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Medical Data Networks, LLC.

Quality Manual

Approvals:

Approving Signature	Name	Role	Date
/s/ Ben West	Ben West	CEO	9/1/2021
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Applicable Facility:

Medical Data Networks, LLC.,537 Montridge Ct.,Franklin, TN 37067 USA

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12. **PURPOSE**

The purpose of this manual is to provide the foundation for the company's Quality Management System. This manual establishes the quality and regulatory policies, defines the authorities and responsibilities of management, and provides general description of all processes comprising the quality system.

The Quality Management System complies with the following domestic and international regulations and standards:

- Code of Federal Regulations (CFR), Title 21, Food and Drug
- 21 CFR Part 820 – Quality System Regulation
- ISO 13485 – Medical Devices – Quality Management Systems
- EU Medical Device Regulation – MDR 2017/745
- EU Medical Device Directive – MDD 93/42/EEC
- Other regulatory authorities as appropriate

2. **SCOPE**

The Quality Management Systems defined in this manual applies to providing "T1Pal"and "CoPilot" cloud-based applications to subscribers, specifically

including the following activities.

- Product Design
- Product Development
- Network Operations
- Customer Care

By "cloud based" we mean that subscribers are enabled to receive the benefits of certain operating software applications, but do not carry or own any part of the servers, and/or database device(s) necessary to deliver features and functions of the product. Subscribers are required to provide their own internet (cloud) access arrangements to access the cloud based applications. We take the FDA's definition of "software" to mean "device" for the purpose of regulatory compliance.

This Quality Manual applies to the following facility:

Medical Data Networks, LLC., 537 Montridge Ct., Franklin, TN 37067

The company has undertaken the following roles:

- ISO 13485 – Design, Manufacturer, Contract Manufacturer, Importer.
- US CFR 21 Part 820 – Specification Developer, Manufacturer, Contract Manufacturer, Importer, etc.

The following applicability **exclusions** apply:

- Sterilization Requirement and Processes (ISO Clause 7.5.5 & 7.5.7) – Our are not provided or distributed sterile products or utilize sterile processes.
- Implantable Medical Devices (ISO Clause 7.5.9.2 & 8.2.6 Partial) – We do not provide or distribute implantable products.

3. TERMS AND DEFINITIONS

Term	Definition
Appropriate Management	CEO, COO, President, Vice Presidents, Directors, Managers, Team Leaders.
Continual improvement	Process of enhancing the Quality Management System to achieve improvements in overall quality, operations, and environmental performance in line with the organization's Quality Policy.
Controlled Document	Any document that affects the quality of the product and is reviewed and approved prior to release for use or reference.
Corrective Action	A process improvement methodology aimed at identifying and eliminating the causes of known nonconformities and to prevent their recurrence.
Customer	The recipient of a product or service provided by the organization.

Term	Definition
Design History File (DHF)	A compilation of records that describes the design history of the finished device.
Device History Record (DHR)	A compilation of records containing the production history of a finished device.
Device Master Record (DMR)	A compilation of records containing the procedures and specifications for a finished device.
Management with Executive Responsibility	Those senior employees who have the authority to establish or make changes to the organization's quality policy and quality system.
Preventive Action	A process improvement methodology aimed at identifying and eliminating potential causes of nonconformities before they occur.
Process	A set of interrelated resources and activities that transform inputs into outputs.
Process Leader	Person with primary process responsibility to document and maintain its procedures, work instructions, and forms; to control records; and to train process users. Selected by management based upon primary job responsibilities.
Product	The result of activities or processes.
Proposal	Offer or quote made by an organization in response to a request for a quote to provide product.
Quality Policy	Statement by the organization of its intentions and principles in relation to its overall quality performance which provides a framework for action and for setting the organization's quality objectives and targets.
Supplier or Vendor	The organization that provides a product or service to an organization.

4. QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

The quality systems have been established, documented, implemented, and maintained to ensure the products and services produced meet the quality standards of the organization and are in compliance with relevant regulatory bodies. Our organization has applied a risk based approach to the control of the appropriate processes needed for the Quality Management Sytstem (QMS).

The Quality Management System is defined through a four level hierarchy:

- **Quality Manual:** ++(This document is the Quality Manual)++ A First-level document that provides a general overview of the Quality System and defines the Quality Policy.

- **Quality Policies and Procedures:** Second-level documents that provide more detailed explanation of the Quality System clauses and detail the structure of the Quality System.
- **Standard Operating Procedures and Work Instructions** (sometimes referred to as "Run Books"): Third-level documents that provide step-by-step instructions on how activities are to be carried out and the requirements of products produced.
- **Forms and Records:** Fourth-level documents or data that contain the information, charts, checklists, or other form of records as evidence to demonstrate conformance to specified requirements and the effective operation of the Quality System. Certain folders contain Templates and Records used in connection with the Procedures are separate from a definition of the procedures. An appropriately labeled README.md file provides a link to individual templates. Templates may contain charts, checklists, or other form of records as evidence to demonstrate conformance to specified requirements and the effective operation of the Quality System.

If a particular development project or customer request cannot be fulfilled by the existing procedures, quality plans are created to ensure that the specific requirements are met. Quality plans are consistent with all other requirements of the Quality System. Consideration shall be given to the resources or skills required to meet specified requirements whenever there is a significant change to an existing product, process, test, inspection, verification, and measurement.

The following key processes and interactions define the organizational structure and responsibilities of the Quality Management System.

These quality system processes are managed in accordance with the requirements of ISO 13485 and applicable regulatory requirements. Changes to be made to these processes shall be:

- Evaluated for their impact on the quality management system
- Evaluated for their impact on the medical devices produce under this QMS
- Controlled in accordance with the requirements of ISO 13485 and applicable regulatory requirements.

For all outsourced processes that may affect conformance to requirements, the company ensures control over these processes through supplier assessment, purchasing and receiving processes, and/or documented procedures as applicable. The company maintains responsibility of conformity to applicable international standards and regulatory requirements. The controls shall be proportionate the risk involved and the ability of the external party to meet the in requirements and include a written quality agreement.

