segregation of all nonconforming product(s) /customers' property(ies)/ sample and recall product. (8) Calibration and operation of warehouse facilities (9) Completeness of fire facilities (10) Cleanliness and temperature and humidity control of the actual environment (11) Warehouse Cleaning Record and Warehouse Temperature Record (12) Functionality of the temperature and humidity control facilities (13) Pest and rodent control (14) Conduct oral assessment for the employees of the third-party logisitc supplier on topics related to daily inspection procedures.

Remark 2: The Logistics Department Manager shall complete this record and the record shall be approved by the Chief Executive Officer.

Remark 3: All nonconforming items shall be handled immediately and the results shall be recorded.

The following section shall be completed by Logistics Department Manager

Section One: Inspection Results

Inspection Date:		Inspector Name:		
The third-party logistic supplier fulfilled the following requirements? (All nonconforming items shall be reported to the Chief Executive Office)				
1	Random inspection of the storage amount of 3 batches of products **Product Number** / **On- site Quantity** / **Quantity in "Stock Record"**		☐Pass	☐Fail
2	Inspection record of all the stock-in/stock-out products. (All import and export date, quantity and inspector signature of the stock shall be recorded)		☐Pass	☐Fail
3	Inspection on the incoming goods according to the First-in First-out Principle (The earliest stock-in products shall be distributed to customer first) **Product Number** / **Conformed with "First-in First-out Principle"** (☐Yes ☐No)		☐Pass	☐Fail
4	Examine the correctness of products location.		☐Pass	☐Fail
5	Random inspection of the expiry date of 3 batches of products **Product Number** / **Lot Number** / **Expiry Date**		☐Pass	☐Fail
6	Unidentified nonconforming product		☐Pass	☐Fail
7	Labeling and segregation of all nonconforming product(s) /customers' property(ies)/ sample and recall product.		☐Pass	☐Fail
8	Calibration and operation of warehouse facilities (All the equipment shall be within effective calibration period and operation normally)		☐Pass	☐Fail

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

9	Completeness of fire facilities (Inspect the effectiveness of the regular fire inspection certificate of the building)	☐Pass	☐Fail
10	Cleanliness, temperature and humidity control of the on-site environment **Items** / **On-site value** / **Standard value** On-site temperature / / 35∘C On-site humidity / / 88% On-site Cleanliness / ☐Clean ☐Not clean	☐Pass	☐Fail
11	Warehouse Cleaning Record and Warehouse Temperature Record	☐Pass	☐Fail
12	Functionality of the temperature and humidity control facilities **Items** / **Operate normally?** Hygrometer / ☐Yes ☐No Fan / ☐Yes ☐No Air-conditioner / ☐Yes ☐No	☐Pass	☐Fail
13	Pest and rodent control	☐Pass	☐Fail
14	Conduct oral assessment for the employees of the third-party logistic supplier on topics related to daily inspection procedures.	☐Pass	☐Fail
If there are any failed items, please list out the implemented corrective and preventive actions and record the results:			
Fail items are corrected? (If no, please notify the Chief Executive Officer)		☐Yes	☐No
Prepared by (Logistics Department Manager)	Date:		

The following Section shall be completed by the Chief Executive Officer.

Section Two: Evaluation and Approval

Based on the above failed items, is it necessary to implement the corrective and preventive procedures?	☐Yes	☐No

Evaluation Results

☐ **The third-party logistic supplier is qualified**

☐ **The third-party logistic supplier is disqualified** (Implement the Third-party Logistic Supplier re-evaluation procedures and determine whether the service provided shall be stopped)

Prepared by: (Chief Executive Officer)	Date:

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.53 Third-party Logistic Supplier Re-evaluation Record

Remark 1: The third-party logistic supplier is the outsourced suppliers that inspect, stock, distribute and record the corporate's products.
Remark 2: The Logistics Department Manager shall conduct re-evaluation of all external logistic companies on the "Approved Supplier List".
Remark 3: If in section two of the "Third-party Logistic Supplier Monitor Record", the Third-party Logistic Supplier is evaluated as "Not Approved", the Logistics Department shall immediately implement the re-evaluation procedures of the Third-party Logistic Supplier.
Remark 4: Besides, at any time, if the following situations occur at the Third-party Logistic Supplier, employees shall report it to the Top Management and the Top Management shall determine whether the external logistic companies need to be re-evaluated.
a. Reoccurrence of serious system or product quality problems with no intention of improvements
b. Continue delay of delivery with no intention of improvements
c. Bad service attitude with no intention of improvements
d. No response to the enquiry phone call and email
e. Other special reasons
Remark 5: All medical device of the corporate shall be distributed by the external logistic companies that are on the "Approved Supplier List".
Remark 6: The Logistics Department Manager shall complete section one of this form and the Top Management shall complete section two.
Remark 7: Administration Manager shall delete the not approved suppliers from the "Approved Supplier List" and maintain this record and related approval documents.

