NISSHA MEDICAL TECHNOLOGIES

Quality Management Systems Manual

NISSHA
MEDICAL TECHNOLOGIES

BUFFALO OPERATIONS - PROCEDURE

Title: **QUALITY MANUAL**		This	Replaces
	Number:	**1-42-01 Rev BL**	**1-42-01 Rev BK**
	Page:	**ii of 36**	**ii of 36**
	Date:	**10/02/23**	**09/16/22**
	Review Date:	**10/02/25**	**09/16/24**

Originator: **Juliana Scotto diCarlo**

Departments: **Quality Assurance / All Departments**

Application: **Nissha Medical Technologies**

PURPOSE:

To define the Nissha Medical Technologies Quality Management System; a system which integrates the operation and development of a quality system with the strategic business planning required to provide our customers with quality products at fair market price. The manual is supported by a document and data system which further defines operations and processes, all of which are in alignment with corporate objectives, and compliant to ISO 13485:2016, ISO 14971:2019, US FDA 21 CFR Part 820, FDA 21 CFR803, FDA 21 CFR806, FDA 21 CFR807, Canadian Medical Devices Regulation (SOR/98-282), *Medical Device Directive 93/42/EEC including Amendment 2007/47/EC and Council Directive 80/181/EEC (1), Australia Therapeutic Goods (Medical Devices) Regulations 2002, Brazilian Health Surveillance Agency (ANVISA) Resolution RDC 665/2022, Resolution RDC 551/2021, Resolution RDC 67 2009, and Japanese MHLW MO 169, Chapter 2.

*Nissha Medical Technologies devices are classified as Class 1 and Class 1M. Nissha Medical Technologies holds an MDD CE Certificate expiring in 2024 for all Class 1M products. In regards to European Medical Device Regulation (2017/745 MDR), Nissha is compliant as per Article 120(3).

DISTRIBUTION:

Copy 1 – NMT Intranet

Copy 2 – NMT Web Site

Revision	Release Date	Revised By	Description of Change
AA	30-May-2003	Mosley	Revise & Rewrite of Quality Manual
AB	22-Aug-2003	Mosley	Revise Corrective/Preventive Action
AC	20-May-2004	Mosley	Establish org as Graphic Controls
AD	27-Sep-2004	Mosley	Remove Navigator Process Flow & Replace Mission Statement
AE	17-Oct-2005	Mosley	Addition of "assembly of Ink Jet equipment" to the scope of business
AF	28-Aug-2006	Jablonicky	Revise Cover artwork, 4.2 provision for posting hard copy documents, 5.3.1 Org changes, 7.1 Measure and monitor update to metrics, 8.3 Internal audits each area min of 1X every 3years. Page II change originator

REVISION HISTORY

Revision	Release Date	Revised By	Description of Change
AG	12-Nov-2007	Lasota	5.3.1 Organizational changes. Page II Originator
AH	20-Feb-2008	Lasota	Revised 7.5.6 to point 7.6; changed descriptive information associated with the Calibration System
AI	28-Aug-2008	Lasota	Revised Organizational Chart 5.3.1
AJ	10-Feb-2009	Lasota	Numbering sequence correction section 5
AK	16-Jun-2009	Lasota	7.3 Design & Development Flow Change
AL	20-Oct-2009	Lasota	Change Purpose, 1.0, 2.0, 3.0 & 4.0 to reference ISO 9001:2008, Modify 5.4.1 Org Chart to include Mgmt Rep title – QA/HSE Mgr
AM	20-Jan-2010	Lasota	Updated Scope to include exclusions relative to ISO 13485
AN	28-Apr-2010	Lasota	Revised Cover Art, Updated to clearly align with ISO 9001:2008, ISO 13485:2003, MDD 93/42/EEC including Amendment 2007/47/EC and Council Directive 80/181/EEC (1)
AO	12-Apr-2011	Jablonicky	Change corporate name from Graphic Controls LLC to Graphic Controls, Reference 21CFR part 820, Redefine org chart with changes, Reference MDD Annex V in scope, Update mission statement to include medical devices. Change 8.2.2 audit frequency from 3yrs to 2yrs
AP	06-Jun-2012	Dugan	Update Org Chart, and titles
AQ	21 Mar 2013	Dugan	Updates – Organization Charts and FDA Listing
AR	05 April 2013	Dugan	Revise Cover, page templates, add GC web page to distribution list, page numbering.
AS	12-May-2014	Dugan	Organization Chart / Scope Add Customer Supplied Material
AT	27-Jan-2015	Dugan	Added Approved SH/ES/BH/JS 1.19.2015
AU	01-Jul-2015	Lasota	Added ISO 13485:2012, removed design/dev from scope of
AV	12-Aug-2015	Lasota	Industrial, eliminated redundant ref to Mission, Org Chart update. Change format, add design to scope, change 7.3, add sales feedback to surveillance. Update Navigator Chart.
AW	7-Jul-2016	Lasota	Update purpose to include EN ISO 13485:2012; Update org chart to current; Update objectives to remove credits % of sales; add PMs
AX	24-Apr-2017	Lasota	Update Mission, Brand, Values, Quality Policy to align with Nissha. Org chart update.
AY	25-May-2017	Lasota	Align with Canadian Medical Device Regulation (SOR/98-282)
AZ	16-Aug-2017	Lasota	Correct 1-Scope ISO 9001:2008 and ISO 13485:2003
BA	15-Sept-2017	Lasota	Add ECG Electrodes to scope of 13485
BB	3-Jan-2018	Talley	Update Org Chart & Remove Calibrated Equip from Intranet
BC	30-April-2018	Talley	Alignment with ISO13485:2016
BD	20-June-2018	Talley	Alignment with MDSAP requirements, Formatting Changes
BE	24-Aug-2018	Talley	Updates for MDSAP clarification
BF	26-Aug-2020	Potter	Rebranding to Nissha Medical Technologies, EU Rep Update, Org Chart
BG	16-Feb-2021	Potter	Update Org Chart, Management Rep
BH	1-Oct-2021	Potter	Updates for MDR
BI	7-Jan-2022	Scotto diCarlo	General updates to KPI's and Org Chart
BJ	17-June-2022	Potter	General updates to Org Chart
BK	19-Sept-2022	Scotto diCarlo	Update to Quality Policy and General Formatting / TOC
BL	02-Oct-2023	Scotto diCarlo	Update to Scope, Quality Objectives and addition of ISO Standards Table

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OUR MISSION, BRAND & SHARED VALUES

NISSHA MEDICAL TECHNOLOGIES

A tradition of excellence, A future of innovation.

