COMMAND
MEDICAL PRODUCTS

QUALITY MANUAL

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FOREWORD

This Manual identifies each section of the applicable ISO Standard and FDA Regulations and provides either a description of how the Quality Management System complies with the requirement, or references the related Level 2, Standard Operating Procedures (SOP's).

Command Medical Products hold FDA Registration Number: 1526611 for the 15 Signal Ave. Ormond Beach Florida facility and Registration Number: 3005382983, Owner Operator Number: 1526611, for the COMMAND MEDICAL NICARAGUA SA Km 12.5 Carretera Norte Parque Industrial Las Mercedes, Edificio 16 and 17 Managua NICARAGUA.

Each section is structured with the ISO section #, its title, and to the right of it, the comparable section of the CFR regulation and title, if applicable.

ISO Section # {Title} (CFR section #) {Title (if different from ISO)}

INTRODUCTION

Command Medical Products is a Contract Manufacturer of Medical devices for various customers

The Quality Management System described in this manual is structured to comply with; **ISO 13485:2016** and **21 CFR Part 820**, Quality System Regulation.

The Quality Manual applies both to Command Medical Product facilities located in Ormond Beach, Florida and Managua, Nicaragua.

1. SCOPE (820.1) Scope

The Quality Management System described in this manual is structured to comply with; **ISO 13485:2016** and **21 CFR Part 820**, QUALITY SYTEM REGULATION.

The Quality Manual applies both to Command Medical Product facilities located in Ormond Beach, Florida and Managua, Nicaragua.

REDUCTION IN SCOPE

a) The following section is an exclusion to the organization, with justification.

Clause / Sub-Clause	Title	Justification
7.3	Design and Development	CMP does not design or develop medical devices

b) The following sections are non-applicable to the organization, with justification.

Clause / Sub-Clause	Title	Justification
7.2.3 d	Advisory notices	Are the responsibility of the customer
7.5.3	Installation activities	CMP does not install medical devices
7.5.4	Servicing	CMP does not perform any servicing activities
7.5.9.2	Particular requirements for implantable medical devices	CMP does not manufacture Implantable Medical Devices
8.2.3	Reporting to Regulatory Authorities	CMP does not report adverse events, this is the responsibility of CMP's customers

2. Normative References

ISO 9000:2015, Quality management systems — Fundamentals and vocabulary.

3. Terms and Definitions (820.3) Definitions

For the purpose of this quality manual, the terms and definitions stated in ISO 9000:2015, *Quality Management Systems – Fundamentals and Vocabulary* shall apply, together with the following terms to describe the supply chain:

4. Quality Management System (820.5) Quality System

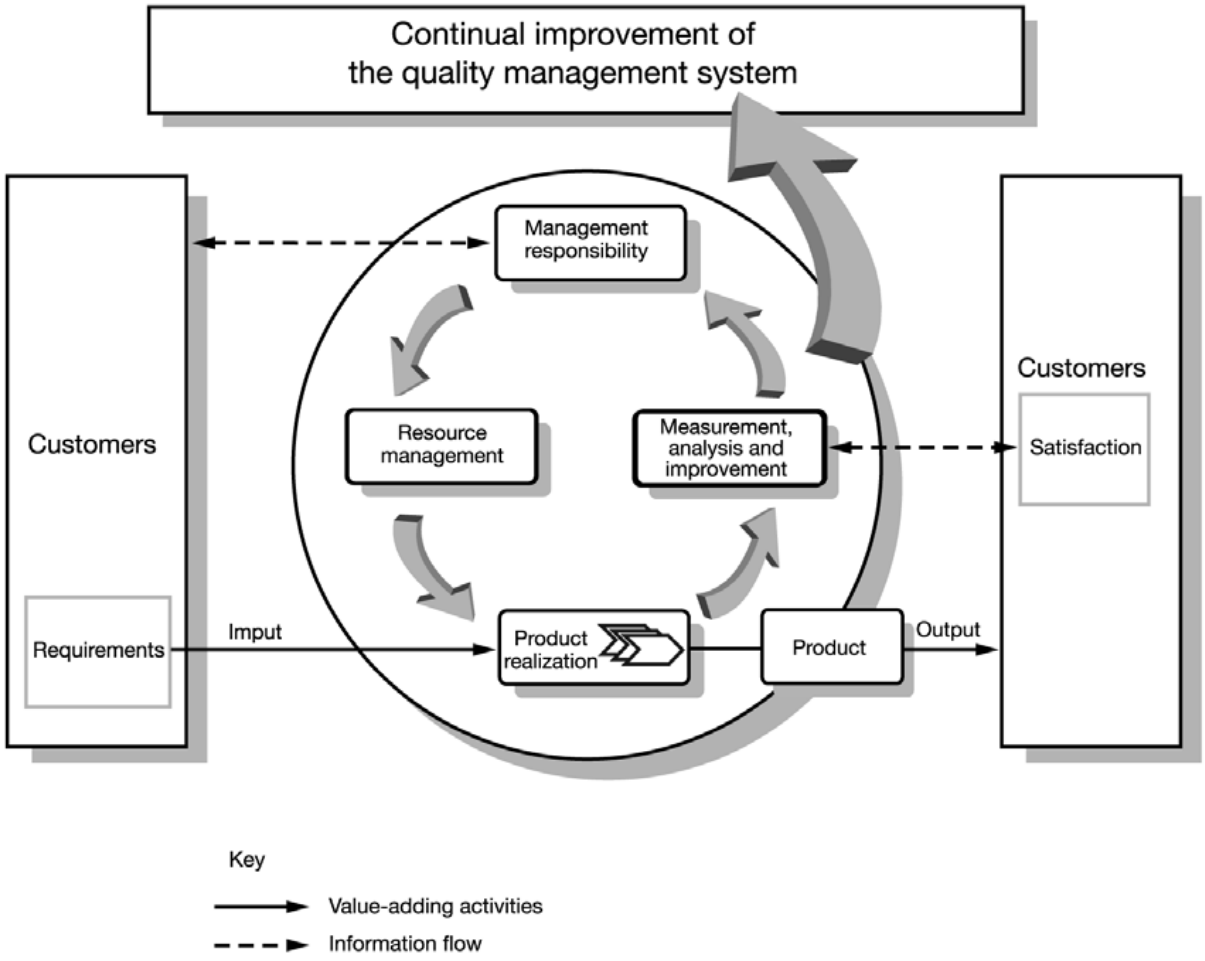
4.1 General Requirements

Command Medical Products has established a quality management system encompassing the requirements of ISO 13485:2016 and FDA 21 CFR Part 820. The system is documented in this Quality Manual, and Standard Operating procedures.

The sequence and interaction of processes are defined below.

Figure A

Quality Systems Management Process Interaction



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4.2 Documentation Requirements

4.2.1 General

Quality management documentation includes the following.

a) A documented Quality Policy including quality objectives.

b) This Quality Manual.

c) Documented Standard Operating Procedures (SOP's).

d) Work Instructions and Forms to ensure effective planning, control, and operation of processes.

e) Records providing evidence of conformity to requirements and of the effective operation of the quality management system.

f) Any other documentation specified by national or regional regulations.

4.2.2 Quality Manual (820.186) Quality System Record

This *Quality Manual*, contains:

a) The scope of the quality management system, including exclusions and not applicable sections.

b) The requirements and a description of the elements of the quality management system and their interaction.

(820.20 e) Quality System Procedures

c) Reference to the documented procedures established to implement the quality system.

The quality manual outlines the structure of the documentation used in the quality management system.

The Master of this Manual is maintained by Document Control. All other copies, including electronic (PDF) are considered uncontrolled copies.

4.2.3 Medical Device file

PR-ENG003, *New Product Development Procedure* has been established to ensure the following, as applicable to CMP.

a) Device specifications include appropriate drawings, composition, formulation, component specifications, and software specifications.

b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications.

c) Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used.

d) Packaging and labeling specifications, including methods and processes used.