The company has documented procedures for the validation of the application of computer software used in the QMS. Such software is validated prior to

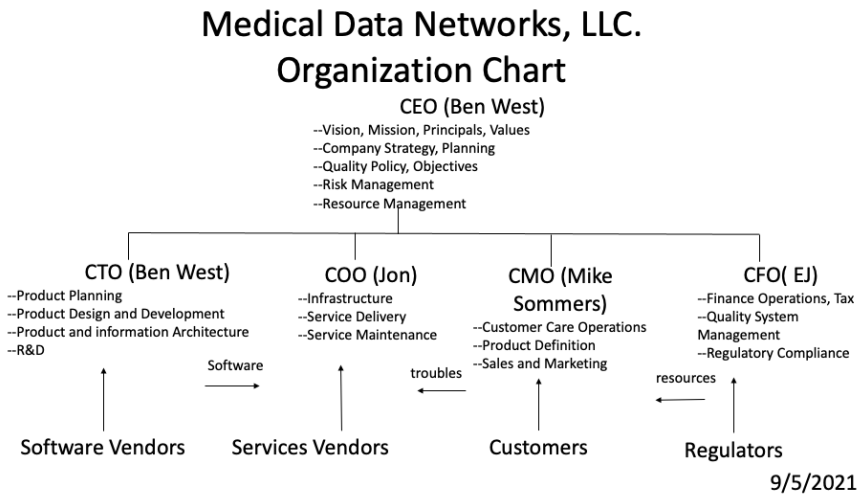

Figure 1: Organization Chart

initial use and, as appropriate, after change to the software or its applications. The specific approach and associated activities shall be proportionate to the risk associated with the use of the software. Records of such activities are maintained.

4.2 Documentation Requirements

4.2.1 General

The responsibility to develop and effectively implement quality system procedures is held by the designated owner for each policy procedure or SOP as determined by management. Procedure details depend upon the complexity of the work, methods used, and the skills and training needed by personnel to carry out the activity.

The Quality Management System includes:

- Quality Manual (this document)
- Documented Quality Policy and Objectives
- Documented procedures and records required by domestic and international regulations
- Documents, including records, determined by the organization as necessary to ensure quality
- Other documentation specified by applicable regulatory requirements

All management affected by the controlled documents are responsible to ensure that their personnel are adequately informed and trained, as necessary, to ensure

the proper implementation of the procedures. Procedures and records may be created and/or maintained in the form of paper copy, electronic copy, or in other media as deemed appropriate.

4.2.2 Quality Manual

The company has established and maintains this document as the Quality Manual. It includes:

- The scope of the quality management system.
- Description and/or definition of procedures established for the quality management system.
- A description of the interactions between the processes of the quality management system.

4.2.3 Device Master Records (DMR)

For each medical device type or medical device family, we have established and maintain one or more files containing or referencing documents generated to demonstrate conformity to the requirement of ISO 13485 and applicable regulatory requirements. The content of the file(s) includes:

- General description of the medical device, intended use/purpose, and labeling, including any instructions for use
- Specifications for the product
- Specifications or procedure for manufacturing, packaging, storage, handling, and distribution
- Procedures for measuring and monitoring

4.2.4 Control of Document

The company has established and maintains procedures to control all documentation and data related to the requirements of the applicable regulatory standards, including external documents, such as standard and electronic media. These procedures define the controls for:

- A review and approval process to ensure adequacy and efficacy of documents
- A review process to ensure document content is accurate and updated
- Clear identification and justification of changes
- Ensuring the availability, readability, and accessibility of current documents
- Ensuring documents of external origin, determined necessary, are identified and controlled
- The prevention of deterioration or loss of documents
- The prevention of inadvertent use of obsolete documentation

4.2.5 Control of Records

It is the responsibility of all personnel to keep records of all work or operations performed in the format prescribed by the various policies and procedures in the quality system. All records shall contain the date of creation and the person responsible for their creation. All records shall be made in a permanent and legible manner and changes to a record shall remain identifiable. Controls necessary for the identification, storage, protection, retrieval, retention time, and disposition of records shall be included within the documented procedure requiring the record. Methods for protecting confidential health information contained in records shall be defined and implemented.

5 MANAGEMENT RESPONSIBILITIES

5.1 Management Commitment

Management is responsible for establishing a custodian of all quality records, including internal audits, management reviews, corrective actions, preventive actions, training records, proficiency test results, and other related records. The record retention time is specified by relevant regulatory requirements or documented procedures, whether hard copy or electronic.

Management demonstrates its commitment to the development and implementation of the Quality Management System, and its continual improvement, by:

- Communicating to the organization the importance of complying with customer, regulatory, and statutory requirements as applicable
- Establishing and communicating the Quality Policy
- Establishing, communicating, and enforcing Quality Objectives
- Conducting management reviews
- Providing necessary resources

5.2 Customer Focus

Company Management ensures that customer requirements and applicable regulatory requirements (needs and expectations) are understood and are met with the aim of enhancing customer satisfaction. These are generally established within product requirements and specifications and within quality management system documentation.

5.3 Quality Policy

The Quality Policy is established by management with executive responsibility. The company quality policy is stated below and is communicated throughout the organization to ensure commitment to quality within the organization. The quality policy provides a framework for establishing and reviewing quality objectives and is reviewed periodically for continued effectiveness.

Quality Policy

Every employee accepts responsibility for the quality of our processes and medical devices.

This is achieved by continuously improving designs, implementing efficient procedures, and partnering with suppliers to meet or exceed the expectations of our customers, and satisfy the requirements of our quality system and appropriate regulations.

5.4 Quality Objectives and Planning

5.4.1 Quality Objectives

The company has identified the following Quality Objectives. These objectives will be reviewed and updated as necessary to meet company goals.

- Establish and maintain a team-oriented working environment in which each employee accepts responsibility for the development, production, and delivery of high quality goods and services.
- Implement and maintain a Quality System compliant with the Quality System Requirements of the United States Food and Drug Administration (FDA), ISO 13485, European Union, and any other applicable regulatory requirements.
- Implement and maintain efficient quality systems and procedures that effectively control the quality of the products and services provided and emphasize continuous improvement.
- Define and monitor metrics of effectiveness for key elements of the business and utilize the data to effectively manage and drive improvement with emphasis on Customers, Products, Services, and Stakeholders.

5.4.2 Quality Management System Planning

Management ensures that the planning of the Quality Management System is implemented by appropriate management and carried out by all employees in order to meet the requirements provided in this manual. Management also ensures the integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented.

5.5 Responsibility, Authority, and Communication

5.5.1 Responsibility and Authority

Management has defined and documented the responsibility, authority, and interrelation of personnel who manage, perform, and verify work within the Quality Management System. These responsibilities are documented in official job descriptions, which define the tasks performed by employees, and an organization chart depicting the interrelation of all employees.

All employees accept responsibility for the maintenance and improvement of the Quality Management System.

This is achieved by understanding and supporting the Quality Policy and the appropriate clauses of the quality system for their areas of work; dedicating efforts to the continuous improvement, understanding how their activities impact quality, elimination and prevention of quality deficiencies; and initiating action to prevent the occurrence of nonconformities related to product and processes.

