REI
Reliance Electronics Inc.

QUALITY MANAGEMENT SYSTEM

(REI-QMS)

RELIANCE ELECTRONICS INC
145 Shepherds Lane
Totowa, NJ 07512

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1. Organization:

Reliance Electronics, Inc. (Reliance) has been in New Jersey under current management since 1998. This is the only Reliance manufacturing site.

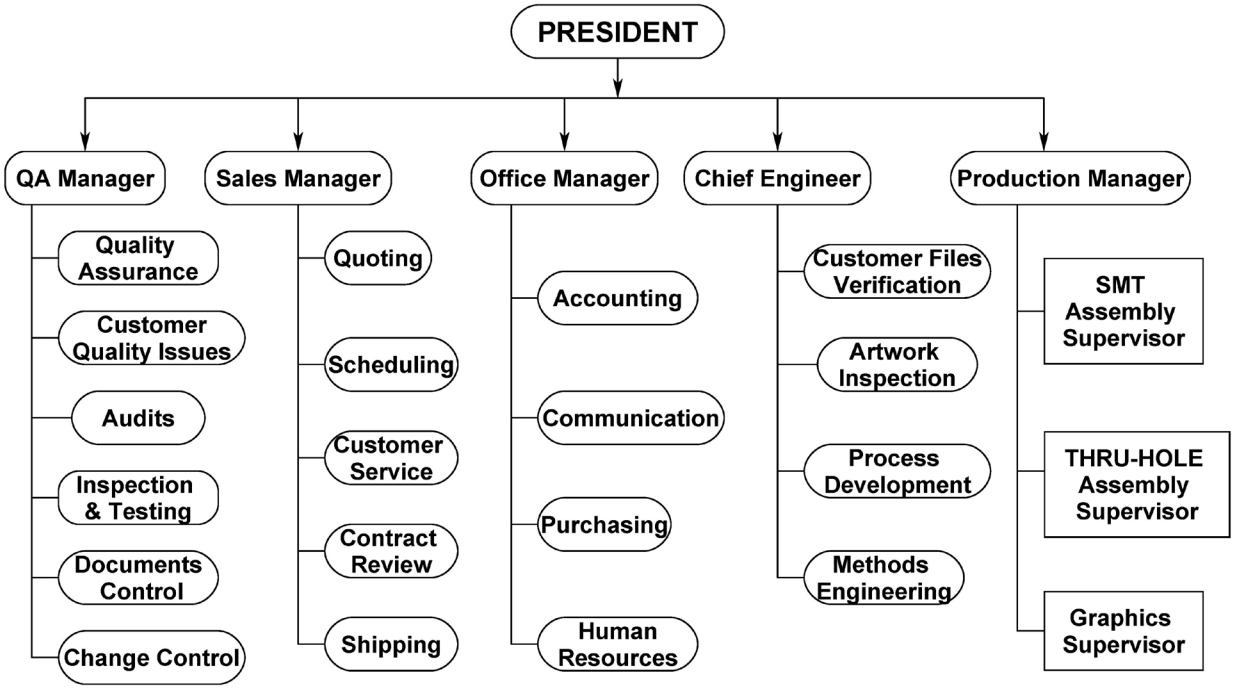
RELIANCE has developed and implemented a Quality Management System (QMS), which uses ISO 13485:2016 as a framework that allows our organization to document and improve our practices to better satisfy the needs and expectations of our customers, stakeholders and interested parties. Even though this Quality Manual follows all pertinent clauses of ISO 13485.2016, it also covers most of the clauses of standard ISO 9001:2015 as shown in paragraph 10 of this document. This quality Manual is also sometimes referred as Quality Business Management System (QBMS).

This manual describes the quality management system, assigns the authorities, inter relationships and responsibilities of personnel operating within the management system. The manual also provides references to procedures and activities that also comprise our quality management system.

The manual is used to familiarize customers and other external Organizations or individuals with the controls that have been implemented and to assure them that the integrity of our quality management system is maintained and is focused on customer satisfaction and continual improvement.

1.1 Organization Chart of Reliance is as follows.

Reliance Organization Chart



2. SCOPE: Reliance is in the business of providing Electronic Contract Manufacturing services that include Assembly of Printed Circuit Boards, and manufacturing of Membrane Switches.

The following are excluded or are not applicable to the scope. This Exclusion of clause or not applicable clauses do not affect the organization's ability to address customer requirements and appropriate legal and regulatory requirements.

2.1 : Exclusion of Clause: Reliance does not do any design and development work for any medical device and hence has excluded entire clause **Design and Development (7.3).**

2.2 Not Applicable Clauses:

2.2.1 Installation Activities (7.5.3): Reliance does not manufacture any complete medical device and also does not install any medical device anywhere and hence Installation activities are excluded from REI QMS scope.