4.2.4 Control of Documents (820.40) Document Controls

PR-QA001, *Document Control Procedure,* has been established to ensure the following.

a) Documents are reviewed and approved for adequacy prior to issue *by designated individuals*.

b) Documents are reviewed and updated as necessary and re-approved.

c) Changes and the current revision status of documents are identified.

d) Relevant versions of applicable documents are available at points of use.

e) Documents remain legible and readily identifiable.

f) Documents of external origin are identified, and their distribution controlled.

g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them and the required retention period.

h) The communication of changes to appropriate personnel in a timely manner

Quality Management System documents are revised according to an established change management process in which changes to documents are reviewed and approved by the original approving function or other designated function which has access to pertinent background information upon which to base decisions.

Document Change Request records include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and the effective date (the last signature date).

Prefixes used for documentation and their meaning, are defined in PR-QA001.

4.2.5 Control of Records (820.180) Records General Requirements

PR-QA012, *Record Retention Procedure*, defines how quality records are controlled and maintained, to demonstrate conformance to specified requirements and the effective operation of the quality management system.

Requirement: *The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements*. CMP does not accept, maintain or control patient medical records.

Device Master Record (820.181) Device master record

ENG003, *New Product Development Procedure* defines the requirements for setting up a device master record.

Device History Record (820.184) Device history record

PR-MP004, *Process Flow Procedure (Device History Record DHR*) includes the requirements and controls for Device History Records.

5 Management Responsibility (820.20) Management Responsibility

5.1 Management Commitment

A Quality Policy has been established by senior management which defines the quality objectives and communicates to the organization the importance of meeting customers as well as statutory and regulatory requirements.

PR-QA015, *Management Review Procedure*, defines the requirements for conducting management reviews, and ensuring the availability of resources.

5.2 Customer Focus

PR-CS001, *Contract Review Procedure*, defines the methods to ensure that customer requirements are determined and are met.

5.3 Quality Policy (820.20) (a) Quality Policy

The *Quality Policy* is appropriate to the purpose of the organization in its *commitment to excellence.* It includes a commitment to comply with *regulatory requirements*, and to *maintaining an effective Quality Management System.*

The policy is posted, communicated, and understood at all levels of the organization through training, and is reviewed for continuing suitability at Management Review, including *establishing and reviewing quality objectives to meet the goals of the organization*.

QUALITY POLICY

Commitment to Excellence

Measured by Customer Satisfaction and

Process Performance

The Quality Policy confirms our commitment to excellence in customer satisfaction, process performance, and regulatory compliance which is achieved through individual excellence from our employees by understanding and complying with customer requirements and maintaining the effectiveness of the Quality Management System.

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5.4 Planning (820.20) (d) Quality Planning

5.4.1 Quality Objectives

Quality Objectives are defined and evaluated during Management Review under PR-QA015.

5.4.2 Quality Management System Planning (820.20) (d) Quality Planning

Quality Management System Planning is carried out to meet the requirements of section 4.1, (Quality Management System) General Requirements. Most of this planning is developed at the initial stages of implementation of the quality management system. It also assists the organization to fulfill its quality objectives and continue to be effective during and after changes in objectives (e.g., attainment of a new Standard or regulation).

It should be noted that the term "quality plan" is more frequently used in conjunction with product realization planning than in conjunction with quality management system planning.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority (820.20) (b.1) Organization

The organizational chart defines the interrelation of all personnel who manage, perform and verify work affecting quality, and ensure the independence and authority necessary to perform these tasks.

The authorities of personnel are defined, documented and communicated within the organization based on job title.

5.5.2 Management Representative (820.20) (b.3) Management Representative

This Quality Manual documents the appointment of the Quality Assurance and Regulatory Compliance Manager as the Management Representative who has the authority and responsibility for:

a) ensuring that the requirements of the quality system are implemented, maintained and communicated;

b) reporting to executive management on the performance of the quality management system and any need for improvement;

c) ensuring the promotion and awareness of regulatory and customer requirements throughout the organization.