The following section shall be completed by Logistics Department Manager

Section One: Basic Information

Information of Third-party Logistic Supplier		
Corporate Name:		
Evaluation		
The Logistics Department Manager had collected the "Third-party Logistic Supplier Monitoring Record" of the past 12 months, conducted analysis on the results before answering the following questions Record period: YYYY/MM to YYYY/MM Number of Record:		
Item	**Evaluation Questions on the "Third-party Logistic Supplier Monitor Record"**	**Total number of disqualification/ qualification (Passing score = less than 3 qualification for each question)**
1	Selective inspection of the storage amount of 3 batches of products	/
2	Inspection certification of all warehouse products	/
3	Check whether the products follow the "First in first out" principle	/
4	Correctness of product placement	/
5	Selective inspection of the expiry date of 3 batches of products	/
6	Identification of unrecognized nonconforming product	/
7	Correctness of the labeling and segregation of all nonconforming product(s) /customers' property(ies)/ sample and recall product.	/
8	Calibration and operation of warehouse facilities	/

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

9	Completeness of fire service facilities	/
10	Cleanliness and temperature and humidity control of the actual environment	/
11	Correctness of the cleanliness and temperature record	/
12	Functionality of the temperature and humidity control facilities	/
13	Pest and rodent control	/
14	Conduct oral assessment for the employees of the third-party logisitc supplier	/
Total Score: /		
Progress of corrective actions for major nonconformity:		
Are there any unsolved nonconformity?		☐Yes / ☐No
Any product recall, advisory notice and adverse incident caused by nonconformity of logistic supplier?		☐Yes / ☐No
Are there any "Third-party Logistic Supplier Monitor Record" with more than 3 disqualified items?		☐Yes / ☐No
Prepared by: (Logistics Department Manager)	Date:	

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

The following section shall be completed by Top Management.

Section Two: Evaluation Results

Re-evaluation Results	
Failure in scoring shall probably result in the qualification of Third-party Logistic Supplier. However, Top Management can determine whether to keep the third-party logistic supplier with sufficient reason, which shall be well specified in the section "Reason of maintaining the disqualified logistic supplier". (1) Questions in section one is marked as unqualified more than 3 times (2) Same noncompliance reoccurred after corrective actions (3) Major nonconformity which results in huge amount of nonconforming products (4) Occurrence of nonconformity that could not be corrected (5) Occurrence of product recall, advisory notice or adverse incident due to the nonconformity of Third-party Logistic Supplier (6) More than 3 unqualified items on the "Third-party Logistic Supplier Monitor Record"	
☐ Maintain as approved Third-party Logistic Supplier	☐ Disqualified the logistic supplier and stop the service (Administration Manager shall delete the disqualified suppliers from the "Approved Supplier List")
Reason of maintaining the disqualified logistic supplier (if applicable):	
Prepared by: (Top Management)	Date:

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.54 Product Maintenance Form

Customer Information		
Customer/ Corporate Name:		
Customer/ Corporate Address:		
Receipt Date:	Tel:	Email:
Reference Number:	☐ Regular Maintenance (☐within maintenance period ☐expired maintenance period) ☐ Repair	

Maintenance Overview		
Device Number	**Name of Device**	**Device Problems**

Inspection Results	
Inspection Date:	Need component replacement? ☐Yes / ☐No
Inspection Results, analysis of core cause:	

Handling method: ☐ Dispose ☐ Replace with device of same model ☐ Replace components

Component Number	Component Name	Quantity	Unit Price	Price

Handling results (Including completion date and reference number of replacing device)

If customer need extra payment, the Invoice number is:_____

Prepared by: (Maintenance Department Engineer)	Date:
Approved by: (Maintenance Department Manager)	Date:

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.55 New Staff Training Record

Remark 1: The Administration Manager shall complete section one of this form. After completion of the training, the Top Management shall conduct evaluation and complete section two of this form.
Remark 2: Administration Manager shall arrange new staff training and safety training for the new employee within two weeks from the report duty date.
Remark 3: Administration Manager shall establish a folder for each new employee. The folder shall include the resume of the staff and the copy of certificate or license that related to his/her work or required by local regulatory.

The following section shall be completed by Administration Manager.

Section One: Basic Information

Information of training staff	
Name and Position:	Department (Administration/ Accounts/Logistic /Sales and Marketing / Quality)
The job duty required any special expertise or professional license? (If yes, please specify the name of the professional license and its effective date)	
Training Items	
New Staff Training: 1. Understand the operation procedures and related documents, including the Quality Manual, Operation Procedures Documents and Work Instruction, of the Quality Management System 2. Understand the corporate structure 3. Understand the contents of Quality Policy 4. Understand the Quality Objectives 5. Understand the expertise requirement and responsibility of employee 6. Understand the category, characteristic, use and existing customer of the products 7. Understand the related local medical regulations that are related to the corporate, the contents are listed in the documents issued by MDCO, they include: - MDCO [Document Number A] Document Name A - MDCO [Document Number B] Document Name B - MDCO [Document Number B] Document Name B - MDCO [Document Number B] Document Name B	Training Date:
Safety Training: 1. Explain the fire escape routes and the use and location of fire prevention tools.	Training Date:
Prepared by: (Administration Manager)	Date:

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

The following section shall be completed by Top Management after the training.