2.2.2 Servicing Activities (7.5.4): Reliance does not manufacture any complete medical device and does not provide any kind of medical device servicing activities and hence Servicing Activities are excluded from REI QMS scope.

2.2.3 Particular requirements for sterile medical devices (7.5.5): Reliance does not manufacture any kind of medical device including sterile medical devices and hence requirements for sterile medical devices are excluded from REI QMS scope.

2.2.4 Particular requirements for validation of processes for sterilization and sterile barrier systems (7.5.7): Reliance does not manufacture any complete medical device and does not have any process that requires sterilization or sterile barrier system and hence requirements for validation of processes for sterilization and sterile barrier systems are excluded form REI QMS scope.

2.2.5 Particular requirements for implantable medical devices, (7.5.9.2): Reliance does not manufacture or distribute any kind of implantable medical device and hence requirements for implantable medical device are excluded from REI QMS scope.

2.2.6 Medical Device File: (4.2.3): Reliance does manufacture components for medical devices but does not manufacture any finished Medical Device and hence Medical Device File requirement is excluded.

2.2.7 Software Validation (applicable paragraph of clause 7.5.6): Reliance does not make any Medical Devices and does not use any custom-made software used in any other medical devices and hence this requirement is excluded.

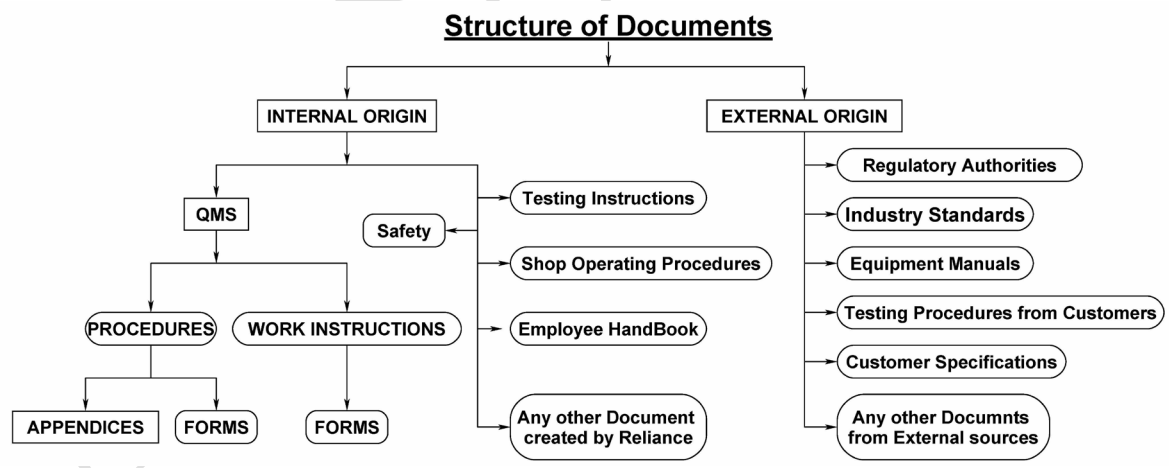
3 Terms and Definitions:

For this Quality Manual, the terms and definitions provided in standards ISO 13485:2016 and ISO 9000 2015 shall apply.