5.5.3 Internal Communication

The methods used to communicate the implementation and effectiveness of the quality management system to COMMAND MEDICAL PRODUCTS employees, include, but not limited to;

- Management Reviews
- Staff Meetings

- All Employee Meetings
- Annual GMP Training

5.6 Management Review (820.20) (c) Management Review

PR-QA015 *Management Review*, defines the process and requirements for Management Review.

6 Resource Management (820.20) (b.2) Resources

6.1 Provision of Resources

PR-QA015, *Management Review*, defines the resources needed to establish, implement, maintain, and improve the quality management system and to meet regulatory requirements. Resources may include personnel, suppliers, information, infrastructure, work environment, and financial resources.

6.2 Human Resources (820.25) Personnel

6.2.1 Competence, Awareness and Training (820.25) Personnel (a) General), (b) Training

PR-HR001, *Competence, Awareness and Training*, defines the requirements for sufficient personnel who are competent to perform the responsibilities based upon appropriate education, training, skills, and experience.

Competency is determined during the hiring process and evaluated during annual reviews. A training matrix is used to identify training needs. Training forms are records of fulfilled training requirements, which also verify the effectiveness of training.

New Hire Orientation and Annual training on Good Manufacturing Practices (GMP) and Quality System requirements ensure that employees are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives and meeting customer requirements.

6.3 Infrastructure (820.70) (f) Buildings (g) Equipment

Command Medical Products utilizes buildings, with appropriate space and utilities. Processing and measurement equipment (hardware and software) are maintained along with supporting services.

EP 00.001, *Preventive Maintenance*, references the requirements for maintenance activities.

6.4 Work Environment and contamination control (820.70) (d) Personnel

6.4.1 Work Environment

PR-MP004, *Process Flow Procedure*, defines the work environment, human and physical factors, needed to provide for product realization.

6.4.2 Contamination control

PR-QA026, *Environmental Monitoring Procedure*, defines the requirements for contamination controls.

7 Product Realization (820.20) (d) Quality Planning

7.1 Planning of Product Realization

PR-MP004, *Process Flow Procedure*, defines the requirements for Product Realization.

Manufacturing Procedures (MP) and Quality Procedures (QP) document the specific requirements for products and identify;

a) quality objectives and requirements for the product;

b) the processes and resources specific to the product;

c) required verification, validation, monitoring, inspection and test activities specific to the realization process and criteria for test acceptance;

d) records needed to provide evidence of service conformance of the realization processes and resulting product.

Risk Management as it relates to the product realization process is managed through the Nonconforming Material, Corrective and Preventive Action process and through the Validation and Change Control process.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements related to the Product

PR-ENG003, *New Product Development Procedure* describe how customer requirements are determined.

7.2.2 Review of Requirements related to the Product

PR-CS003, *Order Processing for Manufactured Product*, describes how customer requirements are reviewed.

7.2.3 Communication

PR-CS001, Contract review provides for communication of product information.

PR-CS003, *Order Processing for Manufactured Product*, addresses inquiries and order handling requirements, including any amendments to orders.

PR-QA004, *Products Complaint Procedure*, addresses customer feedback, including customer complaints, relating to nonconforming services, and advisory notices of adverse process results to customers, potentially requiring regulatory notification by our customers.

(Reduction in Scope/ Exclusion: Advisory notices are the responsibility of the customer)

7.3 Design and Development (820.30)

(Reduction in Scope/ Exclusion: Design and Development activities.)

Command Medical is a contract manufacturer and has no products of its own. Design development is conducted by Command Medical Products' customers and therefore EXCLUDED from Command's Quality System.

7.4 Purchasing (820.50) Purchasing Controls

7.4.1 Purchasing Process (820.50) (a) Evaluations of Suppliers

PR-PUR001, *Purchasing Controls,* establish how purchased product or services conform to requirements, the type and extent of control of the purchased product or service, and supplier evaluations.