At Nissha Medical Technologies we are a thriving and dynamic publicly held global organization. Our vision, mission and values are driven by continued growth and backed by an exciting and innovative entrepreneurial culture. With over 100 years of manufacturing expertise, we continue to lead the way across five distinct business units – Graphic Controls Data Recording, Graphic Controls Transactional Media, Nissha Medical Technologies: Medical Products, Design & Manufacturing and Private Labeled Products.

Our manufacturing sales and distribution operations span the US, Canada, UK, Europe, and the Dominican Republic.

MISSION

We are committed to pursuing a mutually trustful Co-existence with society through our business activities utilizing a unique technology development, based on Printing as a core.

BRAND

"Empowering Your Vision" expresses the relationship of Co-existence between Nissha and our stakeholders. Both we and our customers, shareholders, employees, suppliers, and society have visions, and we mutually affect each other toward realizing it. We maximize our capabilities driven by our technology, passion, and leadership, and with the energy infused in us by our stakeholders, together we create value for the future.

VALUES

Growth Based on Customer Satisfaction
We create new value for our customers and transform it into a driver of growth.

Commitment to Results
We set challenging goals for ourselves and deliver results.

Magnify Leadership
We exhibit leadership and resolve difficulties regardless of division or position.

Diverse Capabilities
We respect diversity that enhances our organizational capabilities and drives growth.

Sustainability Through Integrity
We value individual dignity and conduct fair business as a global corporate partner

INTRODUCTION

Nissha Medical Technologies top management has demonstrated commitment to the establishment of a Quality Management System, maintenance of its integrity and the provision of an environment conducive to the production of quality products and services.

The Nissha Medical Technologies Quality Manual documents management's commitment to the implementation and nurturing of a Quality Management System. All policy statements have been authorized by the CEO of Nissha Medical Technologies.

1- SCOPE

Standard: ISO 13485:2016
Scope of Registration: The QMS as it applies to the design, development, and manufacture a of medical recording charts, leadwires, ECG Electrode Families and design of Defibrillator Pads. Repacking & relabeling of tympanostomy tubes.
Not Applicable: 7.5.3 Installation, 7.5.4 Servicing, 7.5.5 Sterile Medical Devices, 7.5.9.2 Implantable Medical Devices

Standard: ISO 14971:2019 and BS EN ISO 14971:2019 + All: 2021
Scope of Registration: Application of risk management to medical devices.

FDA 21 CFR 803 – Medical Device Reporting
FDA 21CFR806 – Subchapter H--Medical Devices--Part 806 Medical Devices; Reports of Corrections and Removals
FDA 21 CFR 807 – Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices
FDA 21 CFR 820 – Quality System Regulation
Role: Manufacture and Distributor/Importer

Australia Therapeutic Goods (Medical Devices) Regulations 2002 Role: Manufacture
Brazilian Health Surveillance Agency (ANVISA) Federal Law 6360176 Resolution RDC 665 2022, Resolution RDC 552 2021, Resolution RDC 67 2009: RDC 56 2001 Role: Manufacture and Distributor
Canada Medical Devices Regulations (SOR/98-282) Role: Manufacture and Distributor/Importer
Japanese MHLW MO 169, Article 4 to Article 68, PMD Act (as applicable) Role: Manufacture
Basic Requirements Regarding Manufacturing Control and Quality Control of Medical Devices, etc.
***Medical Device Directive: 93/42/EEC including Amendment 2007/47/EC + Annex V** Role: Manufacture
Scope of CE Certification: Medical Device with a Measuring Function

Authorized Representative for Nissha Medical Technologies

*Nissha Medical Technologies devices are classified as Class 1 and Class 1M. Nissha Medical Technologies holds an MDD CE Certificate expiring in 2024 for all Class 1M products. In regards to European Medical Device Regulation (2017/745 MDR), Nissha is compliant as per Article 120(3). Class 1 self declared products fall under jurisdiction of applicable sections of (EU)MDR 2017/745

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2- NORMATIVE REFERENCE

The Nissha Medical Technologies Quality Manual defines our policies, procedures and business practices; all of which are aimed at the provision of high quality standards. It is published, distributed and maintained by the Quality Assurance Department.

The purpose of this manual is to describe a Quality System that meets and exceeds ISO 13485:2016, ISO 14971:2019, USFDA 21CFR Part 820, FDA 21 CFR803, FDA 21 CFR806, FDA 21 CFR807,Canadian Medical Device Regulation (SOR/98-282), *Medical Device Directive 93/42/EEC including Amendment 2007/47/EC, Council Directive 80/181/EEC (1), Australian Therapeutic Goods (Medical Devices) Regulations 2002, Brazilian Health Surveillance Agency (ANVISA), and Japanese MHLW MO 169, Chapter 2. Our policy statements reflect our commitment to continual improvement, prevention of nonconformity, and adherence to the Quality Management System.

3- TERMS AND DEFINITIONS

Nissha Medical Technologies has aligned its Quality Management System Manual to ISO 13485:2016, ISO 14971:2019, USFDA21 CFR Part 820, FDA 21 CFR803, FDA 21 CFR806, FDA 21 CFR807,Canadian Medical Device Regulation (SOR/98-282), *Medical Device Directive 93/42/EEC including Amendment 2007/47/EC, Council Directive 80/81/EEC (1), Australian Therapeutic Goods (Medical Devices) Regulations 2002, Brazilian Health Surveillance Agency (ANVISA), and Japanese MHLW MO 169, Chapter 2 guidelines. All terms used within our documentation and data are reflective of those defined within the ISO Standards, FDA Quality Systems Regulations, *Medical Device Directive, Council Directive and all other applicable regulations.

4- QUALITY MANAGEMENT SYSTEM

The Nissha Medical Technologies Quality Management System has been established, implemented and is maintained to ensure that our products and services conform to all customer-specified, safety, statutory and applicable regulatory requirements.

4.1 - ESTABLISHMENT AND MAINTENANCE OF OUR QUALITY MANAGEMENT SYSTEM

The Quality Management System framework is comprised of controlled inter-related processes, trained personnel, documented policies and procedures, and the delivery of quality products and services. Our change control processes are in place to ensure process changes are evaluated, monitored, measured and analyzed for effectiveness and impact on medical devices and the Quality Management System.