Section Two: Training Effectiveness Evaluation

Evaluation Method
The Top Management shall conduct oral evaluation, the contents of evaluation include: 1. Briefly explain the operation procedures of the corporate Quality Management System. 2. The Quality Management System of the corporate is currently following which international standard and operation documents? 3. Explain the corporate structure 4. Explain the Quality Policy and Quality Objectives 5. Detail explain the personal expertise requirements and job duties 6. Explain how to complete personal responsibility base on the requirements of the Quality Management System 7. Briefly explain the category, characteristic, use and existing customer of the products 8. Enquire local medical regulation related to the corporate 9. Explain the fire escape route and the use and location of fire prevention tools
Evaluation Result
☐ **Pass** ☐ **Fail** (Required another training for the employee)

Approved by: (Top Management)	Date:

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.56 Specific Competence Requirement List

This record shall be filled by the administration Manager,
and approved and signed by the Top Management

Item	Position	Specific Competence Requirements	Prepared by	Approved by
1				
2				
3				
4				
5				
6				

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.57 Employee Training Record

Remark 1: The trained employee shall fill in the Employee Training Record and the Top Management shall approve and sign the completed record.
Remark 2: All job related training shall complete with this record and the Administration Department shall maintain the records.
Remark 3: After completion of training, the following documents shall be submitted to the Administration Department (1) Attendance proof (for example copy of training certificate, copy of training application form or attendance list) (2) Receipt of training course (3) "Employee Training Record" signed by Top Management (4) Exam or assessment results of training (if available)

The following section shall be completed by the trainee before training

Section One: Basic Information

Employees Information		
Trainee name:	Department : (Administration/Accounts/Logistic /Marketing)	
Training Organization		
Name of Training Organization:		
Training Title:		
Training Date:	Training time(hour(s)):	Location:
Training Fee:	Justification of Training Need(s):	
Complete by: (Trainee)	Date:	
Approved by： (Top Management)	Date:	

The following section shall be completed by Top Management after the completion of training

Section Two: Training Evaluation

Evaluation method	
☐ Exam/Test ☐ Oral evaluation ☐Other method (please specify) : _____ Evaluation contents (Examination results, oral evaluation contents)：	
Evaluation Results	
☐**Approved**	☐**Not Approved** (Top Management shall determine whether repeat training is needed)
Evaluated by: (Top Management)	Date:

Applicable to	Route 1	Route 2	Route 3
		✓	✓

1.58 Approved Supplier List

Remark 1: All medical device distributed by the corporate can only be purchased from the suppliers on the "Approved Supplier List".
Remark 2: Administration Department is responsible to the update, release, maintenance and storage of the "Approved Supplier List".
Remark 3: For every update, Administration Department shall send out the updated list to all departments.

Approved Supplier List (Last updated on dd/mm/yyyy)	
1	
2	
3	
4	
5	
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11	
12	
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30	

Applicable to	Route 1	Route 2	Route 3
		✓	✓

1.59 Supplier Evaluation Form

Remark 1: All medical device distributed by the corporate can only be purchased from the suppliers on the "Approved Supplier List".
Remark 2: Sales and Marketing Department Manager shall fill in section one of this form and the Top Management shall fill in section two.
Remark 3: For any additional supplier of the "Approved Supplier List", Administration Manager shall receive (a) this form with evaluation results of "Approved" and (b) the copy of the Business Registration Certificate or similar documents.

This section shall be completed by Sales and Marketing Department Manager

Section One: Basic Information

Supplier information		
Corporate Name:		
Corporate Address:		
Factory Address (If different from above):		
Tel:	Fax:	Email:
Website:	Business Type:	
Information of the responsible person of the quality system		
Name:	Position:	Tel:
Certificates Held by the Supplier: (Copy of certificate shall be attached)		
Supplier Type		
☐ Manufacturer	☐ Distributor	☐ Other:_____
Date of Establishment:	Employee Number	

Does the supplier meet the following requirements? (For reference only, evaluation results are determined by Top Management)			
1	Supplier enforces raw material inspection and specification	☐Yes	☐No
2	Supplier obtains raw material from reliable resources	☐Yes	☐No
3	Supplier inspects all products and maintain inspection record	☐Yes	☐No
4	Supplier encloses the products with effective quality certificates, for example disinfection certificate	☐Yes	☐No
5	Supplier approves product on-site product inspections conducted by the employees of the corporate in its factory	☐Yes	☐No
6	Supplier monitors the lot number of all import and export products and the sour traceable	☐Yes	☐No

Applicable to	Route 1	Route 2	Route 3
		✓	✓

7	Supplier can deliver the products on time	☐Yes	☐No
8	Supplier can reply the corporate enquiry short period of time	☐Yes	☐No

Supplementary Information (If applicable):

Prepared by: (Sales and Marketing Department Manager)	Date:

This section shall be completed by Top Management

Section Two: Scores and Results

Supplier Scores						
Item	Evaluation Criterion	Score Lowest				Highest
1	Supplier Scale and Credit Rating	1	2	3	4	5
2	Product/ Service Quality	1	2	3	4	5
3	Product meet customer requirements	1	2	3	4	5
	Total					

Evaluation Results	
☐ **Approved** – Total score 9 marks or above This supplier shall be placed on the Approved Supplier List and the corporate may purchase from the supplier	☐ **Not Approved** –Total score below 9 marks The corporate shall not purchase any good or service from the supplier.
Completed by: (Top Management)	Date:

Applicable to	Route 1	Route 2	Route 3
		✓	✓

1.60 Supplier Re-evaluation Form

Remark 1: All medical device distributed by the corporate can only be purchased from the suppliers on the "Approved Supplier List".
Remark 2: Sales and Marketing Department Manager shall fill in section one of this form and the Top Management shall fill in section two.
Remark 3: Administration Manager shall delete the disapproved supplier from the "Approved Supplier List" and maintain this record and other related documents.