7.4.2 Purchasing Information (820.50) (b) Purchasing Data

PR-PUR001, *Purchasing Procedure,* defines the how purchasing information/ data is communicated to the suppliers.

7.4.3 Verification of Purchased Product (820.80) (b)

PR-IC004, *Incoming Receiving Procedure,* define the methods for the verification of purchased products.

7.5 Production and Service Provision (820.70) Production and Process Controls

7.5.1 Control of Production and Service Provision

General Requirements (820.120) Device Labeling

PR-MP004, *Process Flow Procedure*, defines the production and process controls.

Control of production and service provision — Specific requirements

7.5.2 Cleanliness of Product

PR-MP004, *Process Flow Procedure*, defines the product cleanliness requirements.

PR-QA026, *Environmental Monitoring Procedure* defines requirements for product manufacturing environments (Clean Rooms).

7.5.3 Installation activities (820.170)

(Reduction in Scope/ Installation Activities are not applicable.)

7.5.4 Servicing Activities (820.200)

(Reduction in Scope/ Services Activities are not applicable.)

7.5.5 Particular requirements for sterile medical devices

PR-QA052, *Sterility Assurance Program*, defines the requirements for Sterilization activities.

7.5.6 **Validation of processes for production and service provision** (820.75) Process Validation

PR-QA053 *Change Control Procedure* defines the requirements for equipment, process validation, and change control.

7.5.7 **Particular requirements for validation of processes for sterilization and sterile barrier systems**

PR-ENG003, *New Product Development Procedure* define the requirements for sterilization and product sterile barrier systems.

7.5.8 **Identification** (820.60) Identification / (820.86) Acceptance Status

PR-QA047, *Handling, Storage, Packaging, Preservation and Delivery Procedure*, defines product Identification requirements including status.

7.5.9 **Traceability** (820.65) Traceability

7.5.9.1 **General**

PR-QA047, *Handling, Storage, Packaging, Preservation and Delivery Procedure*, defines product Traceability requirements.

OP-00.029, Lot Number and Sub-Lot Number Assignment.

7.5.9.2 **Particular requirements for implantable medical devices**

(Reduction in Scope/ CMP does not manufacture implantable medical devices.)

7.5.10 **Customer Property**

PR-QA047, *Handling, Storage, Packaging, Preservation and Delivery Procedure*, defines control of customer property.

7.5.11 **Preservation of Product** (820.130) Packaging, (820.140) Handling, (820.150) Storage, (820.160) Distribution

PR-QA047, *Handling, Storage, Packaging, Preservation and Delivery Procedure*, defines the handling, storage, and preservation processes for product.

7.6 **Control of Monitoring and Measurement Devices** (820.72) (a) (b)

EP 00.037, *Calibration Procedure*, defines the controls, calibration and maintenance requirements for measurement and monitoring equipment.

8 Measurement, Analysis, and Improvement (820.250)

8.1 General

a) PR-MP004, *Process Flow Procedure* demonstrates conformity of the product.

b) PR-QA014, *Internal Audits Procedure*. Results of audits ensure conformity of the quality Management system.

c) PR-QA015, *Management Review*, maintains the effectiveness of the quality management system.

The use of appropriate statistical techniques are defined throughout the quality management system documentation, including PR-QA041, *Statistical Techniques*.

8.2 Measurement and Monitoring

8.2.1 Feedback (820.198) Complaint Files

PR-CS006, C*ustomer Satisfaction Survey and Market Surveillance Procedure*, is used to provide feedback on whether the organization has met customer requirements. Management determines any actions derived from the results including customer complaints, recorded under Management Reveiw.

8.2.2 Complaint Handling

PR-QA004, *Product Complaint Procedure* defines requirements for Customer Complaints.