4. Quality Management System

4.1 General Requirements:

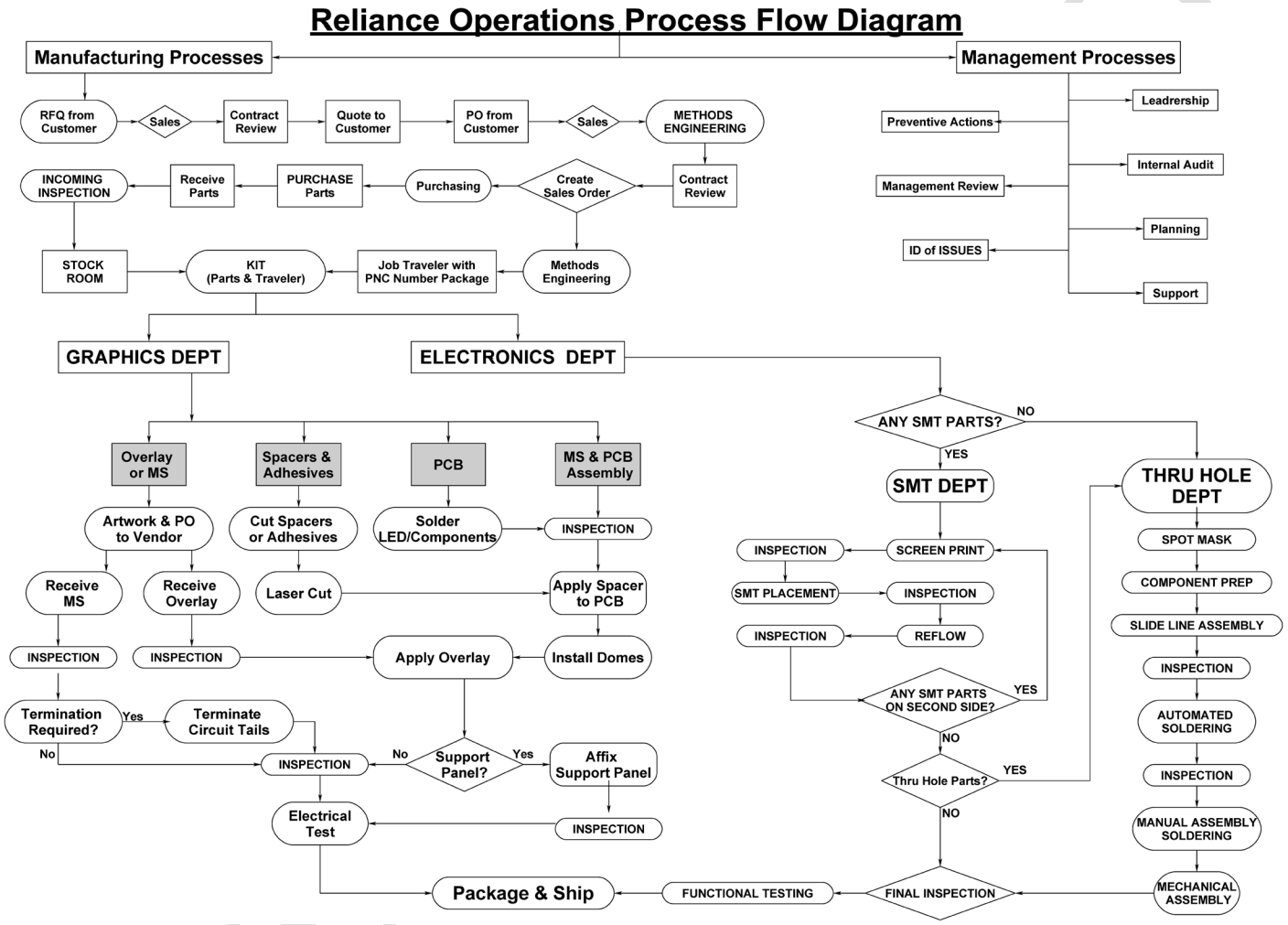
4.1.1 Documented System: RELIANCE has documented Quality Business Management System (QBMS). The structure of all documents is shown in the chart below.



4.1.2 Processes and their interactions:

- RELIANCE shall determine the processes needed for the quality management system and the application of these processes throughout the organization, considering the roles undertaken by the organization.
- RELIANCE shall apply a risk-based approach to the control of the appropriate processes needed for the quality management system.
- Reliance shall analyze and understand and address issues of concerns raised by interested parties to its QMS.

4.1.3 Reliance Operations Process Flow Diagram: RELIANCE shall determine the sequence and interaction of these processes. The processes and their inactions are given in the following chart.



4.1.4 QMS Process: For each Quality Management system process, RELIANCE shall:

- Determine criteria and methods needed to ensure execution and effective management of processes according to Matrix of Key Performance Indicators
- Ensure the availability of resources and information necessary to support the operation and monitoring of these processes as described in chapter 6 of this Quality Manual
- Implement actions necessary to achieve planned results and maintain the effectiveness of these processes.
- Monitor, measure as appropriate, and analyze the process performances, as described in chapter 8 of this Quality Manual.
- Apply actions necessary for achieving planned results and continual improvement of processes, as described in chapter 8 of this Quality Manual

4.1.5 Changes: RELIANCE shall manage these quality management system processes in accordance with the requirements of ISO 13485:2016, ISO 9001:2015 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 products produced under this quality management system.
- Controlled in accordance with the requirements of ISO 13485:2016 and applicable regulatory requirements.
- Changes are made as per Procedure **PR16-ECN**, Engineering Change Notice.

4.1.6 Outsourcing: RELIANCE has very little outsourcing. If outsourcing is needed, RELIANCE shall monitor and ensure control over such processes by ensuring that incoming material is as per applicable specifications. Additionally, RELIANCE shall retain responsibility of conformity to ISO 13485:2016 for outsourced processes. Controls shall be proportionate to the risk involved and the ability of the external party to meet requirements. Control of outsourcing processes is executed according to Procedure for Purchasing and Evaluation of Suppliers

4.1.7 Software Validation: RELIANCE uses only common so-called "off the shelf" software such as OFFICE, AutoCAD etc. and does not use any proprietary or industry standard computer software for implementing the Quality Management System. Hence it does not need to validate any computer software.

4.2 Documentation Requirements

4.2.1 General

Reliance's QMS documentation includes:

- Documented Quality Policy and Objectives.
- Quality Manual
- Procedures
- Records
- Documents received from External sources.