5.5.2 Management Representation

The Management Representative is appointed by management with executive responsibility and is responsible and fully authorized to manage the Quality Management System and related matters on an ongoing basis. Roles and responsibilities of the Management Representative include the following:

- Ensures that the Quality Management System is established, implemented, and maintained in accordance with applicable regulatory requirements.
- Interprets applicable standards and continually verifies compliance.
- Advises management regarding operation and performance of the quality systems and opportunities for improvement.
- Serves as liaison to external parties regarding matters relating to the QMS.
- Ensures the promotion of awareness of applicable regulatory, quality management, and customer requirements throughout the organization.

5.5.3 Internal Communications

The Management Representative has the responsibility to work with other departments to ensure that adequate internal communication exists concerning the effectiveness and implementation of the Quality Management System.

Methods for internal communication include:

- Meetings
- Memos
- E-mails
- Formal Training

5.6 Management Review

5.6.1 General

Management acknowledges responsibility for the quality systems and reviews the systems to ensure continuous suitability and effectiveness in relation to domestic and international regulatory requirement, this Quality Manual, and company objectives. Management representing each key functional area participates in this review that includes assessing opportunities for improvement and the need to change the Quality Management System, including the Quality Policy and Objectives. Records of management reviews are maintained.

5.6.2 Review Input

The activities reviewed during management reviews may include, but are not limited to:

- Feedback
- Customer complaint handling and trending
- Reporting to regulatory authorities
- Internal or third-party audits
- Monitoring and measurement of processes and products
- Corrective and preventive actions
- Previous management review activities
- Changes that could affect the Quality Management System
- New or revised regulatory requirements

5.6.3 Review Output

The output from management review meetings may include decisions and actions relating to:

- Improvement needed to maintain the suitability, adequacy, and effectiveness of the Quality Management System and its procedures
- Improvement of the product, services, training, infrastructure, work environment, and other processes
- Changes needed to respond to applicable new or revised regulatory requirements
- Resource requirements and allocation

6 **RESOURCE MANAGEMENT**

6.1 Provision of Resources

Management has the responsibility and authority to ensure there are adequate resources to support the Quality System throughout their functional areas of responsibility. Each member of management is to provide adequate resources to:

- Implement and maintain the Quality Management System and continually improve its effectiveness
- Enhance customer satisfaction by meeting customer requirements
- Meet regulatory requirements
- Place trained and competent personnel in the right place at the right time to ensure company goals and objectives are met

6.2 Human Resources

Resource and training requirement are identified and addressed on a regular basis in order to support the growth and changing needs of the company. For each job function, management provides sufficient personnel with appropriate background, education, and experience.

The company has established and maintains documented procedures for establishing competence, providing needed training, and ensuring awareness of per-

sonnel. These procedures include:

- Determining the necessary competence of personnel performing work affecting quality
- Providing training or other actions to achieve or maintain the necessary competence
- Evaluation of the effectiveness of the training and other actions taken. The methodology for effectiveness check is proportionate to the risk associated
- Ensuring that personnel are aware of the importance of their activities and how they contribute to the achievement of quality objectives
- Maintaining appropriate records of education, training, skills, and experience.

6.3 Infrastructure

Management maintains responsibility for infrastructure needed to produce quality products and services and documented the requirements for the work environment needed to achieve conformity to product requirements, prevent product mix-up, and ensure orderly handling product. Infrastructure includes:

- Buildings, workspace, and associated utilities
- Process equipment (both hardware and software)
- Supporting services (i.e. transport, communication, or information systems)

This infrastructure is reviewed and adjusted as needed to achieve company objectives.

A documented procedure shall be established for any infrastructure maintenance activities, including interval of performing the maintenance activities when required, necessary to maintain quality and records of such activities shall be maintained. As appropriate, the requirements shall apply to equipment used in production the control of work environment, and monitoring and measurement.

6.4 Work Environment and Contamination Control

6.4.1 Work Environment

The company maintains responsibility and has documented the requirements for the work environment to assure its suitability for achieving conformity to product requirements.

Where appropriate to ensure quality and compliance with applicable Environmental, Health, and Safety (EHS) requirements, the company has established:

- Documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance
- Documented requirements for environmental conditions and instructions for monitoring and controlling these conditions

- Training for personnel working temporarily under special environmental conditions

6.4.2 Contamination Control

As appropriate, the organization has planned and documented arrangements for the control of contamination or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product

7 PRODUCT REALIZATION

7.1 Planning of Product Realization

The quality planning requirements for individual development projects, related processes and supporting documentation are described in the procedures for each process, for example, the design control procedure, supplier qualification procedure and other process procedures. The company has developed a documented risk management procedure and maintains records of risk management activities.

The quality planning process, when initiated, shall provide for the following:

- Identification and acquisition of necessary controls, equipment, fixtures, resources and skills needed to achieve business goals and objectives.
- Provision for procedures, work instructions, inspections, tests, etc. to ensure product is manufactured to customer expectations and requirements including infrastructure and work environment.
- Required verification, validation, monitoring, measurement, inspection, test, handling, storage, distribution, and traceability activities specific to the product together with the criteria for product acceptance.
- Records needed to provide evidence that the realization processes and resulting product meet requirements.

The company has established and maintains a process for identifying hazards associated with products and processes, estimating and evaluating the associated risks, controlling these risks and monitoring the effectiveness of the control including post-production information. Documented risk management activities are included throughout the product realization process, where appropriate. Records arising from risk management are maintained in a risk management file.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

The determination of the requirements relating to the product includes:

- Requirements specified by the customer including delivery, service and support, and product performance

- Requirements not specified by the customer but necessary for intended use, where known
- Statutory and regulatory requirements relating to the product
- Any user training needed to ensure specified performance and safe use of the product
- Additional requirements determined by the organization

7.2.2 Review of Requirements Related to the Product

Contracts, including purchase orders, are reviewed to ensure customer requirements and amendments are communicated in a controlled manner. The contract review requires the appropriate review of each proposal, contract, or order to ensure that:

- Product requirements are defined and documented
- Contract or order requirements differing from those previously expressed are resolved
- Applicable regulatory requirements are met
- Any user training identified in accordance with 7.2.1 is available or planned to be available
- The organization has the ability to meet the defined requirements

Amendments to a contract or customer's specification are handled and correctly transferred to the concerned functions within the company and confirmed with the customer.

All management affected by the controlled documents are responsible to ensure that their personnel are adequately informed and trained, as necessary, to ensure the proper implementation of the procedures. Procedures and records may be created and/or maintained in the form of paper copy, electronic copy, or in other media as deemed appropriate.