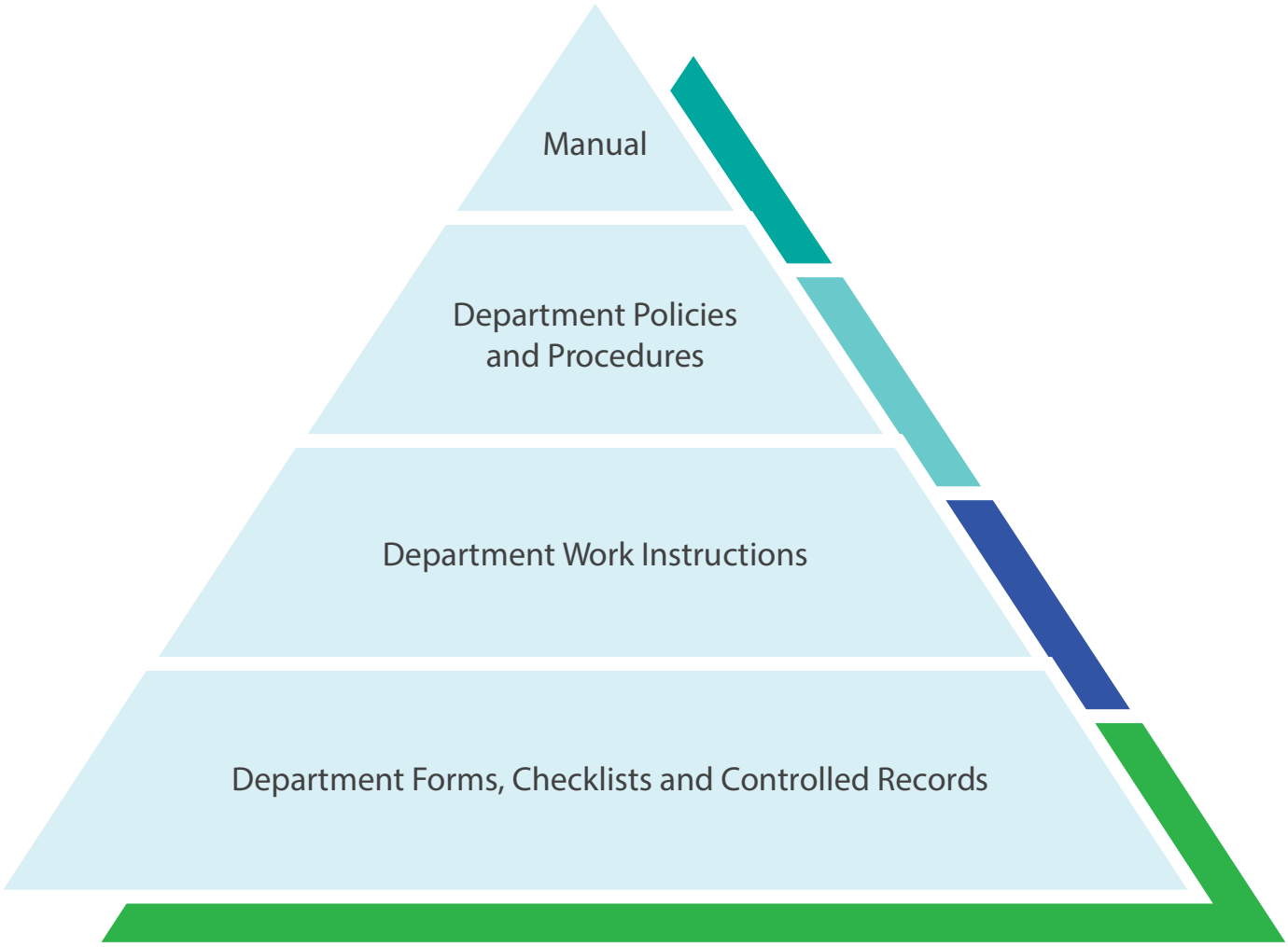
4.2 - OUR CORPORATE QUALITY MANAGEMENT SYSTEM AND DOCUMENTATION

Documented corporate policies and procedures link ISO 13485:2016, ISO 14971:2019, USFDA 21CFR Part 820, FDA 21 CFR803, FDA 21 CFR806, FDA 21 CFR807,Canadian Medical Device Regulation (SOR/98-282), *Medical Device

Directive 93/42/EEC, (EU)MDR 2017/745, Australian Therapeutic Goods (Medical Devices) Regulations 2002, Brazilian Health Surveillance Agency (ANVISA), and Japanese MHLW MO 169, Chapter 2 with our Quality System and organizational objectives.

4.2.1 - Structure of Quality System Documentation

Level 1 – Corporate Quality Management System Manual
Level 2 – Department Policies and Procedures
Level 3 – Department Work Instructions
Level 4 – Department Forms, Checklists, and Controlled Records



4.2.2 - Quality Management System Manual

The Quality Management System Manual has been established to define the scope of our business system, identify our inter-related processes, characterize our QMS and outline the structure of our documentation system. There are two approved and controlled Quality Management System Manuals. The manual is documented, housed and maintained on the Nissha Medical Technologies Intranet site and Nissha Medical Technologies website. Any printed copy of any portion of this manual is considered to be uncontrolled.

4.2.3 - Medical Device File

Nissha Medical Technologies has established and maintains a file for each type or family of medical device which contains or references documents generated to demonstrate conformity with requirements.

At a minimum, files include:

- General description of medical device, intended use/purpose, labeling and any instruction for use
- Specifications for product
- Specifications for procedures for manufacturing, packaging, storage, handling & distribution
- Procedure for measuring and monitoring

(Installation requirements and servicing procedures are not applicable, see ISO 13485 scope)

4.2.4 - Document and Data Control

Constant evolution of the Quality Management System and frequent document changes are necessary to support our emphasis on continual improvement and technological advancement. For the purpose of this Quality Management System, the range and detail of procedures is dependent upon the complexity of work and methods of production. All documentation, including procedures, work instructions, checklists, training and records are maintained, monitored, and are in alignment with the Corporate Quality Management System.

Procedures have been established to define the controls required by the QMS including:

- Review and approval of documents for adequacy prior to use
- Review and update as necessary and re-approve documents
- Ensure changes and current revision status of documents are identified
- Relevant versions of documents are readily available at points of use
- Ensure documents remain legible, identifiable and handled/stored to prevent deterioration or loss
- Documents of external origin are identified and their distribution controlled
- Obsolete documents are removed from QMS and suitably identified/stored as such to prevent unintended use

The Quality Management System Manual, Departmental Policies and Procedures, and Departmental Work Instructions are available on the intranet and are maintained by Document Control. Level 1, 2 and 3 documents are considered controlled when viewed online; a copy may be printed but is considered an uncontrolled document.

Changes to correct grammar, typos, titles and format / numbering may be implemented for immediate change through Document Control.

4.2.5 - Control of Quality Records

Quality Records are established and maintained to provide objective evidence of conformity to requirements and to establish that our Quality Management System operates effectively. Records may be in the form of any type media.