A complete list of all documents is in Appendices 1 & 2 to the Procedure **PR01-DOC-RCD**, Procedure for Document & Record Control.

The structure of Documents: A graphical Chart of Structure of Document is shown in paragraph 4.1.1 of this document.

4.2.2 Quality Manual

The general description of the structure and way of functioning of the quality management system at Reliance is given in this Quality Manual. The detailed description is given in Procedures and Work Instructions listed in paragraph 9 of this document.

A person, either a Reliance Employee or any outside expert consultant, appointed by QA Manager creates the Quality Manual, which is approved by the Quality Manager. The Quality Manual is periodically reviewed by any Internal Auditor at least once a year.

The pdf copy of the Quality Manual is given to the customers, certification bodies or third parties with approval of QA Manager as an UNCONTROLLED COPY. A pdf copy is also available on Reliance's website for downloading. All pdf copies have a water mark **UNCONTROLLED COPY**. The original Quality Manual is stored in the Company's server computer.

4.2.3 Medical Device File: Reliance does not manufacture any finished Medical Device but manufactures only components for medical devices and hence Medical Device File requirement is excluded.

4.2.4 Control of Documents:

Reliance controls records to provide evidence of conformance with requirements and about the functioning quality management system according to Procedure for Document and Record Control, **PR01-DOC-RCD.**

4.2.5 Control of Records Reliance controls records to provide evidence of conformance with requirements and about the functioning quality management system according to Procedure for Document and Record Control, **PR01-DOC-RCD.**

5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

5.1.1 Reliance's senior management demonstrates its commitment to the development and application of the quality management system and continual improvement of its effectiveness by:

- Informing employees of Reliance about the importance of meeting customer requests and legal and regulatory requirements through internal meetings, direct communication, and communicating the Quality Policy
- Establishing quality objectives at management review meetings and plans for their achievement.
- Providing necessary resources, as described in chapter 6 of the Quality Manual

5.2 Customer Focus

RELIANCE views its product and service quality as being defined by its customers. RELIANCE works closely with its customers to understand their businesses and their expectations. This close working relationship helps RELIANCE better meet its customers' expectations today and to anticipate and meet their needs in the future.

The RELIANCE Business Management Team ensures that not only are customer requirements and applicable regulatory requirements understood, but they are determined and met with the aim of enhancing customer satisfaction.

Customer requirements are determined and met by complying with clause 7.2 and clause 8.2.1 of this Quality Manual**.**

5.3 Quality Policy

Reliance Quality Policy is:

"Reliance is committed to meeting Customer Expectations and meeting Quality Objectives."

The RELIANCE Business Management Team ensures that the quality policy is communicated to all employees. It is included in the employee training on the QMS. It is posted throughout the facility to maintain high standards within the organization. The management ensures that this policy is (1) appropriate to the purpose of the organization, (2) it includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system, (3)) provides a framework for establishing and reviewing quality objectives, (4) is communicated and understood within the organization, and (5) is reviewed for continuing suitability.

Since Reliance's paramount focus is meeting Customer Expectation, this Quality Policy is appropriate to the purpose and context of the company and supports its strategic direction.

Periodically Reliance convenes a general meeting of all employees to explain the company Quality Policy and its effect on their employment.

5.4 Planning

5.4.1 Quality Objectives:

RELIANCE Business Management Team ensures that quality objectives are established to support the organization's commitment and efforts in achieving our quality policy and reviewed semi-annually for suitability. Reliance follows normal industry standards for quality Objectives which can be reviewed and modified in Quarterly Management Meeting.

No	Quality Objective	Industry Standard	Reliance's Goals
1	Rejection Rate	Less than 1%	Reliance's Goals are set in Management meetings. Reliance's performance is reviewed in subsequent Management meeting
2	Late Deliveries	5% Maximum	
3	First Pass Yield	More than 95%	
4	Customer Complaints	Less than 5%	
5	Supplier Performance	95%	
6	Non-Conformities from Audits	5% Maximum	
7	RFQ Capture Ratio	25%	
8	Sales Trend (Growth in Sales)	5% Annualized	

These quality objectives are measurable and consistent with the quality policy.

Reliance retains documented information on the status of our quality objectives on a quarterly basis in the form **PR14-DATA**.

This filed up form is presented in the Quarterly Management meeting. The results of evaluations are discussed and appropriate Correction Actions, if required, are taken. If shortfalls are identified, management may revise objectives, issue corrective action requests, or take other appropriate actions to address the issue.

5.4.2 Quality Management System Planning

Regularly performed management review is the basic means of planning the QMS. Special attention is paid to those planning processes necessary for the functioning of the QMS, provision of resources and improvement of the overall performance of the system.

5.5 Responsibility, Authority and Communication:

5.5.1 Responsibility and Authority

The RELIANCE Business Management Team ensures that responsibilities are defined, documented, and communicated within the organization.