This section shall be completed by Sales and Marketing Department Manager

Section One: Basic Information

Supplier Information						
Corporate Name:						
Supplier Evaluation						
Item	Evaluation Criterion	Score (1 is lowest 5 is highest)				
1	Supplier obtains raw material from reliable resources	1	2	3	4	5
2	Supplier maintains high quality products	1	2	3	4	5
3	Supplier monitor the lot number of all export products and the sources are traceable	1	2	3	4	5
4	Supplier can deliver the products on time	1	2	3	4	5
5	Supplier can reply the corporate enquiry short period of time	1	2	3	4	5
6	Products of the supplier have adverse event, advisory notice or rec	1	2	3	4	5
Total： / 30						
Supplementary Information (If applicable):						
Completed by: (Sales and Marketing Department Manager)	Date:					

Applicable to	Route 1	Route 2	Route 3
		✓	✓

This section shall be completed by Top Management

Section Two: Evaluation Results

Re-evaluation Results	
☐ Maintain (If the total score of section one is below15marks, the reason of maintaining this supplier shall be explained in the supplementary information)	☐ Remove (Administration Manager shall remove the supplier from the Approved Supplier List and shall not purchase any good or service form such supplier
Supplementary Information (If applicable):	
Completed by: (Top Management)	Date:

Applicable to	Route 1	Route 2	Route 3
		✓	

1.61 Customer Satisfactory Survey

*******Remark: This survey is for internal use only, all information provided are confidential**********

Customer Name:						
Satisfactory Rating						
Evaluation Criterion		Score Lowest				Highest
Section One：Service Quality						
1	Time for preparing quotation (shall not exceed 3 working days)	1	2	3	4	5
2	Response time towards customer enquiry and complaints	1	2	3	4	5
3	Sufficiently reply and satisfy customer enquiry	1	2	3	4	5
4	On-time delivery of products	1	2	3	4	5
5	Good Staff attitude	1	2	3	4	5
6	Reasonable products price	1	2	3	4	5
Section Two: Product Quality						
7	Maintain high quality of delivered products (in terms of product cleanliness, package conformity, etc.)	1	2	3	4	5
8	Products fulfill customer requirements	1	2	3	4	5
9	Products are safe and reliable	1	2	3	4	5
Improvement:						

Customer Information	
Customer Name:	Position:
Tel:	Email:
Signature:	Date:
~~Survey completed, Thank you for your opinion! ~~~~~~~~~~~~~~~~~~	

Please return this completed survey by email, fax or mail. Thanks.

Email： **Fax：**
Mailing Address：

This section shall be completed by ABC Medical Device Distribution Company	
Approved by: (Administration Manager)	Date:

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.62 Customer Complaint Feedback Form

Remark 1: Sales and Marketing Department Manager shall complete section one and two of this form and Top management shall approve and sign the completed form.

Section One: Feedback Content (Completed by Sales and Marketing Department Manager)		
Customer Name:	Feedback Date：	
Contact Name:	Tel:	Email:
Feedback Content:		
Feedback Inspection Results: (Verification of customer complaints? Any evidence? If the inspection cannot be completed within a month, please explain)		
Feedback Type: ☐Improvement Suggestion ☐Customer Complaint ☐Other:_____		
Recommended follow-up action(s) and the expected completion date:		
Is it necessary to initiate the corrective and preventive action? ☐Yes ☐No, please specify the reason:		
Is it necessary to implement the Adverse Incident Reporting System? ☐Yes ☐No, please specify the reason:		
Prepared by: (Sales and Marketing Department Manager)	Date:	
Approved by: (Top Management)	Date:	
Section Two: Follow up results（Completed by Sales and Marketing Department Manager）		
Reply the follow up results and improvement suggestions to customer Contact Date: Contact person(Position): Reply Description:		
Follow up action(s) results ☐ Completed follow up action ☐ Incomplete follow up action(s), the reason are:		
Prepared by: (Sales and Marketing Department Manager)	Date:	
Approved by: (Top Management)	Date:	

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.63 Corrective and Preventive Action Record

Remark 1: If any employees discover any nonconformity, he/she shall report to the Administration Department related department

Remark 2: Administration Manager or Internal Auditor shall complete section one and two of this form and the Top Management shall approve and sign the completed form.