Records of contracts, contract reviews, proposals and contract amendments are maintained in the customer file.

7.2.3 Customer Communication

The company plans and documents effective arrangements for communicating with customers in relation to:

- Product information
- Inquiries, contracts, and order handling, including amendments
- Customer feedback, including customer complaints, and customer satisfaction
- Advisory notices We have documented procedures for communicating with regulatory authorities in accordance with applicable regulatory requirements

7.3 Design and Development

7.3.1 General

The company has documented and implemented procedures for the control of design and development.

7.3.2 Design and Development Planning

Documented procedures shall be used to control and verify the development of new products to ensure that the specified requirements are met.

The **legacy** development process is executed in several phases.

Each phase has a checkpoint to ensure that all required elements for the specific phase have been properly planned and completed. These planning records are maintained.

- Management reviews each phase to ensure that organizational and technical interfaces, which provide input into the design process, are defined.
- Necessary information is documented, transmitted, and regularly reviewed.

Design and development activities are planned the following items are documented:

- The design and development stages
- The review(s) needed at each design and development stage
- The verification, validation, and design transfer activities that are appropriate at each design and development stage
- The responsibilities and authorities for design and development
- The methods to ensure traceability of design and development outputs to design and development inputs
- The resources needed, including necessary competence of personnel

7.3.3 Design and Development Inputs

Design input requirements relating to the product are identified, documented, and reviewed for adequacy. Design input requirements include:

- Functional, performance, usability, and safety requirements, according to its intended use
- Applicable statutory and regulatory requirements and standards
- Applicable output(s) of risk management
- As appropriate, information derived from previous similar designs
- Other requirements essential for design and development of the product and processes

Design input requirements are reviewed for adequacy and incomplete, ambiguous, or conflicting requirements are resolved. Requirements shall be complete,

unambiguous, able to be verified or validated, and not in conflict with each other.

7.3.4 Design and Development Outputs

Design outputs are provided in a form suitable for verification against design input and are approved prior to release. Design outputs:

- Demonstrate that input requirements have been met
- Provide appropriate information for purchasing and production
- Contain or reference product acceptance criteria
- Specify product characteristics essential for its safe and proper use

7.3.5 Design and Development Review

The design control procedure requires that systematic design and development reviews be conducted to:

- Evaluate the ability of the design to meet the requirements
- Provide for a review by participants representing concerned functions as well as other specialized personnel
- Identify any deficiencies and propose necessary actions

Participants in these reviews include representative from relevant functional areas and specialist personnel, concerned with the design stage being reviewed.

Records of the results of design reviews and any necessary actions are maintained and include the identification of the design under review, the participants involved and the date of the review.

It is the responsibility of all personnel to keep records of all work or operations performed in the format prescribed by the various policies and procedures in the quality system. All records shall contain the date of creation and the person responsible for their creation. All records shall be made in a permanent and legible manner and changes to a record shall remain identifiable. Controls necessary for the identification, storage, protection, retrieval, retention time, and disposition of records shall be included within the documented procedure requiring the record. Methods for protecting confidential health information contained in records shall be defined and implemented.

Management is responsible for establishing a custodian of all quality records, including internal audits, management reviews, corrective actions, preventive actions, training records, proficiency test results, and other related records. The record retention time is specified by relevant regulatory requirements or documented procedures, whether hard copy or electronic.

7.3.6 Design and Development Verification

Design and development verification is performed in accordance with planned and documented arrangements to ensure that design outputs comply with design input requirements. The company documents verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rational for sample size.

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced.

Management demonstrates its commitment to the development and implementation of the Quality Management System, and its continual improvement, by:

- Communicating to the organization the importance of complying with customer, regulatory, and statutory requirements as applicable
- Creating records of the results and conclusions of design verification and any necessary actions.

7.3.7 Design and Development Validation

Design validation is performed in accordance with planned and documented arrangements to ensure that the design is capable of meeting the requirements for the specified application or intended use, where known.

The company documents validation plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.

As part of design and development validation, the organization shall perform clinical evaluation or performance evaluations of the medical device in accordance with applicable regulatory requirements. A medical used for clinical evaluation or performance evaluation is not considered to be released for use to the customer.

If the intended use requirement that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced.

Validation will be performed prior to the release for use of the product to the customer

Records of the results and conclusions of design validation and any necessary actions are maintained.

7.3.8 Design and Development Transfer

Design transfer is performed in accordance with planned and documented arrangements to ensure the transfer of design and development outputs to manufacturing. These procedures ensure that design and development outputs are

verified as suitable for manufacturing before becoming final production specification and that production capability can meet production requirements.

Records and conclusions of the results of design validation and any necessary actions are maintained.

7.3.9 Control of Design and Development Changes

Design changes and modifications are identified, documented, reviewed, and approved by appropriate management prior to implementation. The company determines the significance of the change to function, performance, usability, safety, and applicable regulatory requirements for the medical device and its intended use.

Design and development changes are identified and before implementation, the changes are reviewed, verified, validated (as appropriate), approved.

The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management, and product realization processes.

The company has identified the following Quality Objectives. These objectives will be reviewed and updated as necessary to meet company goals.

- Establish and maintain a team-oriented working environment in which each employee accepts responsibility for the development, production, and delivery of high quality goods and services.
- Implement and maintain a Quality System compliant with the Quality System Requirements of the United States Food and Drug Administration (FDA), ISO 13485, European Union, and any other applicable regulatory requirements.
- Implement and maintain efficient quality systems and procedures that effectively control the quality of the products and services provided and emphasize continuous improvement.
- Define and monitor metrics of effectiveness for key elements of the business and utilize the data to effectively manage and drive improvement with emphasis on Customers, Products, Services, and Stakeholders.

7.3.10 Design and Development Files

The company maintains a design and development file for each medical device type or medical device family. This file includes or references records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.

7.4 Purchasing

7.4.1 Purchasing Process

The company has established and maintains procedures to ensure that purchased products or services conform to specified information. We establish criteria for the evaluation and selection of suppliers based upon the performance of the supplier, the effect of the purchased product on the quality of the medical device, and risk associated with the medical device.

The company plans the monitoring and re-evaluation of supplier. Supplier performance in meeting requirements for the purchased product is monitored. The results of the monitoring provide an input into the supplier re-evaluation process.

Non-fulfillment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements. Supplier performance is monitored, and actions are taken as necessary to address any failure to meet specified requirements. These actions may include disqualification of the supplier.

Records of the results of evaluation, selection, monitoring, re-evaluation of supplier capability or performance and any necessary actions arising from these activities is maintained.