The RELIANCE Business Management Team documents the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.

An organizational chart has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of key positions. Quality System SOPs, job descriptions and the organizational chart are reviewed and approved by Management. The RELIANCE Organizational Chart is shown on page 1 of this document.

5.5.2 Management Representative

The RELIANCE President has appointed the Quality Assurance Manager as the management representative. As management representative, irrespective of other responsibilities, he or she has the following responsibilities and authority that includes:

- Establishing, maintaining and improving of the QMS by monitoring the execution of corrective and preventive measures, and continual monitoring of system performance, nonconformities and possibilities for improvement
- Raising awareness of employees about the importance of meeting customer requests by informing them about their influence on customer satisfaction and realization of the objectives of the organization
- External communication related to issues regarding the quality management system.

5.5.3 Internal Communication

RELIANCE has documented procedures for communication among various parties associated with Reliance's Quality management system. Communication is conducted by many methods, including but not limited to e-mails, phones, Meetings, and bulletin boards.

5.6 Management Review

RELIANCE has documented procedure for Management Review **PR15-MAN-RVW**. The Management Reviews are conducted every quarter of the year and hence are called Quarterly Management Meetings. This review assesses the opportunities for improvement and ensures its continuing suitability, adequacy, and effectiveness.

6. RESOURCE MANAGEMENT

Reliance is fully committed to providing adequate resources required for the establishment, implementation, maintenance, and continual improvement of its QMS. These resources include competent employees, state-of-the-art industry equipment, well maintained work environment and financial resources. Planning and Review of Resources is normally done in Quarterly Management Review Meeting. But any senior employee, if needs arise, can request the president any time for needed resources.

6.1 Provision of Resources

The president working with the top-level Reliance Employees reviews resource needs, as needed. This team determines and provides the resources needed to maintain the quality management system and continually improve its effectiveness, and to enhance customer satisfaction by meeting customer requirements.

6.2 Human Resources

During the planning and reviewing of resources in Quarterly Management Review Meeting, the attendees determine needs for additional staff and their competence, education, skills, and experience according to Procedure for Human Resources. All activities related to Human Resources are described in detail in **PR02-HR**, Procedures for Human Resources.

6.3 Infrastructure

RELIANCE documents the requirements for the infrastructure needed to achieve conformity to product requirements, preventing product mix-ups and ensuring orderly handling of the product.

Infrastructure includes, as appropriate:

- buildings, workspace, and associated utilities,
- process equipment (both hardware and software) and
- supporting services (such as transport, communication, or information systems)

By conducting documented activities, Reliance provides constant availability and reliability of equipment according to Procedure for Infrastructure and Work Environment, **PR03-INF-ENV** and Procedure for Equipment Maintenance and Measuring Equipment **PR11-MAINT**.

6.4 Work Environment and Contamination Control

The RELIANCE Business Management Team ensures that the working environment and contamination control meets the requirements of process, product, and laws and regulations according to Procedure for Infrastructure and Work Environment

Reliance maintains a suitable work environment for each department to achieve quality product. The management considers human and physical comfort factors such as heating, air conditioning, ventilation, cleanliness, noise levels, safety procedures, and material handling methods. Each employee is encouraged to suggest improvement in the work environment. These suggestions are discussed in Quarterly Management Review Meetings.

As appropriate, RELIANCE shall plan special arrangements for the control of contaminated or potentially contaminated products to prevent contamination of work environment, personnel, or product.

RELIANCE does not manufacture sterile medical devices.

7 PRODUCT REALIZATION

7.1 Planning of Realization Processes

The RELIANCE Management Team is responsible for planning and developing processes needed for product realization according to Procedure for Production and Service Provision **PR08-PR** and the Procedure for Risk Management **PR04-RISK**.

7.2 Customer-related Processes Requirements for Products and Services: Requirements for products and services are managed by Methods Engineering and Sales department.

The sales manager and the Methods Engineers are responsible for determining and reviewing requests for products and communication with customers according to Procedure for Sales **PR05-SALES** and Procedure for Customer Complaints & Feedback **PR06-CC-FB**.

7.3 Design and Development

Reliance does not perform any kind of design activity or perform any medical device related Development and hence has taken Exclusion of this requirement (entire **clause 7.3**) in our QMS scope.

7.4 Purchasing:

By documenting an adequate method for evaluation and selection of suppliers, Reliance ensures that the delivered product is compliant with specified purchasing requests according to Procedure for Purchasing and Evaluation of Suppliers **PR07-PUR-AS.**

7.5 Production and Service Provision:

7.5.1 Control of Production and Service Provision

Reliance plans, carries out, monitors, and controls production operations to ensure that the product conforms to specification as per Procedure for Production Provision **PR08-PR**. Reliance does not carry out any Service activity. The production process is described in detail in procedure **PR08-PR**.