At a minimum, our records must include the following:

- Management Review
- Maintenance Activities
- Customer Contracts
- Product Design Files
- Product Change History
- Quality Plans – Acceptance Records
- Calibration Records
- On-Hold Records
  - o Records of Accept on Deviation
  - o Records of Rework
  - o Final Disposition
- Customer Return Goods Authorization
- Medical Recall, Correction Removal Records
- Master Revision Lists
- Internal Audits
- Training Records
- Customer Purchase Orders
- Advisory Notices
- Device Master Records
- Device History Records
- Technical Documentation
- Supplier Approval Records
- Supplier Evaluation Records
- Customer Complaints
- Customer Feedback & Report Cards
- Customer Account Adjustments
- Corrective & Preventive Actions
- Medical Device Reporting Records
- Quality System Dashboard Charts

Each department will maintain Quality Records; records will be stored securely, maintained to ensure legibility, and be readily identifiable and retrievable within their respective areas.

Retention period for individual Quality Records will be based upon content and risk management. The Control of QMS Records Policy defines record-specific retention periods.

5- MANAGEMENT RESPONSIBILITY

5.1 - MANAGEMENT COMMITMENT

Nissha Medical Technologies senior management is committed to the development and implementation of its Quality Management System and the continual improvement of its effectiveness.

Commitment is illustrated through:

- Communication to the organization of the importance of meeting customer, statutory and regulatory requirements
- Establishment of the Quality Policy
- Ensuring that Quality Objectives are established
- The conduct of Management Reviews
- Ensuring the availability of resources

5.2 - CUSTOMER FOCUS

Nissha Medical Technologies senior management is dedicated to ensuring that customer, safety, statutory and applicable regulatory requirements are met.

- Determination and review of customer, safety, statutory and applicable regulatory requirements
- Monitoring of customer feedback through report cards, complaints, and sales channels

5.3 - QUALITY POLICY

Nissha Medical Technologies Quality Policy

Nissha Medical Technologies products and services enhance value for customers and society through the establishment, operation and maintenance of an effective quality management system that is designed to ensure quality, cost, robust supply chains, and compliance with relevant laws and regulations.

5.4 - PLANNING

5.4.1 - Quality Objectives

It is the objective of Nissha Medical Technologies top management to provide products and services which consistently meet all applicable regulatory requirements and the needs and expectations of our customers in relation to price paid and to the nature of competitive offerings. In doing so, Nissha Medical Technologies strives to be the industry leader in product quality. Our quality objectives are monitored, measured and reviewed to ensure that they are in alignment and consistent with our Quality Policy and principles.

Quality Objective Key Performance Indicators (KPIs) include:

- Enhancing the value for customers.
- Continuously improving to ensure a robust quality management system.
- Maintaining compliance to applicable regulatory requirements.
- Producing quality products efficiently in cost effective manners.
- Maintain a safe environment and system to support the conformity of product.

5.4.2 - Quality Management System Planning

Nissha Medical Technologies top management realizes that strategic business planning and the nurturing of a Quality Management System are interrelated processes. Our goal is to understand customer needs and satisfy customer expectations while operating our business as effectively and efficiently as possible. Historical business performance data, in conjunction with current market segment analysis, provide the avenues needed for sales, marketing and operational resource forecasting. Through forecasting management is able to set daily, monthly, quarterly and annual objectives, and ensure resource availability and capacity required to attain goals.

The Nissha Medical Technologies Quality Management System continues to develop as our business system evolves. Nissha Medical Technologies top management ensures the integrity of the Quality Management System through extensive planning, risk assessment and controlled implementation of processes.

5.5 - RESPONSIBILITY, AUTHORITY AND COMMUNICATION

5.5.1 - Responsibility and Authority

To ensure that our objectives are achieved, a defined organizational structure is in place with defined lines of authority and responsibility. The defined structure is maintained and is included in this manual.

Senior management is ultimately responsible for the quality of products and services. All personnel are empowered and responsible for the quality of their work, and have the authority to prevent occurrences of discrepancies.

Senior Management is responsible for ensuring:

- Personnel receive the tools, training, development and environment to be successful
- Personnel are in the position to make a difference in meeting or exceeding our customer expectations

- Personnel are encouraged to initiate, recommend or provide solutions through designated channels
- Personnel are empowered to overcome obstacles related to products, processes, and their own success
- Personnel can report discretion to their operation leader at any time and make suggestions for continuous improvements

Senior management will ensure that responsibilities and authorities of all individuals are defined, documented and communicated within the organization.

5.5.1 - Management Representative

The President / CEO has authorized the Quality Manager, hereafter referred to as the Management Representative, to review and approve the Quality Management System.

The Management Representative reports directly to the Vice President of Global Quality & Regulatory, and responsibilities and authorities include:

- Ensuring that processes needed for the Quality Management System are established, documented, implemented and maintained
- Reporting to top management on the performance of the Quality Management System and any need for improvement
- Ensuring the promotion of awareness of regulatory and customer requirements throughout the organization

5.5.2 - Internal Communication

Nissha Medical Technologies senior management actively communicates quality policies, business objectives and organizational accomplishments with personnel. Management also encourages personnel to voice concerns and suggestions for improvement.

Channels of organizational communication include:

- Outlook Meetings
- Team meetings
- Intranet (Organizational & Departmental)
- Focus Groups
- Employee Surveys
- Notice boards
- Email
- "Open-door" policy and approach to management

5.6 - MANAGEMENT REVIEW

5.6.1 - Reviewing Our Quality Management System

Nissha Medical Technologies senior staff reviews the Quality Management System at a minimum of once annually to ensure continuing suitability, adequacy, effectiveness and support of its stated Quality Policy, and Quality

Objectives. In addition, the review process evaluates the overall effectiveness of the system and considers evolving customer needs, developing technologies and opportunities for improvement. Records of Management Reviews are documented and maintained within the Quality Assurance Department.

5.6.2 - Inputs to Management Review Include:

- Feedback
- Complaint handling
- Reporting to regulatory authorities
- Audits
- Monitoring and measurement of processes & product
- Corrective and Preventive Action
- Follow-up actions from previous Management Reviews
- Changes that could affect the Quality Management System
- Recommendations for improvements
- Applicable new or revised regulatory requirements

5.6.3 - Outputs from Management Review Include:

- Improvements needed to maintain the suitability, adequacy, and effectiveness of the Quality Management System and its processes
- Improvement of product related to customer requirements
- Changes needed to respond to applicable new or revised regulatory requirements
- Resources needed

6- RESOURCE MANAGEMENT

6.1 - PROVISION OF RESOURCES

Nissha Medical Technologies senior management will determine and provide the resources required to maintain our Quality Management System's effectiveness. An effective Quality Management System is defined as one that attains our Quality Objectives while meeting all customer, safety, statutory and regulatory requirements.