7.4.2 Purchasing Information

Purchasing documents clearly and completely describe or reference ordered products. Purchasing documents clearly define, including as appropriate:

- Product specifications
- Requirements for product acceptance, procedures, processes, and equipment
- Requirements for qualification of supplier personnel
- Quality Management System requirements

Purchasing reviews and approves all purchasing data for adequacy and completeness prior to communication to suppliers.
Purchasing information includes, as applicable, a written agreement that the supplier notify us of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements

The Management Representative has the responsibility to work with other departments to ensure that adequate internal communication exists concerning the effectiveness and implementation of the Quality Management System.

Methods for internal communication include:

Where required for traceability purposes, purchasing information is maintained.

7.4.3 Verification of Purchased Product

The company shall establish and implement the necessary inspection activities to ensure that purchased product meets specified purchase requirements. The

extent of verification activities shall be based on the supplier evaluation results and proportionate to the risk associated with the purchased product.

When we become aware of any changes to the purchased product, we will determines whether these changes affect the product realization process or the medical device.

When verification of purchased product is required at the supplier's premises (source inspection), purchasing documents will define the verification arrangements and the method of quality release.

Records of purchased product verification are maintained.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Production and service provision is planned, carried out, monitored, and controlled to ensure that product conforms to specification. As appropriate, product control include but are not limited to:

- Documentation of procedures and methods for the control of production
- Qualification of infrastructure
- Implementation of monitoring and measurement of process parameters and product characteristics; availability and use of monitoring and measuring equipment
- Availability and use of monitoring and measurement equipment
- Implementation of measuring processes where required to assure product quality
- Implementation of suitable release, delivery and post-delivery activities
- Implementation of defined operations for labeling and packaging

Records are maintained for each medical device or batch of medical devices produced as necessary to meet traceability requirements. These records identify the amount of product manufactured and approved for distribution. These records are reviewed and approved.

7.5.2 Cleanliness of Product and Contamination Control

The company documents requirements for cleanliness of product or contamination control of product if:

- Product is cleaned by the organization prior to sterilization or its use
- Product is supplied non-sterile and is to cleaned prior to sterilization or its use
- Product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use

- Product is supplied to be used non-sterile, and its cleanliness is of significance in use
- Process agents are to be removed from product during manufacture

If product is cleaned in accordance with the 1st two bullets, the requirements contained 6.4.1 do not apply prior to the cleaning process.

Notwithstanding these generic requirements, all of the software (as a device) products provided by this company are operated in a private data center and are not physically delivered to any customer or subscriber. There is no need for cleaning or sterilization any physical device.

7.5.3 Installation Activities

The company documents requirements for medical device installation and acceptance criteria for verification of installation, as appropriate.

If installation activities are performed by an external party, we provide documented requirements for the medical device installation and verification of installation.

All records of installation activities and verification of installation performed by us or our suppliers are maintained.

7.5.4 Servicing Activities

If servicing activities are a specified requirement, the company documents servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirement are met.

The company analyses records of servicing activities carried out by us or our suppliers to determine if the information is to be handled as a complaint and/or as appropriate, for input to the corrective and preventative action process.

All records of servicing activities performed by us or our suppliers are maintained.

7.5.5 Particular Requirements for Sterile Medical devices

All records of sterilization process parameters used for each sterilization batch are maintained and traceable to each production batch of medical devices.

The output from management review meetings may include decisions and actions relating to:

- Improvement needed to maintain the suitability, adequacy, and effectiveness of the Quality Management System and its procedures
- Improvement of the product, services, training, infrastructure, work environment, and other processes

- Changes needed to respond to applicable new or revised regulatory requirements

As discussed above, notwithstanding these generic requirements, all of the software (as a device) products provided by this company are operated in a private data center and are not physically delivered to any customer or subscriber. There is no need for cleaning or sterilization any physical device.

7.5.6 Validation of Processes for Production and Service Provision

The company validates processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement. This includes any processes where, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results consistently. Validation procedures are documented and include, where applicable:

- Defined criteria for review and approval of the processes
- Equipment qualification and qualification of personnel
- Use of specific methods, procedures, and acceptance criteria
- As appropriate, statistical techniques with rational for samples sizes
- Requirement for records and revalidation, including criteria for revalidation
- Software that may affect conformance to requirements
- Records of validation shall be maintained

The company documents procedures for the validation of the application of computer software sued in production and service provision. Such software applications are validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation are proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications. Records of the results and conclusions of validation and necessary actions from the validation are maintained.

7.5.7 Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems

The company documents procedures for the validation of processes for sterilization and sterile barrier systems. Processes for sterilization and sterile barriers systems are validated prior to implementation and following product or process changes, as appropriate.

Records of the results and conclusion of validation and necessary actions from the validation are maintained.

7.5.8 Identification

The company has implemented documented procedures for product identification and identify product by suitable means throughout product realization.

Product is identified with respect to monitoring and measurement requirements though product realization. Identification of product is maintained throughout production, storage, installation, servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used, or installed.

If required by applicable regulatory requirements, we shall document a system to assign unique device identification to the medical device. We document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.

7.5.9 Traceability

7.5.9.1 General

Documented procedures define procedures for traceability. These procedures define the extent of traceability in accordance with applicable regulatory requirements and the records are maintained.

7.5.9.2 Particular Requirements for Implantable Medical Devices

The records required for traceability of implanted medical devices include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements.

The company requires that suppliers of distribution services or distributors maintain records of the distribution of implantable medical devices to allow traceability and that these records are available for inspection.

Records of the name and address of the shipping package consignee are maintained.

7.5.10 Customer Property

The company has established documented procedures for preventing damage or deterioration to customer supplied materials through identification, handling, storage, packaging, preservation and delivery. If any customer property is lost, damaged or otherwise found to be unsuitable for use, we shall report this to the customer and maintain records.

7.5.11 Preservation of Product

Management maintains responsibility for infrastructure needed to produce quality products and services and documented the requirements for the work environment needed to achieve conformity to product requirements, prevent product mix-up, and ensure orderly handling product. Infrastructure includes:

The company has established documented procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device. We protect product from alteration, contamination, or damage when exposed

to expected conditions and hazards during processing, storage, handling, and distribution by designing and constructing suitable packaging and shipping containers and documenting requirements for special conditions needed if packaging alone cannot provide preservation. If special conditions are required, they shall be controlled and recorded.

7.6 Control of Monitoring and Measuring Equipment

All monitoring and measurement equipment, comparative references (such as gauges and templates), and test equipment used in the inspection of product, validation of the product, or the validation of production processes are calibrated and maintained within the Calibration Program. Instruments used for purposes other than product inspections or control of production processes are exempted from the Calibration Program. Calibration and verification is completed in accordance with documented procedures.