7.5.2 Cleanliness of product and contamination Control

Reliance's products are used as non-sterile products. Reliance has established documented requirements for cleanliness or contamination control according to Procedure for Production Provision **PR08-PR**.

7.5.3 Installation Activities: Reliance does not manufacture any complete medical device and also does not install any medical device anywhere and hence Installation activities are excluded from REI QMS scope.

7.5.4 Servicing Activities: Reliance does not manufacture any complete medical device and also does not provide any kind of medical device servicing activities and hence Servicing Activities are excluded from REI QMS scope.

7.5.5 Particular requirements for sterile medical devices: Reliance manufactures components for medical devices and does not manufacture any complete medical device. There is no requirement for sterilization of components manufactured by Reliance and hence requirements for sterile medical device are excluded from REI QMS scope.

7.5.6 Validation of processes for production and service provision

Reliance does not provide any Service activity, so it validates only processes for production provision. This is done as per Procedure for Production Provision **PR08-PR**.

Software Validation (applicable paragraph of clause 7.5.6): Reliance does not make any Medical Devices and also does not use any custom-made software used in any other medical devices and hence this requirement is excluded.

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

Reliance does not manufacture any complete medical device and does not have any process that requires sterilization or sterile barrier system and hence requirements for validation of processes for sterilization and sterile barrier systems are excluded form REI QMS scope.

7.5.8 Identification: The process of identification of the product manufactured at every step, from raw material to finished product shipped to the customer is done according to Procedure for Production Provision **PR08-PR**.

7.5.9 Traceability: The process of traceability allowing for complete and up-to-date histories of all batches of products from the starting materials to the complete final product at Reliance is done as per the Procedure for Production Provision **PR08-PR**.

Particular requirements for implantable medical devices, (7.5.9.2): Reliance does not manufacture or distribute any kind of implantable medical device and hence requirements for implantable medical device are excluded form REI QMS scope.

7.5.10 Customer Property

Care will be exercised while customer property is under control or being used by Reliance. Reliance will identify, verify, protect, and safeguard customer property provided for use or incorporation into the product (when applicable) while it is under Reliance's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, it will be reported to the customer in accordance with Procedure for Production Provision **PR08-PR**

7.5.11 Preservation of Product

Reliance preserves product conformity during processing, storage, handling, and shipping as per procedure for Production Provision **PR08-PR.**

7.6 Control of Monitoring and Measuring Equipment

Reliance identifies processes where measurements are conducted to demonstrate quality of processes or products. Based on needs for controlling and testing of product, Reliance identifies necessary measuring equipment according to Procedure for Equipment Maintenance and Measuring Equipment, **PR11-MAINT**.

8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

Reliance has controls at all stages to demonstrate the conformity of both the product and the Quality Management System (QMS), and to continually improve the QMS.

Reliance is responsible to identify activities requiring control through statistical techniques.

Documented procedures are maintained to apply statistical techniques for the control, verification, and continuous improvement of process activities. Production performance, in-process inspection, and test results are recorded in electronic databases and tracked.

Individual employee performance is tracked and recorded as part of production performance.

8.2 Measurement and Monitoring: Monitoring and measurements are conducted for various quality objectives and other QMS related items. This information is gathered from various sources and placed into reports for management to understand and take appropriate action when necessary.

8.2.1 Customer Feedback

The sales manager gathers and monitors information relating to whether the organization has met customer requirements. All activities related to the sales process, feedback, the customer's requests for delivery of product and service are described in Procedure for Customer Complaints and Feedback, **PR06-CC-FB**.

8.2.2 Complaint Handling

Customer Complaints are handled as per Procedure for Customer Complaints and Feedback, **PR06-CC-FB**.

8.2.3 Reporting to Regulatory Authorities

Any issue that requires reporting to Regulatory authorities is implemented as per Procedures for Adverse Event Investigating and Reporting **PR10-ADVRS-EVNT**.

8.2.4 Internal Audit

Reliance conducts internal audits in planned intervals to demonstrate conformance and effectiveness of the Quality Management System according to Procedure for Internal Audit, **PR12-AUDIT**

8.2.5 Measurement and Monitoring of Processes

Effectiveness of product realization processes is monitored and measured through parameters for every identified Key objective described in paragraph 5.4.1. If Key Objectives are met, it is considered that product realization processes are working successfully as intended to work.

8.2.6 Monitoring and Measurement of Product

Product characteristics are measured and monitored throughout the manufacturing process, to ensure the product meets established requirements. Evidence of conformity with the acceptance criteria is maintained, and electronic records identify inspection and test activities according to Procedure for Production Provision, **PR08-PR.**

8.3 Control of Nonconforming Product

Reliance handles non-conforming products in a way that prevents its further use or delivery, according to Procedure for Control of Non-Conforming Product, **PR09-NCP**.