6.2 - HUMAN RESOURCES

Nissha Medical Technologies is committed to the education, training and development of personnel regarding policies, procedures and processes and will ensure that the necessary competencies are documented for effective and efficient operation of the Quality System.

6.2.1 - Competence, Awareness and Training

Nissha Medical Technologies management will:

- Determine resources required to fulfill organizational objectives
- Evaluate and determine necessary competencies to perform work function
- Educate, train, and develop skills of personnel
- Develop methods to achieve and maintain necessary competencies
- Provide avenues for employee involvement
- Ensure that personnel understand the relevance and importance of their activities, and the contribution those activities make to our business and quality objectives
- Implement employee rewards and recognition programs
- Establish channels of communication
- Employ methods for evaluation and verification of system effectiveness

Personnel performing activities which affect product and service quality must be provided with the proper training required to perform those activities. It is the process area manager's responsibility to identify training requirements, ensure implementation, verify effectiveness and maintain training records. Personnel are qualified to perform specific assigned tasks based upon determined competency, appropriate records of education, training, skills and/or experience.

6.3 - INFRASTRUCTURE

Nissha Medical Technologies senior management is equally committed to providing a work environment and infrastructure beneficial to employee gratification and to the manufacture of high quality products.

The manufacturing facility is configured with adequate means for people flow and space provided to prevent product mix-up and ensure orderly handling of products.

Top management provides a building, workspace and associated utilities; process equipment (hardware and software); supporting services such as transport, communication and information systems; and an environment conducive to the production of quality products and services. Maintenance of facilities and equipment are planned, documented and records are maintained.

6.4 WORK ENVIRONMENT AND CONTAMINATION CONTROL

6.4.1. Work Environment

When considering if controlled conditions or cleanliness requirements are applicable for a given process/product, Nissha Medical Technologies will consider the impact on quality or regulatory compliance and/or comply with specific customer requirements.

If controls are necessary to ensure there is no adverse effect on product, applicable controls will be documented within the associated process or product work instructions.

Documented procedures for the health, cleanliness and clothing requirements of Nissha Medical Technologies personnel, contractors and visitors have been established to prevent adversely affecting product or work environment and medical device safety and performance.

6.4.2. Contamination Control

Nissha Medical Technologies has established documented requirements for control of contamination with microorganisms and particulate matter and maintains the required cleanliness for production, assembly and packaging processes.

Contaminated or potentially contaminated product shall be segregated and documented to prevent the contamination of other product, the work environment, or personnel.

Where chemicals are used as part of the pest control program, the company ensures they do not affect product quality.

7- PRODUCT REALIZATION

The Nissha Medical Technologies Quality Management System is the culmination of an interrelated series of processes and support activities. All processes and activities, from quote to invoice, are carried out under controlled conditions which are monitored, measured, and analyzed for effectiveness.

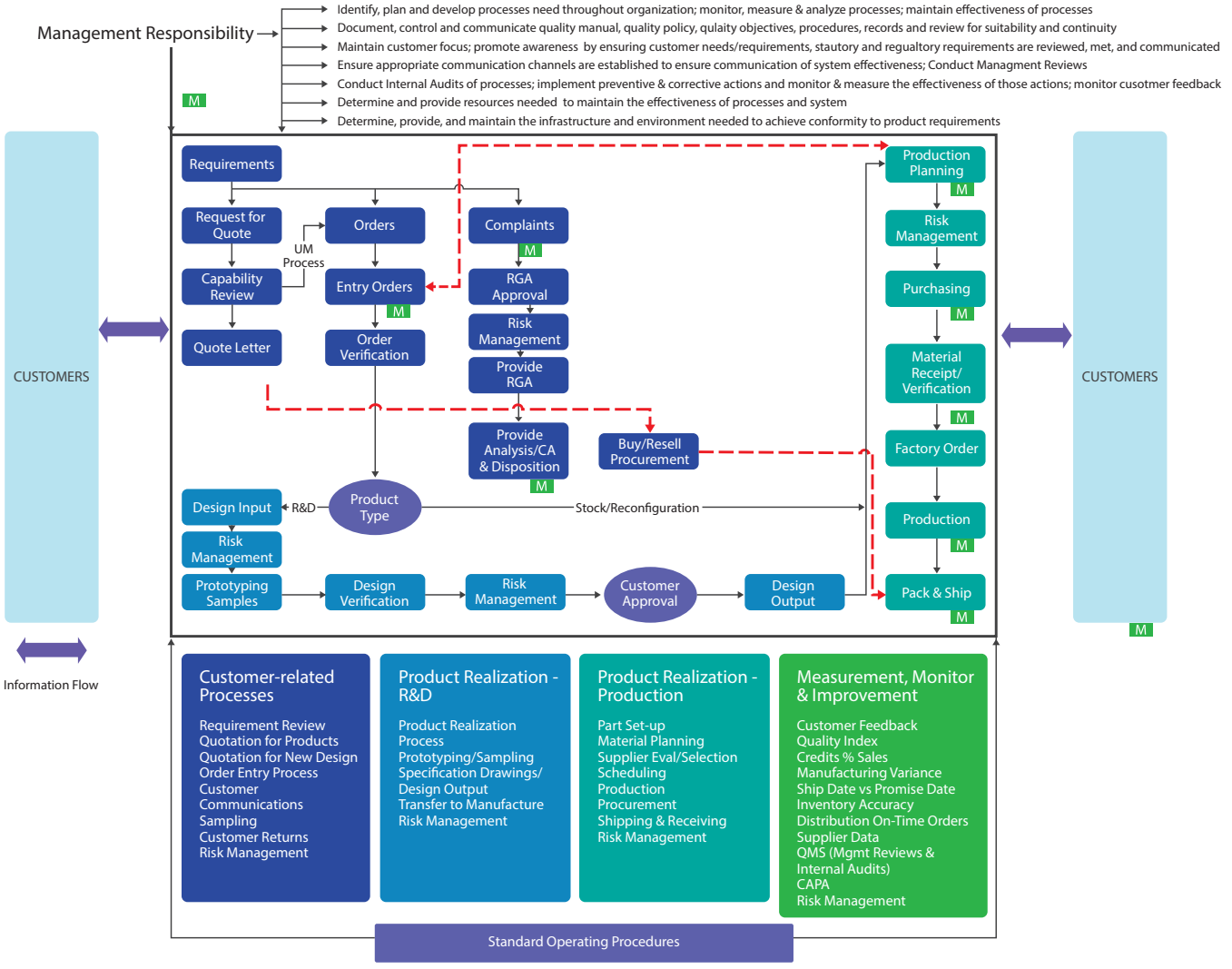
7.1 - PLANNING OF PRODUCT REALIZATION

Nissha Medical Technologies top management:

- Identifies processes and activities needed to meet customer requirements
- Ensures availability of resources to achieve desired outputs
- Documents processes to support effective and efficient operation
- Captures and records individual product specifications
- Implements verification, validation if required, monitoring and test activities specific to the criteria for product acceptance
- Mitigates risk, ensuring the safety of our products
- Periodically reviews process performance to ensure consistency with operating plans
- Provides methods for implementation and monitoring of process changes to ensure the integrity of product, customer requirements and the organization remain intact

In the event that validation results are not fully measurable and verifiable and/or where processing deficiencies may become apparent only after product is in use, Nissha Medical Technologies will validate product at our customer's site. These processes will be continuously monitored, controlled and carried out by qualified personnel to ensure all specified requirements are met.