As necessary to ensure valid results, measuring equipment is:

- Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. When no such standard exists, the basis used for calibration or verification shall be recorded.
- Adjusted or re-adjusted as necessary. Such adjustments or re-adjustments shall be recorded.
- Identified in order to determine it calibration status
- Safeguarded from adjustments that would invalidate the measurement result
- Protected from damage and deterioration during handling, maintenance, and storage.

In addition, we assess and record the validity of past measurement results when equipment is found not to conform to requirements and take appropriate actions in regard to the equipment and any product affected. Records of calibration and verification activities are maintained.

The company has documented procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. Such software application shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications. Records of the results and conclusion of validation and necessary actions from the validation shall be maintained.

8 **MEASUREMENT, ANALYSIS, AND IMPROVEMENT**

8.1 General

The company plans and implements the monitoring, measurement, analysis, and

improvement processes needed to:

- Demonstrate conformity of the product
- Ensure conformity of the Quality Management System
- Maintain and continually improve the effectiveness of the product
- Maintain and continually improve the effectiveness of the QMS

8.2 Monitoring and Measuring

8.2.1 Feedback

As one of the measurements of the effectiveness of the quality management system, the company gathers and monitors information relating to whether the organization has met customer requirements. The methods for obtaining and using this information are documented. This feedback process includes provisions to gather data from production as well as post-production activities.

The information gathered in the feedback process serves as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.

If applicable regulatory requirements require us to gain specific experience from post-production activities, the review of this experience shall form part of the feedback process.

8.2.2 Complaint Handling

The company has implemented documented procedures for timely complaint handling in accordance with applicable regulatory requirements.

These procedures include at a minimum requirements and responsibilities for:

- Receiving and recording information
- Evaluating information to determine if the feedback constitutes a complaint
- Investigating Complaints
- Determining the need to report the information to the appropriate regulatory authorities
- Handling of complaint-related product
- Determining the need to initiate corrections or corrective actions

If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented.

If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved.

Complaint handling records are maintained.

8.2.3 Reporting to Regulatory Authorities

If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, we have documented procedures for providing notification to the appropriate regulatory authorities. Records of reporting to regulatory authorities are maintained.

8.2.4 Internal Audits

The company conducts internal audits at planned intervals to determine whether the quality management system:

The company has implemented a documented procedure to descript the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.

The audit program is planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval, and methods are defined and recorded.

The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors do not audit their own work.

Records of the audits and their results, including identification of the processes and areas audited and the conclusions, are maintained.

The management responsible for the area being audited ensures that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

8.2.5 Monitoring and Measurement of Processes

Documented procedures shall define the methods used for controlling the manufacturing processes and make reference to any applicable instructions utilized to define how work is conducted. Where required, these procedures are available at the workstation.

The effectiveness of these processes is evaluated based on their ability to produce products and/or services that are consistent with the Quality Policy and Quality Objectives. They will be evaluated during management review meetings.

8.2.6 Monitoring and Measurement of Product

Product shall be inspected and/or tested in order to verify that the specified requirements for the product are met. Required inspection and/or testing and the records to be established are detailed in the quality plan and/or documented procedures. In-process inspection and testing are performed as required by documented procedure.

Company procedures ensure that in-process inspection and testing are carried out, and defines the criteria for holding of products until these inspection and tests activities have been completed and necessary reports have been documented. All final testing is conducted in accordance with the quality plan or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

The quality plan or documented procedures require that:

- Product is held until all the required testing has been carried out and the results meet specified requirements
- Final inspection may include accumulation of in-process inspection results or specific final testing as appropriate
- Final inspection and testing includes the verification that all previous inspection and testing activities, including those specified at receipt of products or in-process, have been carried out with results meeting the specified requirements.

All inspection and testing is recorded and approved by the personnel performing the inspection and/or testing to provide evidence the product has been inspected and/or tested. The identity of the person authorizing release of product shall be recorded.

- These records show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria.
- As appropriate, these records identify the test equipment used to perform measurement activities.
- Traceability exists between the test records and the product tested.
- Where the product fails to pass any inspection and/or test, the procedure for control of nonconforming product shall apply.

8.3 Control of Nonconforming Product

8.3.1 General

Product that does not conform to specified requirements shall be identified and controlled to prevent its unintended use or delivery. The company has implemented a documented procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product.

The evaluation of nonconformity includes a determination of the need for an investigation and notification of any external party responsible for the nonconformity. Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation, and the rationale for decisions is maintained.

8.3.2 Actions in Response to Nonconforming Product Detected before Delivery

The company manages nonconforming product by one or more of the following ways:

- Taking action to eliminate the detected nonconformity
- Taking action to preclude its original intended use or application
- Authorizing it use, release, or acceptance under concession

The company ensures that nonconforming product is accepted by concession only if the justification is provided, approval is obtained, and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession are maintained.

8.3.3 Actions in Response to Nonconforming Product Detected after Delivery

When nonconforming product is detected after delivery or use has started, we take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taking are maintained.

The company has documented procedures for issuing advisory notices in accordance with applicable regulatory requirements. These procedures are capable of being put into effect at any time. Records of actions relating to the issuance of advisory notices shall be maintained.

8.3.4 Rework

The company completes rework in accordance with documented procedures that take into account the potential adverse effect of the rework on the product. These procedures shall undergo the same review and approval as the original procedure.

After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements. Records of rework are maintained.

8.4 Analysis of Data

Quality data are collected and analyzed to determine the effectiveness of the Quality Management system and to identify opportunities for improvement. Data relating to customer satisfaction, product conformity to requirements, supplier performance, process performance and product trends used to determine corrective and preventive actions, are reviewed during management review meetings and documented in the minutes. Trends in company level data are analyzed and compared to overall business goals and objectives. Key product and service features are included in the analysis and if deficiencies are noted, action is taken to correct them to ensure customer satisfaction.

8.5 Improvement

8.5.1 General

The company will identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy, and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, post-market

surveillance, analysis of date, corrective actions, preventive actions, and management review.

8.5.2 Corrective Actions

The company has established and maintains documented procedures to implement corrective actions to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered.

- Reviewing non-conformities (including complaints)
- Determining the cause of nonconformities
- Evaluating the need for action to ensure that nonconformities do not recur
- Planning and documenting action needed and implementing such action, including, as appropriate, updating documentation
- Verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device
- Reviewing the effectiveness of the preventive action taken, as appropriate

Records of the results of any investigation and of action taken are maintained.