8.4 Analysis of Data

By systematic gathering, processing, and analyzing of data, Reliance evaluates the effectiveness of the organization related to defined plans and objectives and identifies areas for improvement defined in Procedure for Data Analysis, **PR14-DATA**.

8.5 Improvement

8.5.1 General

Reliance is committed to the continual improvement of the quality management system. This is accomplished through the use of the quality policy, quality objectives, analysis of quality data, audit results, corrective and preventive actions, and management reviews.

8.5.2 Corrective Action

Reliance has established a corrective action system to investigate and document the root cause and actions to correct internally and externally reported nonconformities. Corrective actions are assigned to a responsible individual and tracked by number and completion date according to Procedure for Corrective and Preventive Actions, **PR13-CAP**.

8.5.3 Preventive Action

Reliance has established a preventive action system to report, investigate and prevent potential nonconformities. The preventive action system emulates the corrective action system.

The preventive actions taken will be appropriate to the effects of the potential problems according to Procedure for Corrective and Preventive Actions, **PR13-CAP**.

9. List of Documents for QMS: Following is the list of all documents for Reliance's QMS.

GROUP	DOC. ID	DESCRIPTION
Quality Manual	**REI-QMS**	Quality Management System
Procedures	**PR01-DOC-RCD**	Documents & Records Control
	PR02-HR	Human Resources
	PR03-INF-ENV	Infrastructure and Work environment
	PR04-RISK	Risk Management
	PR05-SALES	Sales
	PR06-CC-FB	Customer Complaints and Feedback
	PR07-PUR-AS	Purchasing and Evaluation of Suppliers
	PR08-PR	Production Provision
	PR09-NCP	Control of Non-Conforming Products
	PR10-ADVRS-EVNT	Adverse Event Investigation and Reporting
	PR11-MAINT	Maintenance of production and Measuring Equipment
	PR12-AUDIT	Internal Audit
	PR13-CAP	Corrective and Preventive Actions
	PR14-DATA	Data Analysis
	PR15-MAN-RVW	Management Review
	PR16-ECN	Engineering Change Notice
	PR17-COMM	Communication
Work Instructions	**WIN01-METH**	Methods Engineering
	WIN02-INSP	Inspection
	WIN03-ESD	ESD Management
	WIN04-SMT	SMT Placement
	WIN05-TH-MAN	Thru Hole and Manual Assembly
	WIN06-MSW	Membrane Switches

10. Correspondence between ISO 9001:2015 and REI-QMS (This document): As mentioned in paragraph 1, this document was written to comply with requirements of the standard ISO13485:2016. However, it also covers all relevant clauses of standard ISO9001:2015 as shown in table below.

ISO9001:2015 Clauses		Corresponding Paragraphs of REI-QMS	
Clause	**Description**	**Paragraph**	**Description (if there is any)**
1	Scope	1	Scope
4	Context of the organization	4	Quality management system
4.1	Understanding the organization and its context	4.1	General requirements
4.2	Understanding the needs and expectations of interested parties	4.1	General requirements
4.3	Determining the scope of the quality management system	4.1	General requirements
4.4	Quality management system and its processes	4.1	General requirements
5	Leadership	5	Management responsibility
5.1	Leadership and commitment	5.1	Management commitment
5.1.1	General	5.1	Management commitment
5.1.2	Customer focus	5.2	Customer focus
5.2	Policy	5.3	Quality policy
5.2.1	Establishing the quality policy	5.3	Quality policy
5.2.2	Communicating the quality policy	5.3	Quality policy
5.3	Organizational roles, responsibilities and authorities	5.4.2	Quality management system planning
		5.5.1	Responsibility and authority
		5.5.2	Management representative
6	Planning	5.4.2	Quality management system planning
6.1	Actions to address risks and opportunities	5.4.2	Quality management system planning
		8.5.3	Preventive action
6.2	Quality objectives and planning to achieve them	5.4.1	Quality objectives
6.3	Planning of changes	5.4.2	Quality management system planning
7	Support	6	Resource management
7.1	Resources	6	Resource management
7.1.1	General	6.1	Provision of resources
7.1.2	People	6.2	Human resources
7.1.3	Infrastructure	6.3	Infrastructure
7.1.4	Environment for the operation of processes	6.4.1	Work environment
7.1.5	Monitoring and measuring resources	7.6	Control of monitoring and measuring equipment
7.1.5.1	General	7.6	Control of monitoring and measuring equipment
7.1.5.2	Measurement traceability	7.6	Control of monitoring and measuring equipment
7.1.6	Organizational knowledge	6.2	Human resources
7.2	Competence	6.2	Human resources
7.3	Awareness	6.2	Human resources
7.4	Communication	5.5.3	Internal communication
7.5	Documented information	4.2	Documentation requirements
7.5.1	General	4.2.1	General