7.1.1 - DIAGRAM: PROCESS MAPPING



7.2 - CUSTOMER-RELATED PROCESSES

The Nissha Medical Technologies Sales and Marketing Departments are responsible for market research, competitive analysis, defining of customer requirements and verification of process capabilities prior to acceptance of contract.

7.2.1 - Determining the Requirements Related to the Product

Nissha Medical Technologies Sales and Marketing will:

- Determine customer requirements including product, delivery and post-delivery activities
- Determine and communicate with customer necessary information, where known, regarding specified or intended use
- Determine user training needed to ensure specified performance and safe use of medical device
- Identify organizational requirements in conjunction with product realization

7.2.2 - Review of Requirements Related to the Product

Customer Service is the interface utilized to process customer requirements through the Nissha Medical Technologies on-line operating system.

Prior to acceptance of contract Nissha Medical Technologies Customer Service will:

- Ensure customer requirements are reviewed
- Ensure customer requirements are clearly defined and/or documented
- Ensure all discrepancies between quotes, proposals and customer requirements are communicated and resolved
- Ensure applicable regulatory requirements are met
- Ensure any user training identified is available or planned to be available
- Ensure the organization has capability to meet defined requirements
- Confirm acceptance of contract requirements with customer

7.2.3 - Customer Communication

Upon acceptance of contract Nissha Medical Technologies Customer Service will:

- Enter order into the Nissha Medical Technologies operating system
- Confirm all product, delivery and post-delivery requirements
- Amend and document customer order requirements as necessary
- Notify relevant personnel upon change to requirements

Customer Service, as the interface between our customer and operating system, will communicate with customers regarding:

- Product information including price and availability
- Order status inquiries and amendments
- Customer feedback, including customer complaints

Nissha Medical Technologies will issue advisory notices to our customers as required in accordance with product safety, statutory and regulatory requirements. An advisory notice will be issued in the event that subsequent to delivery of product it becomes necessary to provide our customers with supplementary information and/or advise them of actions needed to be taken in reference to device use, a modification made to the device, return of device to Nissha Medical Technologies or destruction of the device.
Nissha Medical Technologies will communicate with regulatory authorities in accordance with applicable regulatory requirements.

7.3 - DESIGN AND DEVELOPMENT

7.3.1 Design and Development Process

The Nissha Medical Technologies product design and development process ensures quality products that meet customer, functionality, safety, statutory and applicable regulatory requirements. Design processes may vary among projects and are detailed to meet specific requirements associated with individual product development.

Products requiring new product development are defined as products produced using new technology and/or materials. Those products utilizing established technology and which are sold to existing and new customers within existing markets, or to new customers outside established markets, are considered re-configurations or product line extensions; such products do not require new product development.

7.3.2 - Design and Development Planning

Design and development is planned, and controlled. A project file is devised to capture design and development stages, assign responsibilities and ensure that review, verification, validation and design transfer activities occur as appropriate. All stages of design and development are documented within project files; project files are retained for the product's life cycle.

7.3.3 - Design and Development Inputs

New product development projects are structured, defined and approved adequate at onset. Inputs include needs and expectations, risk management data, information derived from previous similar designs when applicable, and all essential functional, performance, usability, and safety requirements according to intended use, and applicable regulatory requirements and standards.

7.3.4 - Design and Development Outputs

Our design and development team is responsible for ensuring project outputs are verified against predefined inputs. Our R&D group coordinates efforts with Purchasing, Planning, Manufacturing and Quality, ensuring that all acceptance criteria is met, and that we have the capabilities necessary to achieve quality results. All characteristics of the product that are deemed essential for safe and proper use are identified and documented.

7.3.5 - Design and Development Review

Design and development reviews are planned and executed at appropriate project stages. Reviews include an interrelated grouping of individuals, each concerned with functions and requirements of the specific stage being evaluated. Reviews are utilized and documented to identify problems, propose necessary actions and determine course of actions to be taken.

7.3.6 - Design and Development Verification

Verification of product design and development as defined in the project plan is carried out and documented. Outputs of design and development are evaluated against initial inputs to ensure our products meet all customer, functionality, safety, statutory and applicable regulatory requirements.

7.3.7 - Design and Development Validation

We at Nissha Medical Technologies are committed to ensuring our products are capable of meeting all requirements for intended use within specified applications. It is essential design and development validation is carried out and documented in accordance with planned arrangements prior to implementation of our products into the marketplace.

7.3.8 - Design and Development Transfer

The Design Transfer process is intended to be ongoing as various sections of the design are transferred into production specifications or Design Outputs. Design Outputs can be generated throughout the design process.

After Design Verification, Design Validation and Final Design Review are complete and approved; a change request is submitted to transfer all final Design Outputs into final revision controlled documentation releases. Final revisions shall be reviewed, approved and controlled prior to release for manufacturing.

7.3.9 - Control of Design and Development Changes

All changes within design and development are documented in the project files. Changes are reviewed, verified and validated as appropriate prior to implementation; review includes evaluation of the effect of the changes on constituent parts within the product. After new designs and processes are initially qualified, manufacturing processes are monitored to ensure that the processes are in control and remain unaffected over time. In the event that design changes are required post market release, they will be reviewed, verified and validated as appropriate; review includes evaluation of the changes on all constituent parts within in the product and the impacted processes. Approval will be required by organizations affected by the design change. Customers will be notified when change has the potential to affect form, fit or function of the product. Post market release product changes are documented through the Engineering Product Change Request/Notice process.

7.3.10 – Design and Development Files

Design and Development Files are maintained for each medical device type or family. Files include records generated to demonstrate conformity to the requirements and records for design and development changes.