8.5.3 Preventive Actions

The company has established and maintains documented procedures to implement preventive actions and eliminate the causes of potential nonconformities proportionate to the effects of the potential problems. This documented procedure includes: * Determining potential nonconformities and their causes * Evaluating the need for action to prevent occurrence of nonconformities * Planning and documenting action needed and implementing such action, including, as appropriate, updating documentation * Verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device * Reviewing the effectiveness of the preventive action taken, as appropriate

Records of the results of any investigations and of actions taken are maintained.

9. APPENDIX: REGULATORY REQUIREMENT REFERENCE

This appendix enumerates applicable regulatory requirements and provides a link for each to an applicable document in this Quality Management System.

ISO 13485:2016

Management Subsystem	QMS Document
Quality Management System/ Quality Manual / Quality Policy (4.1/4.2/5.3)	Quality Manual
Organizational Roles (4.1.1) * Quality Planning (5.4)	Quality Manual
Customer Focus/ Customer Satisfaction (5.2)	Quality Manual

Management Subsystem	QMS Document
Management Commitment/ Responsibility/ Authority/ Internal Communication (5.1/5.5)	Quality Manual
Provision of resources (6.1/6.2)	QP-0013
Management review/ Analysis of Data (5.6/8.4)	QP-0013

Documentation and Records Subsystem	QMS Document
Approval of documents and changes (4.2.4)	QP-0003
Control of documents of external origin (4.2.4)	QP-0003
Device Master Records (4.2.3)	QP-0003
Approval of labelling incl. translation process (4.2.4)	QP-0003 / QP-0006
Document distribution and linkage to the training process (4.2.4)	QP-0003 / QP-0006
Document and Records retention (4.2.1/ 4.2.5)	QP-0018

Human Resources(Source)	QMS Document
Competence evaluation and training (6.2/ 6.2)	QP-0004
Records of education, training, skills and experience (4.2.5)	QP-0004
Quality System, MDR (6.2)	QP-0004

Risk Management(Source)	QMS Document
Risk Management (7.1/ MDR)	QP-0017

Purchasing Controls Subsystem	QMS Document
Supplier evaluation and selection (7.4.1)	QP-0023
Supplier controls and monitoring (7.4.1)	QP-0023
Verification of purchased products- process (7.4.3)	QP-0005
Specifications (adequacy) for products and services (7.4.2)	QP-0005

Design and Development Subsystem	QMS Document
Design and Development Planning (7.3.2)	QP-0002
Design and Development Inputs (7.3.3)	QP-0002
Design and Development Outputs (7.3.4)	QP-0002
Design and Development Review (7.3.5)	QP-0002
Design and Development Verification (7.3.6)	QP-0002

Design and Development Subsystem	QMS Document
Design and Development Validation (7.3.7)	QP-0002
Design and Development Transfer (7.3.8)	QP-0002
Control of Design and Development Changes (7.3.9)	QP-0002 QP-0009
Design and Development Files (7.3.10)	QP-0002

Production & Process Controls Subsystem	QMS Document
Process to control nonconforming products (8.3)	QP-0008
MRB- review, investigation and disposition of nonconforming products (8.3/8.5.2).	QP-0008
Nonconforming products in distribution- internal company vs. customer controlled (8.3/8.5.2)	QP-0008
Receiving Inspection (7.4.3, 8.3)	QP-0005
Requirements for products and materials	QP-QP-0005
Acceptance activities, status and records	QP-0005
Handling of materials (6.3, 7.5.11)	QP-0016
Warehousing (6.3/ 6.4)	QP-0022
Control of production (7.5.1)	"Run Books"
Product/ material identification and traceability (7.5.8)	QP-0007
Process control and monitoring (7.5)	QP-0013
monitoring and control of process parameters (8.2.5)	QP-0013
approval of processes and process equipment (7.5.6):	QP-00133
Handling of products (7.5.11)	QP-0016
In-process and finished device testing/acceptance status (7.5.8/ 8.2.6)	"Run Books"
Labeling and packaging operations (7.5.1)	QP-0006
Device History Records- review (4.2.4)	QP-0007
Handling of customer property (7.5.10)	QP-0019
Calibration System- monitoring and measuring equipment (7.6)	QP-0004
Preventive Maintenance program (6.3)	QP-0014
Equipment qualification/ validation and process validation incl. software validation (7.5.6)	QP-0026

Outsourcing / Planning of Product Realization	QMS Document
Identification and control of Outsourced processes (4.1/ 7.4.1)	QP-0023
Notification of changes to Notified Body/ Health Canada (4.1, 7.2.1/ 7.3.7)	QP-0028 / QP-0029

Customer Related Processes	QMS Document
Contract Review (7.2.1/7.2.2/7.2.3)	Run Books

CAPA Subsystem	QMS Document
Experience from post-production phase/ Customer communication/ Feedback (7.2.3/8.2.1)	QP-0011
CAPA- corrective/ preventive actions, Distribution of Nonconforming Products (8.3/8.5.1-3)	QP-0012
EU Vigilance System incl. Advisory Notices (8.5.1)	QP-0011
Mandatory Problem Reporting/ Recall (8.5.1)	QP-0021
Analysis of data- Monitoring & Measurement of Processes/ Statistical Techniques (8.4/8.2.3)	QP-0013

Internal Audits & Improvement	QMS Document
Audit program incl. ISO 13485, CMDR, MDR, other requirements (8.2.4)	QP-0015
Process, documentation, linkage to CAPA (8.2.4/8.5.2)	QP-0015

FDA CFR 21 Part 820 – Quality System Regulation

Subpart A – General Provisions

Requirement	Document ID
Scope (820.1)	Quality Manual QM-0001
Definitions (820.3)	Quality Manual QM-0001
Quality System (820.5)	Quality Manual QM-0001

Subpart B – Quality System Requirements

Requirement	Document ID
Management Responsibility (820.20)	QP-0013 / Quality Manual QM-0001
Quality Audit (820.22)	QP-0015
Personnel (820.25)	QP-0004

Subpart C – Design Controls

Requirement	Document ID
Design Controls (820.30)	QP-0002

Subpart D – Document Controls

Requirement	Document ID
Document Controls (820.40)	QP-0003

Subpart E – Purchasing Controls

Requirement	Document ID
Purchasing Controls (820.50)	QP-0005

Subpart F – Identification and Traceability

Requirement	Document ID
Identification (820.60)	QP-0007
Traceability (820.65)	QP-0007

Subpart G – Production and Process Controls

Requirement	Document ID
Production and Process Controls (820.70)	Run Books
Inspection, Measuring, and Test Equipment (820.72)	QP-0014
Process Validation (820.75)	QP-0026