ISO9001:2015 Clauses		Corresponding paragraphs of REI-QMS	
Clause	**Description**	**Paragraph**	**Description (if there is any)**
7.5.2	Creating and updating	4.2.4	Control of documents
		4.2.5	Control of records
7.5.3	Control of documented Information	4.2.3	Medical device file
		4.2.4	Control of documents
		4.2.5	Control of records
		7.3.10	Design and development files
8	Operation	7	Product realization
8.1	Operational planning and control	7.1	Planning of product realization
8.2	Requirements for products and services	7.2	Customer-related processes
8.2.1	Customer communication	7.2.3	Communication
8.2.2	Determining the requirements for products and services	7.2.1	Determination of requirements related to product
8.2.3	Review of the requirements for products and services	7.2.2	Review of requirements related to product
8.2.4	Changes to requirements for products and services	7.2.2	Review of requirements related to product
8.3	Design and development of products and services	7.3	Design and development
8.3.1	General	7.3.1	General
8.3.2	Design and development planning	7.3.2	Design and development planning
8.3.3	Design and development inputs	7.3.3	Design and development inputs
8.3.4	Design and development controls	7.3.5	Design and development review
		7.3.6	Design and development verification
		7.3.7	Design and development validation
		7.3.8	Design and development transfer
8.3.5	Design and development outputs	7.3.4	Design and development outputs
8.3.6	Design and development changes	7.3.9	Control of design and development changes
8.4	Control of externally provided processes, products and services	4.1	General requirements (see 4.1.5)
		7.4.1	Purchasing process
8.4.1	General	7.4.1	Purchasing process
8.4.2	Type and extent of control	4.1	General requirements (see 4.1.5)
		7.4.1	Purchasing process
		7.4.3	Verification of purchased product
8.4.3	Information for external providers	7.4.2	Purchasing information
		7.4.3	Verification of purchased product
8.5	Production and service provision	7.5	Production and service provision
8.5.1	Control of production and service provision	7.5.1	Control of production and service provision
		7.5.6	Validation of processes for production and service provision
8.5.2	Identification and traceability	7.5.8	Identification
		7.5.9	Traceability
8.5.3	Property belonging to customers or external providers	7.5.10	Customer property
8.5.4	Preservation	7.5.11	Preservation of product

ISO9001:2015 Clauses		Corresponding paragraphs of REI-QMS	
Clause	**Description**	**Paragraph**	**Description (if there is any)**
8.5.5	Post-delivery activities	7.5.1	Control of production and service provision
		7.5.3	Installation activities
		7.5.4	Servicing activities
		8.2.2	Complaint handling
		8.2.3	Reporting to regulatory authorities
		8.3.3	Actions in response to nonconforming product detected after delivery
8.5.6	Control of changes	7.3.9	Control of design and development changes
8.6	Release of products and services	7.4.3	Verification of purchased product
		8.2.6	Monitoring and measurement of product
8.7	Control of nonconforming outputs	8.3	Control of nonconforming product
9	Performance evaluation	8	Measurement, analysis and improvement
9.1	Monitoring, measurement, analysis and evaluation	8	Measurement, analysis and improvement
9.1.1	General	8.1	General
		8.2.5	Monitoring and measurement of processes
		8.2.6	Monitoring and measurement of product
9.1.2	Customer satisfaction	7.2.3	Communication
		8.2.1	Feedback
		8.2.2	Complaint handling
9.1.3	Analysis and evaluation	8.4	Analysis of data
9.2	Internal audit	8.2.4	Internal audit
9.3	Management review	5.6	Management review
9.3.1	General	5.6.1	General
9.3.2	Management review inputs	5.6.2	Review input
9.3.3	Management review outputs	5.6.3	Review output
10	Improvement	8.5	Improvement
10.1	General	8.5.1	General
10.2	Nonconformity and corrective action	8.3	Control of nonconforming product
		8.5.2	Corrective action
10.3	Continual improvement	5.6.1	General
		8.5	Improvement

11. REVISION LOG:

REV	DATE	DESCRIPTION OF CHANGE	*Written By*	*Reviewed By*	*Approved By*
0	3-12-18	Original Release	Yogesh Patel	Ramesh Joshi	Peter Patel
1	6-1-21	Revised entire document to incorporate requirements of ISO 13485:2016 standards	Yogesh Patel	Ramesh Joshi	Peter Patel
2	6-25-21	Revised to address concerns raised by External Auditor from Dekra in Stage 1 audit.	Yogesh Patel	Ramesh Joshi	Peter Patel
3	9-1-21	Incorporated comments made by external auditor from Dekra in stage 2 audit. Added new paragraph 10.	Yogesh Patel	Ramesh Joshi	Peter Patel
4	10-15-22	Revised paragraph 5.5.3. In paragraph 9, added procedure PR-17 Communication	Yogesh Patel	Darshan Kunjadiya	Peter Patel