7.3 - DIAGRAM: DESIGN AND DEVELOPMENT / NAVIGATOR FLOW

DRIVING NEW PRODUCTS TO MARKET				
PHASE 1	**PHASE 2**	**PHASE 3**	**PHASE 4**	**PHASE 5**
Concept and Feasibility	Design Input	Design Output	Verification and Validation	Production Transfer
• Quotation / Contract Review • Intended use/ purpose • Quality Agreement • Customer Requirements • Design Specification Traceability Matrix • Competitive Product Evaluation • Patent Search / IP Review • Human Factors / Usability Analysis • Draft Concept Selection Matrix • Design & Development Plan	• Project Schedule • Design Input Worksheet • Concept Drawings/ CAD Models • Concept Design Reviews • Engineering prototypes/Test Reports • Design for Manufacturing/ Assembly (DFMA) • Risk Management Plan • Hazard Analysis • Risk Evaluation Checklist	• Design Engineering Analysis Reports • Detailed Design – Mechanical • Detailed Design – Electrical • Detailed Design – Software • Product Specifications • Packaging • Manufacturing Flow Chart • uFMEA • dFMEA • pFMEA • Master Validation Plan • Review Cost Targets	• TMV/GR&R Reports • Design Verification Protocols/Reports • Process Validation Protocols/Reports • Packaging/ Transportation Testing • Biocompatibility • Sterilization • Cleaning & Disinfection • Thermal Response Testing • UL/IEC Testing • Software Validation • Clinical Evaluations • New Material Qualification • Product Performance Qualification • Software User Acceptance Test • Computer System Validation	• Validation Summary Report • ECR Release for Production Specifications • Risk Management Plan/Report • EU Declaration of Conformity • Post-Market Surveillance • Regulatory Information Form • Device Master Record • Regulatory Dossier Compilation • Complete Design & Development Plan

Note: Deliverables for each phase are defined through the development process, and will not be applicable to every project.

7.4 - PURCHASING

Nissha Medical Technologies senior management empowers its Purchasing Department to ensure all purchased products meet our high standards of quality and satisfy organizational needs. Organizational needs are dictated by customer, safety, statutory and applicable regulatory requirements and those of the industry channel.

7.4.1 - Purchasing Process

The Purchasing Department is required to:

- Define the extent of due-diligence exercised over suppliers, dependent upon type of product and its application
- Ensure products conform to specified requirements
- Evaluate suppliers based on their ability to provide product and delivery in a manner which satisfies our customer requirements
- Review product quality, price, and performance as compared to competitors
- Establish method for inspection or verification of product quality
- Rate suppliers based on quality, service and delivery performance
- Establish and maintain a listing of approved suppliers based on rating and evaluation of products and services
- Establish planned monitoring of suppliers to provide input to supplier re-evaluation process

7.4.2 - Purchasing Information

Purchasing translates Nissha Medical Technologies products into individual requirements to be procured from our suppliers. All material/product requirements and terms of purchase are documented and reviewed for adequacy and accuracy prior to issue of purchase order. It is essential that all materials/products directly impacting form, fit or function of our finished product are traceable by lot to our supplier.

7.4.3 - Verification of Purchased Product

Nissha Medical Technologies has established and implemented incoming receiving and inspection processes as appropriate. Diligence in meeting material/product requirements lies within our supplier relationships and is verified through internal process checks.

7.5 - PRODUCTION AND SERVICE PROVISION

Nissha Medical Technologies senior management recognizes that product realization is a complex interrelation of processes and activities carried out by trained, educated and empowered employees. Through simultaneous monitoring and measurement of our system and industry channels Nissha Medical Technologies strives to meet current market expectations while anticipating future needs. Future successes are reliant upon the manufacture and distribute of quality products in conjunction with the maintenance and continual improvement of our Quality Management System.

7.5.1 - Control of Production and Service Provision

Nissha Medical Technologies top management plans, carries out, monitors and controls the product and service provisions required to ensure products conform to specifications.

Product Controls include:

- Product cleanliness maintained in accordance with application and design requirements
- Documented information that describes specifications and characteristics of products
- Documentation of procedures, methods, work instruction, quality plans and reference materials whenever lack of such would have adverse effect on quality of product or service
- Personnel trained to perform specific processes
- Suitable facilities and equipment for the provision of quality product and services
- Written quality agreements for outsourced processes that affect product conformity to requirements
- Proper devices for the measuring and monitoring of process parameters and product specifications
- Defined operations for labeling and packaging
- Implemented policies and procedures for the release, shipment, and post-delivery activities associated with manufactured products
- Operation metrics measure, monitor and drive continual improvement within the Quality Management System

7.5.2 - Cleanliness of Product

The organization has developed requirements to maintain the cleanliness of product and control contamination during the manufacturing process. Procedures have defined the necessary steps and hygiene requirements in order to work in manufacturing, distribution and controlled manufacturing areas. It is the responsibility of all employees to uphold these requirements while working with both raw material and finished devices.

7.5.3 - Installation (Not Applicable to our Business)

7.5.4 - Servicing (Not Applicable to our Business)

7.5.5 - Sterile Medical Devices (Not Applicable to our Business)

7.5.6 - Validation of Processes for Production and Service Provision

In those cases where product cannot be adequately measured and/or deficiencies may become apparent only after product has been delivered. The organization will utilize a risk-based approach to validate the processes, procedures, methods, computer software, equipment and personnel dedicated to its manufacture to achieve planned results consistently. These processes will be documented, controlled and retained.

7.5.7 - Validation of Processes for Sterilization (Not Applicable to our Business)

7.5.8 - Identification

All products supplied by Nissha Medical Technologies are identified by a unique part number, and are recognized as such throughout the organization's written and electronic documents. The part number is used to identify customer specific requirements as the product moves from acceptance of contract through planning, manufacturing, storage, dispatch and delivery.

Raw materials used in the manufacture, converting and finishing processes are assigned unique identifying part numbers. The assigned part number is recognized throughout the organization on all written and electronic documents from receipt to finishing. Those materials considered critical to the product are lot coded for traceability.

Global language requirements will be determined during product design/configuration based on intended market, i.e. Labeling and IFUs will be communicated through icons and/or wording in the appropriate languages.

7.5.9 – Traceability

Products are lot coded for traceability of raw materials and other tangible inputs in accordance with applicable regulatory requirements and the records required maintained.

7.5.9.1 - Distribution Records

Distribution records shall be maintained by Nissha Medical Technologies or any of its agents in the distribution of finished goods manufactured by Nissha Medical Technologies to allow for complete and rapid traceability.

7.5.9.2 - Implantable Medical Devices (Not Applicable to our Business)

7.5.10 - Customer Property

There are documented procedures for the identification, verification, protection and storage of customer-supplied product. Any customer-supplied product determined to be lost, damaged or otherwise considered unsuitable for use will be reported to the customer and records will be maintained.