Section 1: Identification, Content, Improvement Suggestions of Nonconformity

Nonconformity/ Potential Nonconformity	
Associated Department(s): (Administration/Accounts/Logistic /Marketing)	Associated Procedures:
Contents of Nonconformity/ Potential Nonconformity : (Including identification and description of nonconformity)	
Inspection and Results of Nonconformity/ Potential Nonconformity : (Including the cause and analysis of nonconformity) Inspection Staff(s):	
Recommended corrective and preventive action	
Recommendation: Estimated Completion Date: Responsible Staff(s):	
Prepared by: (Administration Manager or Internal Auditor)	Date:
Approved by: (Top Management)	Date:

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

Section Two: Results of Corrective and Preventive Action

Results of Corrective and Preventive Action	
Inspection Date: Inspection Details:	Inspection Staff:
Inspection Results: (Please choose one of the following) ☐ Completed Corrective and Preventive Action (Ensure the nonconformity is eliminated and will not repeat) ☐ Revised and Completed Corrective and Preventive Action based on the situation (The revise reason and contents shall be listed in the "Supplementary Information" section) ☐ Incomplete Corrective and Preventive Action (The reason and follow up action shall be listed in the "Supplementary Information" section)	
Supplementary Information:	
Prepared by: (Administration Manager or Internal Auditor)	Date:
Approved by: (Top Management)	Date:

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.64 Product Recall Form

Remark 1: The Administration Manager shall complete section one and two of this record. The Top Management shall sign and confirm the record.

<table>
<tr><td colspan="7">Section One: Basic Information</td></tr>
<tr><td colspan="7">Reason for product recall:</td></tr>
<tr><td colspan="4">Starting date of product recall:</td><td colspan="3">Expected completion date:</td></tr>
<tr><td colspan="7">Section Two: Implementation Procedures</td></tr>
<tr><td>1</td><td colspan="2">Notify Top Management of the product recall</td><td colspan="4">Notifying Date:</td></tr>
<tr><td rowspan="3">2</td><td colspan="6">Details of recalled product</td></tr>
<tr><td>Product Number</td><td>Lot Number</td><td>Quantity</td><td>Recalled from customer</td><td colspan="2">Recalled Date</td></tr>
<tr><td></td><td></td><td></td><td></td><td colspan="2"></td></tr>
<tr><td colspan="7">Stock location of the recall product:</td></tr>
<tr><td>3</td><td colspan="2">Setup service hotline</td><td colspan="2">Tel:</td><td colspan="2">Setup Date:</td></tr>
<tr><td rowspan="5">4</td><td colspan="2">Contact Local Responsible Person (LRP) [1]</td><td colspan="5">Responsible personnel:</td></tr>
<tr><td colspan="7">Documents/ information transfer to LRP:</td></tr>
<tr><td colspan="2">Name of LRP：</td><td colspan="2">Tel:</td><td colspan="2">Email:</td></tr>
<tr><td colspan="2">Contact personnel:</td><td colspan="5">Completion Date:</td></tr>
<tr><td colspan="7">Recommended action from LRP:</td></tr>
<tr><td rowspan="5">5</td><td colspan="2">Contact Manufacturer</td><td colspan="5">Responsible personnel:</td></tr>
<tr><td colspan="7">Documents/ information transfer to manufacturer:</td></tr>
<tr><td colspan="2">Name of manufacturer:</td><td colspan="2">Tel:</td><td colspan="2">Tel:</td></tr>
<tr><td colspan="2">Contact personnel:</td><td colspan="5">Completion Date:</td></tr>
<tr><td colspan="7">Recommended action from manufacturer:</td></tr>
<tr><td>6</td><td colspan="2">Recalled all distributed products[2]</td><td colspan="5">Notified all related customer? (Y/N)：</td></tr>
<tr><td>7</td><td colspan="7">Other action, please specify:</td></tr>
<tr><td>8</td><td colspan="7">Is it necessary to implement the corrective and preventive action? (Y/N)</td></tr>
<tr><td colspan="5">Prepared by
(Administration Manager)</td><td colspan="2">Date:</td></tr>
<tr><td colspan="5">Approved by:
(Top Management)</td><td colspan="2">Date:</td></tr>
</table>

[1] The LRP shall notify the Medical Device Control Office within 10 calendar days.
[2] Recall procedure of distributed products shall be triggered within one week.

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.65 Nonconforming Product Report

The following section shall be completed by Sales and Marketing Department Manager

Section One: Identification of nonconforming product	
Item code, Lot number and Quantity of nonconforming product:	Description of nonconforming product:
Identification Date:	
Section Two: Nonconforming product inspection	
Handling Method： ☐ Re-packaging ☐ Use as sample ☐ Dispose ☐ Other_____	
Return of nonconforming product to manufacturer for quality inspection? ☐ Yes ☐ No	
Are there any nonconforming product distributed to the market? If yes, please list the recommended action(s):	
Prepared by: (Sales and Marketing Department Manager) Date:	

The following section shall be completed by Top Management

Section Four: Follow up action
Necessary to enforce corrective and preventive action(s)? ☐ Yes ☐ No
Approved by: (Top Management) Date:

Applicable to	Route 1	Route 2	Route 3
			✓

1.66 Risk Management Report

1. Scope

1.1 This Risk Management Report record the evaluation of XXXX products, XXXX products included

Product Name	Manufacturer	Product Code

2. Risk Management Team

The Risk Management Report shall be established by the Risk Management Team and the Team consists of member from different departments. The main duty of the team is to evaluate and analyze the product risk and to establish the Risk Management Report. Risk Management Team included:

Risk Management Team	
Members	Department/ Person
Risk Management Team leader	
Risk Management Team Member	
Risk Management Team Member	
Risk Management Team Member	
Risk Management Team Member	

3. Product Background[3]

4. Role of Distributor[4]

5. Classification of Hazards

5.1 Hazard Classification Table:

The hazards are based on <Annex E(Informative) - Examples of hazards, foreseeable sequences of events and hazardous situations > - < Table E.1 - Examples of hazards > of the ISO14971:2007 standard. The Hazard Code is classified according to the Hazard Classification Table of this risk management document.