8.2.3 Reporting to Regulatory authorities

(Reduction in Scope/ CMP does not report adverse events is Not Applicable)

8.2.4 Internal Audit (820.22) Quality Audit

PR-QA014, *Internal Audits*, defines the use of Internal Quality Audits to assure effective implementation and compliance to the quality management system, and applicable regulatory requirements.

Audits are conducted by trained, qualified individuals that do not have direct responsibility for the area or work being audited.

PR-QA015, *Management Review*, references the results of audits as an input to verify the effectiveness of the Quality Management System.

8.2.5 Monitoring and Measurement of Processes

PR-QA015, *Management Review*, provides the framework (review inputs and outputs) for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action are taken, as appropriate, to ensure conformity of the product.

8.2.6 Monitoring and measurement of Product (820.80) (c) (d) Acceptance Activities

PR-IC004, Incoming Receiving Procedure and PR-MP004, Process Flow Procedures establishes the receiving, in-process and final inspection activities as they relate to manufacturing, to assure that purchased supplies and services supplied to customers conform to specified acceptance criteria.

8.3 Control of Nonconforming Product (820.90) Nonconforming Product

8.3.1 General

PR-QA011, *Control of Nonconforming Product*, establishes requirements for product that does not conform to specified requirements.

8.3.2 Actions in response to nonconforming product detected before delivery

PR-QA011, *Control of Nonconforming Product*, establishes requirements for product that does not conform to specified requirements detected before delivery.

8.3.3 Actions in response to nonconforming product detected after delivery

PR-QA011, *Control of Nonconforming Product*, establishes requirements for product that does not conform to specified requirements detected after delivery.

8.3.4 Rework

PR-QA011, *Control of Nonconforming Product*, establishes requirements for rework.

8.4 Analysis of Data

PR-QA015, *Management Review Procedure,* establishes methods (review inputs) for the analysis of data in order to determine the effectiveness of the quality management system and identify areas of improvement.

8.5 Improvement

PR-QA015, *Management Review Procedure,* The Management review process is used to maintain the continued suitability, adequacy, and effectiveness of the quality management system, assessing opportunities for improvement and to identify the need for changes to the quality management system, including the quality policy and quality objectives.

PR-QA004, Product *Complaint Procedure* manages records of all complaints and investigations and corrective action as needed, and the requirement to notify customers of any adverse products immediately upon discovery of such results.

8.5.1 Corrective Action (820.100) Corrective and Preventive Action

PR-QA008, *Corrective and Preventive Action Procedure,* establishes a system for reducing or eliminating the cause of nonconformities to the degree appropriate based on the magnitude of the problems and commensurate with the risks and effects of the nonconformities encountered.

8.5.2 Preventive Action (820.100) Corrective and Preventive Action

PR-QA008, *Corrective and Preventive Action Procedure,* establishes a system for reducing or eliminating the cause of potential nonconformities.