Subpart H – Acceptance Activities

Requirement	Document ID
Receiving, In-Process, and Finished Device Acceptance (820.80)	QP-0005
Acceptance Status (820.86)	Run Books

Subpart I – Nonconforming Product

Requirement	Document ID
Nonconforming Product (820.90)	QP-0008

Subpart J – Corrective and Preventive Action

Requirement	Document ID
Corrective and Preventive Action (820.100)	QP-0012

Subpart K – Labeling and Packaging Control

Requirement	Document ID
Device Labeling (820.120)	QP-0006
Device Packaging (820.130)	QP-0006

Subpart L – Handling, Storage, Distribution, and Installation

Requirement	Document ID
Handling (820.140)	QP-0016
Storage (820.150)	QP-0016
Distribution (820.160)	Run Books
Installation (820.170)	Run Books

Subpart M – Records

Requirement	Document ID
General Requirements (820.180)	QP-0018
Device Master Record (820.181)	DMRs
Device History Record (820.184)	QP-0007
Quality System Record (820.186)	QP-0018
Complaint Files (820.198)	QP-0011

Subpart N – Servicing

Requirement	Document ID
Servicing (820.200)	Run Books & WI

Subpart O – Statistical Techniques

Requirement	Document ID
Statistical Techniques	QP-0013

FDA CFR 21 Other Applicable Regulations

Part 11 – Electronic Records; Electronic Signatures

Requirement	Document ID
General Provisions	Run Books
Electronic Records	Run Books
Electronic Signatures	Run Books

Part 801 – Labeling

Requirement	Document ID
General Labeling Provisions	QP-0006
Labeling Requirements for Unique Device Identification	QP-0006
Labeling Requirements for Over-the-Counter Devices	QP-0006
Exemptions from Adequate Directions for Use	QP-0006
Special Requirements for Specific Devices	QP-0006

Part 803 – Medical Device Reporting

Requirement	Document ID
General Provisions	QP-0021
Generally Applicable Requirements for Individual Adverse Event Reports	QP-0021
User Facility Reporting Requirements	QP-0021
Manufacturer Reporting Requirements	QP-0021

Part 830 – Unique Device Identification

Requirement	Document ID
Requirement for a Unique Device Identifier	QP-0025
FDA Accreditation of an Issuing Agency	QP-0025
FDA as an Issuing Agency	QP-0025
Global Unique Device Identification Database	QP-0025

EU MDR Medical Device Regulation

Requirement	Document ID
EU Authorized Representative	QP-0028
Safety and Performance Requirements (Annex I)	QP-0002 / QP-0027
Information supplied by manufacturer (Annex I)	QP-0006
Unique Device Identification (Article 27 & 28)	QP-0025
Information and notification of post-production incidents (Chapter VII)	QP-0010/QP-0024
Clinical Evaluation and Post Market Surveillance (Chapter 27)	QP-0024/QP-0027

Canadian Medical Device Regulations

Requirement	Document ID
Review of Canadian Device Licenses/ Amendments	QP-0029
Safety and Effectiveness Requirements	QP-0002
Labeling Requirements	QP-0006

10. APPENDIX: Quality System Quick Access Facility

This appendix enumerates each of the Quality Procedures used to operate Medical Data Networks, LLC so as to deliver quality products that align with applicable rules and regulations. The state of the approval for each such document is provided.

Quality System Procedures

Document ID	**Procedure**	**Record-Keeping Template(s)**	**Implementation Status**
QP-0001 R1 (this document)	Quality Manual Update Process	N/A	Approved 9/1/2021
QP-0002 R1	Design Control Process	QF-0002 Design_Control_Records	Approved 9/1/2021
QP-0003 R1	Document Control Process	N/A	Approved 9/1/2021
QP-0004 R1	Training and Competency Process	QF-0004 Training and Competency Records	Approved 9/1/2021

Document ID	Procedure	Record-Keeping Template(s)	Implementation Status
QP-0005 R1	Purchasing and Receiving Process	QF-0005 Purchasing Controls	N/A
QP-0006 R1	Labeling and packaging Control	N/A	N/A
QP-0007 R1	Traceability Records	Not defined yet	N/A
QP-0008 R1	Nonconforming Product process	QF-0008 Non Conforming Product	Not defined yet
QP-0009 R1	Change Control Process	N/A	Approved 9/1/2021
QP-0010 R1	Software Validation Process	N/A	Approved 9/1/2021
QP-0011 R1	Customer Complaint Handling Procedure	QF-0011 Customer Complaints	Approved 9/1/2021
QP-0012 R1	Corrective and Preventive Action	QF-0012 CAPA Forms	Approved 9/1/2021
QP-0013 R1	Management Review and Data Analysis Process	QF-0013 Management Review	Not defined yet
QP-0014 R1	Calibration and Preventive Maintenance Process	QF-0014 Calibration and Preventive Maintenance Process	Not defined yet
QP-0015 R1	Quality Audit Process	QF-0015 Internal Audit Records	Not defined yet
QP-0016 R1	Preservation of Product Process	N/A	Approved 9/1/2021
QP-0017 R1	Risk Management Process	N/A	Approved 9/1/2021
QP-0018 R1	Record Management Process	N/A	Approved 9/1/2021
QP-0019 R1	Customer Property Control Process	N/A	Not defined yet

Document ID	Procedure	Record-Keeping Template(s)	Implementation Status
QP-0020 R1	FDA Audit Management Process	N/A	Not defined yet
QP-0021 R1	Medical Device Reporting and Recall Process	QF0021 Medical Device Reporting and Recall Records	Not defined yet
QP-0022 R1	Infrastructure and Work Environment	N/A	Not defined yet
QP-0023 R1	Supplier Management Process	Not defined yet	
QP-0024 R1	Post Market Surveillance Process	QF-0024 Post Market Surveillance	Not defined yet
QP-0025 R1	Unique Device Identification Process		Not defined yet
QP-0026 R1	Process Validation Procedure	N/A	Not defined yet
QP-0027 R1	Technical File Process	N/A	Not defined yet
QP-0028 R1	European Union Medical Device Directive Procedure		Not defined yet
QP-0029 R1	European_Union_Medical_Device_Regulation_Procedure		Not defined yet
QP-0030 R1	Canadian Medical Device Regulations Procedure	N/A	Not defined yet

12. REVISION HISTORY

This Quality Manual is subject to change. Major revisions are enumerated below.
The "latest" and only official version is found in the github document management system governs all QMS activity.

REV #	Doc ID	Effective Date	Description of Change
01	Quality Manual	12/17/2014	Initial Release of the Quality Manual