[3] This section shall list out the intended function of the medical device, qualified medical device user (the general public or medical employees with related professional qualifications/ related professional training) and the guidelines and reminders of the product usage.

[4] This section shall list out the role of the medical device distributor in the distribution processes, including the quality inspection, medical device repair and maintenance service and the labeling or repackaging procedures.

Applicable to	Route 1	Route 2	Route 3
			✓

Examples of energy hazards	Examples of biological and chemical hazards	Examples of operational hazards	Examples of information hazards
A. Electromagnetic energy A1. Line Voltage A2. Leakage current Enclosure leakage current Earth leakage current Patient leakage current A3. Electric fields A4. Magnetic fields **B. Radiation energy** B1. Ionizing radiation B2. Non-ionizing radiation **C. Thermal energy** C1. High temperature C2. Low temperature **D. Mechanical energy** D1. Gravity Falling Suspended masses D2. Vibration D3. Stored energy D4. Moving parts D5. Torsion, shear and tensile force D6. Moving and positioning of patient D7. Acoustic energy Ultrasound energy Infrasound energy Sound D8. High pressure fluid injection	**E. Biological** E1. Bacteria E2. Viruses E3. Other agents (eg. prisons) E4. Re-or cross-infection **F. Chemical** F1. Exposure of airway, tissues, environment or property, eg. to foreign materials: Acids or alkalis Residues Contaminates Additives or processing acids Cleaning, disinfecting or testing agents Degradation products Medical gasses Anaesthetic products **G. Biocompatibility** G1. Toxicity of chemical Allergenicity/ irritancy pyrogenicity	**H. Function** H1. Incorrect or inappropriate output or functionality H2. Incorrect measurement H3. Erroneous data transfer H4. Loss or deterioration of function **I. Use error** I1. Attentional failure I2. Memory failure I3. Rule-based failure I4. Knowledge-based failure I5. Routine violation	**J. Labeling** J1. Incomplete instruction for use J2. Inadequate description of performance characteristics J3. Inadequate specification of intended use J4. Inadequate disclosure of limitations **K. Operating instructions** K1. Inadequate specification of accessories to be used with the medical device K2. Inadequate specification of pre-use checks K3. Over-complicated operating instructions **L. Warning** L1. Of side effects L2. Of hazards likely with re-use devices **M. Specification of service and maintenance**

6. Medical device characteristics related to product safety

Q1	What is the intended use of this medical device and how to use this device? (A-M)
Answer	
Q2	This medical device will be implanted? (E-G)
Answer	
Q3	This medical device will contact with patients or other person? (E-G)
Answer	
Q4	This medical device needs to be cooperated with or contact with what materials and/ or components? (E-G)
Answer	
Q5	Are there any energy transfer between the medical device and the patient? (A-D, H1)
Answer	
Q6	Are there any substance transfer between the medical device and the patient? (E-G, H1)
Answer	
Q7	Is this medical device used to handle biological materials that will be used again, for transfer or for transplant? (E-G)
Answer	
Q8	Is this medical device sterile or shall be disinfected by the user or shall be handled with other microbiological methods? (E-G)
Answer	

Applicable to	Route 1	Route 2	Route 3
			✓

Q9	This medical device requires regular cleaning and disinfection by the user? (E-G, I-K)
Answer	
Q10	This medical device will improve the patient environment? (C, D, H1)
Answer	
Q11	This medical device is used for measurement? (H-K)
Answer	
Q12	This medical device will conduct data analysis? (H, I4)
Answer	
Q13	This medical device will be cooperated with other medical device, drugs or medical techniques?(I, K)
Answer	
Q14	Are there any emissions of undesired energy or substance? (A-G, L)
Answer	
Q15	This medical device is sensitive to the environment? (A-F, L)
Answer	
Q16	This medical device will affect the environment ? (A-F，J-L)
Answer	
Q17	Are there any related consumables or accessories for this medical device? (H1, H4)
Answer	
Q18	Is it necessary to have maintenance or calibration? (H2, M)
Answer	
Q19	This medical device includes any software? (I, K)
Answer	
Q20	This medical device have limitation on the storage period?
Answer	
Q21	Are there any errors or problems for long-term use? (H, L)
Answer	
Q22	This medical device has to withstand what type of mechanical force? (D)
Answer	
Q23	What determine the lifespan of the medical device? (M)
Answer	
Q24	This medical device is for single-use? (H1，H4，L2)
Answer	
Q25	This medical device needs special handling for disposal? (F，J)
Answer	
Q26	The use and installation of this medical device need any special training or professional techniques? (J，K)
Answer	
Q27	How to provide information of safe use? (K)
Answer	
Q28	Require the establishment or introduction of new manufacturing procedures?
Answer	
Q29	The proper use of this medical device mainly depends on human factor, for example user interface.
Q29.1	Any characteristics of the user interface may lead to misuse of the device?(H，I)
Answer	
Q29.2	When using the medical device, will the inattention of the device user caused the misuse of device? (I1)
Answer	
Q29.3	This medical device has any connecting components or accessories? (I, K)
Answer	
Q29.4	This medical device has control interface? (H, I, K)
Answer	
Q29.5	This medical device displays information?(H，I，K)