REVISION HISTORY

REVISION	EFFECTIVE DATE	DOCUMENT CHANGE SUMMARY	DR#
Original	05/07/98	Original Issue	3152
A	06/08/98	Added to: 1) 4.1.5 (page 10) auditor training requirements; 2) 4.2.3 (page 12) added "Related Procedures." Revised Organization Chart; 3) 4.9.3 (page 21) added a, b, c; 4) 4.13.3 (page 28) added acceptance of nonconforming product conditions	3186
B	04/19/99	Revise Organizational Chart – 1) Delete Q.C. Tech and Q.C. Engineering from Q.C. Manager; 2) Delete Sales Associate; 3) Delete Maintenance Supervisor; and 4). Add M.W. Regional Sales Manager	3452
C	11/06/99	Revise Organizational Chart – 1) Add Director of Operations, delete Plant Manager, and add Program Development Manager; 2) Delete Extrusion Supervisor; 3) Moved Incoming Inspection under Q.C. Manager; 4) Add another Sales Representative under Director of Sales; 5) Move Human Resources Manager under Director of Operations; 6) Director of QA/RA to report to Director of Operations	3619
D	08/18/00	Changes to Organizational Chart	3950
E	02/02/01	Changes to Organizational Chart	4075
F	05/10/01	Changes to Organizational Chart	4154
G	01/22/03	Changes to Organizational Chart	4790
H	11/17/03	Changing to incorporate Design Control throughout procedure	4944
I	1/26/05	Change title of Quality Manager update ISO reference number	5131
J	09-06-05	Updates Quality Manual to ISO 13485:2016 requirements.	5290
K	10-24-05	Adds ISO, and MDD revisions	5336
L	1-10-07	Deletes references to Canadian and MDD regulations and updates procedures numbers.	5746
M	12-2007	Changes Quality Assurance Manager to Manager of Quality Assurance and Regulatory Affairs revises procedure numbers, org. chart, and process map.	6069
N	5-22-08	Adds additional cross references from QSR to ISO 13485	6197
O	10-20-08	Adds references to Medical Device Directive, 93/42/EEC Annex 2, and MHLW Ministerial Ordinance No. 169,2004	6385
P	11-24-09	Changed section 3.2-page 15	6743
Q	1-7-11	Add Ref. to form 191 remove organization chart section 2.0 page 9, change ref. QAP 4.11 for EP 00.037 section 6.6 and remove ref. PR-QA024 obsolete section 3.2 and 7.1	7094
R	2-18-11	Make Quality Manual specific to Management Review changes	7134
S	10-25-11	Complete rewrite of Quality Manual. Took out reference to MDD	7328
T	3-20-12	Added Quality Objectives Form 862 and changed Risk Management Procedure number per CAPAs 703 & 706	7507
U	10-11-12	Made exclusion for Design Controls Removed references to MHLW regulation	7709
V	12-12-14	Added continuous improvement statement and general update of the Quality Manual.	8491
W	06-01-16	Updated definitions, Quality system process maps, documentation levels, responsibilities, added Director of New Product Integration & Director of	8747

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		New Business Development, referenced & defined FDA 21 CFR Part 803 Medical Device Reporting, referenced OP 00.020 Employee Clothing, Health & Personnel Practices, various minor syntax & formatting changes.	
X	10-16-17	Update Quality manual to comply with the changes in ISO 13485:2016	9875
Y	03-21-18	Removed the exclusion of 7.5.9.2. - Particular Requirements for Implantable Medical Devices – CMP is not responsible for these types of products. Updated Titles and Departments (Supply Chain and Operation Excellence.	10170
Z	11-05-18	Updated the Quality Policy; Removed ISO 13485, 7.5.9.2 as an exclusion	10494
AA	01-14-2020	Added the cover page to be part of the document Removed Section 1.3 Definitions Updated references to clauses 7.5.3 and 7.5.4 as NOT APPLICABLE clauses. Abbreviated Quality Management System to QMS revised the verbiage for customer property. Removed test "prior to initial use of the sterilization method" from Section 7.5. Updated verbiage in 8.5 to support any clients relating to advisory notices since CMP is not the design authority for products manufactured.	10953
AB	04-16-2020	Updated the document to include the new set of procedures PR-IT – Information Technology under section "Document Requirements"	11127
AC	01-07-2021	Updated Section 3.0 Organizational Charts	11486
AD	09/24/2021	Added Exclusion 7.5.9.2 Implantable Medical Devices, section 1.1 per ISO Audit AF-39. Updated all sections to align with requirements of ISO and FDA.	11856
AE	09-08/2022	Updated 4.2.3, Medical Device File, removed from reduction in scope section 1, added reference to PR-QA006.	12318
AF	11/28/2022	Section 4.2.5 added Exclusion for Confidential Health Information. Sections 7.4.1 removed callout of PR-PUR002 and 003.	12375
AG	09-27-2023	Removed Exclusion for Confidential Health Information page 5 and 4.2.5. Per SGS, not allowed. Removed reference to PR-QA021 (obsolete document) sections 7.2.1 & 7.5.7. Removed PR-QA006, (obsolete) sections 7.2.1, 7.5.7.	12765

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