Applicable to	Route 1	Route 2	Route 3
			✓

Answer	
Q29.6	Is this medical device controlled by the function menu? (H，I)
Answer	
Q29.7	This medical device will be used by people with special needs? (J3，K)
Answer	
Q29.8	Can the user interface control the user motion? (H, I, K)
Answer	
Q30	This medical device has an alert system? (L)
Answer	
Q31	Under what circumstance will lead to intended misuse of this medical device? (I5，L)
Answer	
Q32	This medical device maintains important data of the patient? (H)
Answer	
Q33	Is this medical device transportable or portable? (H)
Answer	
Q34	The use of the medical device depends on its performance? (H)
Answer	

7. Product Design Risk Evaluation[5]

8. Failure Mode Effects Analysis

Item: XXXX Product	Manufacture responsibility:	Date:
Risk Management Team leader:	Risk Management Team Member:	

Remark: The full version of PFMEA list shall obtain from the Administration Manager. After the enforcement of inspection and control policy, all risk cause by the product distribution procedures can be prevented. The evaluation shall be regarded as acceptable, no residue risk and no occurrence of new hazards.

9. Risk-benefit Analysis

Base on the evaluation of the risk management plan, the residue risk of XXXX product will not derivate new risk. The risk will decrease to acceptable level after the implementation of control policy, so the Risk-benefit Analysis is exempted.

10. Evaluation of overall residual risk acceptability[6]

10.1 After the implementation of policy lowering the risk, the overall residue risk of XXXX product decrease to the acceptable level. No risk will be derived and no foreseeable impact of the residue risk.

10.2 After the discussion of the Risk Management Team, no risk of this product shall be disclosed.

11. The completeness of risk control

11.1 The Risk Management Team guarantees the XXXX product distributed by the

[5] If the distributor do not involve in the design of medical device, this blank shall be fill with "As the corporate do not responsible to the product design, the manufacturer shall be responsible to the Product Design Risk Evaluation"

[6] If the residue risk is still higher than the acceptable level (as defined by the manufacturer or distributor), distributor must proposes corrective action immediately to lower the risk to acceptable level.

Applicable to	Route 1	Route 2	Route 3
			✓

corporate had already considered all hazards and hazardous situations, completed all risk control procedures and recorded in this "Risk Management Report".

	Approval Date
Implemented all risk management procedures	
All risk are considered and controlled	
All residue risk had decreased to acceptable level	
Established and implemented distribution information collection and analysis	

Established by: _____ Approved by: _____
Risk Management Team Member Risk Management Team leader

Date: _____ Date:_____

12. Manufacture and Distribution Information

12.1 Distribution Information Analysis

Date	Adverse Event	Established by	Signature

Until XXXX year XX month XX date, there is no adverse event report of (1) XXXX product distributed by the corporate or (2) similar products of other brand.

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.67 Internal Audit Checklist

Assessment Plan			
Audit Period		Audit Organization: (Self/ Third party)	
Audit Scope			
Audit Standards/ Practice			
Audit Team			
Lead Internal Auditor			
Internal Auditor(s)			

Area	**MDGDP Clause(s)**
***Clause Exclusion: As listed on Quality Manual ***	

Assessment Plan Preparation and Approval	
Prepared by: (Lead Internal Auditor)	Date:
Approved by: (Top Management)	Date:

Chapter 6. Form Sample
Internal Audit Checklist

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

Document To Be Audited: Quality Manual			
Department To Be Audited:	Date of Audit:	Name of Auditor:	
Audit Method (Already Prepared For)		(a) Audited Items (b) Non-conformity and Audit Findings	Conformity Lv.
1	Examine the description of corporate structure.		
2	Examine the corporate structure.		
3	Examine the products scope covered by MDGDP.		
4	Examine whether the Quality Manual can cover all the MDGDP requirements.		
5	Examine the appointment of Management Representative		
6	Examine the establishment of Quality Policy, Quality Objectives, Quality Manual, Documented Procedures and Work Instructions.		
7	Examine if the Quality Objectives are measurable parameters.		
8	Examine the promotion of Quality Policy.		
9	Examine the evaluation results record of Quality Policy.		
10	Examine whether Quality Objectives are correlated to Quality Policy.		
11	Examine whether Quality Objectives are successfully achieved.		
12	Random inspection of one employee on his/her understanding of Quality Policy and Quality Objectives.		
13	Examine whether the documented procedures and the corresponding records are available as required by MDGDP.		
14	Examine the flow chart of Quality System.		
15	Examine the descriptions of procedures and procedure relationships in the Quality Manual		
16	Examine whether the procedure descriptions and relationships correlate with the actual situation.		
17	Examine the documents checklist, check if 4-tiers documentations are correctly named, numbered and cross-linked with MDGDP clauses.		
18	Examine the exempted MDGDP clauses in Quality Manual		
Conformity level： —：Not applicable ✓：Complied O：Partially complied ?：Further investigation required X：Not complied			

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.68 Adverse Incident Report

Remark 1: Sales and Marketing Department Manager shall complete section one and two of this record and the Top Management shall sign and approve the record.

Section One: Basic Information		
Report adverse incident/ event[7]:		
Name, lot number and quantity of involved product:		
Name of product manufacturer:	Contact Person:	Tel:
Name of local responsible person(LRP):	Tel:	Email:
Name of employees contact the LRP (Position):		Contact date:
Recommended handling method from the LRP:		
Documents transferred to the LRP (If available):		
Prepared by : (Sales and Marketing Department Manager)	Date:	
Approved by: (Top Management)	Date:	
Section Two: Follow-up items		
The corporate shall handle the following (1)follow-up actions and (2)follow-up results:		
Prepared by : (Sales and Marketing Department Manager)	Date:	
Approved by: (Top Management)	Date:	

[7] Adverse incidents that result in death or serious injury or of a serious public health concern must be reported by the LRP to MDCO as soon as possible, but not later than 10 elapsed calendar days after the LRP becomes aware of the incident. All other reportable adverse incidents must be reported by the LRP to MDCO as soon as possible, but not later than 30 elapsed calendar days after the LRP becomes aware of the incident.

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.69 Equipment Calibration Record

Remark 1: This record shall be completed by the Administration Manager and the Top Management shall sign and approve the record.
Remark 2: (1) Not calibrated devices or (2) devices that expired the effective calibration period shall be delivered to the calibrating organization for further calibration.
Remark 3: Administrative Department shall pay attention to the next calibration date of the device.

Section One: Basic Information

Device Name:	Product Number:	Stock Location:
Defined Deviation Value:		

Section Two: Calibration Record

Calibration Date	Next Calibration Date	Labeled the updated device?	Name of calibrating organization	Prepare by (Administration Manager)	Approve by (Top Management)
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		☐			

1.70 Document Distribution List

Distribute Date	Name	Document Code and Version	Return Date	Signature of Administration Manager

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.71 Regulatory Update Form

(Update the documents once a month and record the results on this form)

Date	Document Name/Update Version/Update Date (If no update, please fill in "No")	Follow up Action(s) (If no, please fill in "No")	Completed by	Confirmed by

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

1.72 Record Disposal Form

Remark1: For the record disposal procedures and the maintenance period of the record, please refer to COP-1 Document Control Procedures.

Record Disposal Date:	**Responsible employees (Department):**	
Doc No.	**Doc Name**	**Period of Disposed Record**
Form 01	Quotation Record	
Form 02	Quotation	
Form 03	Tender Record	
Form 04	Purchase Order	
Form 05	Invoice Record	
Form 06	Invoice	
Form 07	Stock Record	
Form 08	Delivery Note	
Form 09	Warehouse Cleaning Record	
Form 10	Warehouse Cleaning Record	
Form 11	Specific Competence Requirement List for third-party employee	
Form 12	External Training Record	
Form 13	Third-party Logistic Supplier Monitor Record	
Form 14	Third-party Logistic Supplier Re-evaluation Record	
Form 15	Product Maintenance Form	
Form 16	New Staff Training Record	
Form 17	Specific Competence Requirement List	
Form 18	Employee Training Record	
Form 19	Approved Supplier List	
Form 20	Supplier Evaluation Form	
Form 21	Supplier Re-evaluation Form	
Form 22	Customer Satisfactory Survey	
Form 23	Customer Complaint Feedback Form	
Form 24	Corrective and Preventive Action Record	
Form 25	Product Recall Form	
Form 26	Nonconforming Product Report	
Form 27	Risk Management Report	
Form 28	Internal Audit Checklist	
Form 29	Adverse Incident Report	
Form 30	Equipment Calibration Record	
Form 31	Document Distribution List	
Form 32	Regulatory Update Form	
Form 33	Record Disposal Form	
N/A	Management Review Meeting Minutes	
N/A	Quality Assessment Result issued by the Manufacturer	
N/A	Revised Order Email Sample	
N/A	Revised Delivery Note Email Sample	
N/A	Advisory Notice Sample	
N/A	Customer List of Advisory Notice Recipients	
N/A	Related Documents Submitted to Regulatory Authority	
N/A	Email Sample for Inviting Customer Filling in the “Customer Satisfactory Survey”	
N/A	“Monthly Stock Record” Issued by Logistic Supplier	
N/A	“Stock Receipt” Issued by Logistic Supplier	
N/A	“Warehouse Floor Plan” Issued by Logistic Supplier	

Chapter 6. Form Sample

Record Disposal Form

Applicable to	Route 1	Route 2	Route 3
	✓	✓	✓

N/A	"Purchase Order" from customer	
Prepared by: (Administration Manager)	Date	
Approved by: (Top Management)	Date	