7.5.11 - Preservation of Product

Nissha Medical Technologies top management ensures appropriate facilities are available to preserve the quality and integrity of all products.

Preservation of product includes:

- Proper product identification
- Utilization of proper equipment and trained personnel
- Secure packaging to avoid damage of product in transit
- Appropriate storage conditions
- First In First Out (FIFO) stocking and fulfillment to prevent degradation of product

Stock products are assessed as part of physical inventory and cycle counts; detection of product or package deterioration during these processes will result in segregation, rework and/or scrap of product.

Products with limited shelf-life are identified through our operating system and/or through product labeling. Processes are in place to ensure that these items are planned, produced and shipped with optimal shelf-life intact.

7.6 - CONTROL OF MEASURING AND MONITORING DEVICES

Nissha Medical Technologies maintains control over all monitoring and measurement equipment utilized in the development, manufacture and testing of products and processes. Measuring and monitoring devices must be capable of measuring characteristics within tolerances prescribed by industry standards or customer requirements, as applicable.

All equipment used for the monitor, measure or control of product is calibrated and traceable to U.S. National Institute of Standards and Technology. All equipment maintained within the Calibration System is visibly marked with a unique identifying control number. Equipment control number, description, assigned location and date of next scheduled calibration are logged, maintained and searchable within a database.

Equipment is protected and maintained from damage and deterioration. In the event that equipment is damaged, out of calibration and/or considered unsuitable for use, the equipment is segregated and labeled as such. The equipment will be reintroduced into the system once it has undergone repair and/or recalibration.

In the event monitoring and/or measuring equipment is found to be out of calibration, Nissha Medical Technologies will assess the validity of previous measuring results and verify the quality of all product potentially affected by the non-conforming equipment.

8- MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 - DEMONSTRATING CONFORMANCE OF OUR PRODUCTS AND QUALITY MANAGEMENT SYSTEM

Nissha Medical Technologies Quality System Metrics are utilized for measurement and analysis of our Quality Management System and impacts to our customers. Through collection of various data, management is able to identify organizational strengths, weaknesses and potential areas for improvement. Quality System Metrics are compiled and reviewed by management on a monthly basis, and continual improvement actions are taken. Quality System Metrics are posted throughout the facility to inform employees of our performance against Quality Management System goals, and communicate the impact each individual has on the system.

8.2 - MONITORING AND MEASUREMENT

Nissha Medical Technologies monitors and measures our ability to meet customer requirements. Our ability, as an organization, to meet customer requirements encompasses many facets; it is for this reason that Nissha Medical Technologies monitors, measures and analyzes our internal processes, supplier relationships and capabilities of meeting all customer, safety, statutory and applicable regulatory requirements.

8.2.1 - Customer Satisfaction & Feedback

Nissha Medical Technologies has established means for collecting customer satisfaction data from production as well as post-production activities; we have systems in place dedicated to receiving, collecting and analyzing customer feedback. Customer satisfaction is measured through sales analysis, our customer complaint processes, sales feedback, and customer issued "performance report cards". Information is compiled and assessed in Management Review, where action plans are developed toward continual improvement.

8.2.2 – Complaint Handling

Nissha Medical Technologies has established procedures for timely complaint handling. Receiving, recording and evaluating information, determining if feedback constitutes a complaint, investigating complaint, determining the need to report information to appropriate regulatory authorities, handling of complaint-related product and determining need to initiate corrections or corrective actions are documented and maintained.

If an investigation determines activities outside the organization contributed to the complaint, Nissha Medical Technologies will exchange relevant information with the external party.

8.2.3 – Reporting to Regulatory Authorities

Nissha Medical Technologies has documented procedures for providing notification to the appropriate regulatory authorities, if applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events and issuance of advisory notices.

Records of reporting to regulatory authorities are documented and maintained.

8.2.4 - Internal Auditing

Nissha Medical Technologies utilizes the Internal Audit as a management tool to evaluate the efficiency and effectiveness of our Quality Management System. Internal audits provide an opportunity to ensure our processes and systems are operating as planned, are in compliance with all regulatory requirements as applicable, and to the guidelines established in our Quality Management System. Documented procedures provide framework and methodology for the internal audit process. It is the responsibility of the Management Representative to ensure Internal Audits are scheduled, planned and coordinated efficiently; the Management Representative will also ensure that audits are conducted and verified for effectiveness in a timely manner.

Internal Audits:

- Scheduled based on risk and impact to the Quality Management System
- Scheduled and executed in each area as dictated by previous audit findings, issuance of corrective action requests and/or changes implemented within the process area
- Performed in each area at a minimum interval of once every year; areas prone to non-compliance may be audited more frequently to ensure effectiveness and compliance
- Conducted by trained personnel, objectively, impartially and independent of the process being audited
- Findings are recorded and brought to the attention of the manager responsible for the area audited and the implementation of corrective action
- Summarized results are reported as an integral part of the input conveyed at Management Reviews

Audit details, corrective actions and follow-up activities, as applicable, are captured in the Audit Report and maintained within the Quality Assurance Department as objective evidence.

8.2.5 - Monitoring and Measurement of Processes

Nissha Medical Technologies evaluates process performances and incorporates measurement results into daily management operations.

Process Evaluations:

- Capabilities
- Cycle Time
- Measurable Aspects of Dependability
- Utilization of Technologies
- Cost Allocation and Reduction
- Reaction Time
- Yield
- Effectiveness and Efficiency of Personnel
- Waste Reduction

8.2.6 - Monitoring and Measurement of Product

Nissha Medical Technologies has established and documented monitoring and measurement requirements for its products.
Quality Plans identify critical characteristics to be monitored and measured, methods of monitoring and measurement, test equipment used, and the required frequency. Product is not released unless all acceptance criteria are met. Measurement results are recorded and kept on file.

8.3 - CONTROL OF NONCONFORMING PRODUCT

8.3.1 – Management Commitment to Quality Products

Nissha Medical Technologies top management believes that quality is a culture; the production of high quality products meeting all customer, safety, statutory and applicable regulatory requirements is our goal and expectation. Personnel have been trained and educated to their job functions and are empowered to cease production upon detection of suspect product.

8.3.2 – Nonconforming Product Detected Before Delivery

Documented procedures have been established for the handling of nonconforming products to prevent use, release or delivery of such. Nonconforming products are clearly identified and segregated from conforming product for documentation of evaluation, any investigation, disposition of product and rationale for decisions. Product will be accepted and released on concession only if justification is provided, approval obtained, and all customer, safety, statutory and applicable regulatory requirements can be met.

8.3.3 – Nonconforming Product Detected After Delivery

In the event nonconforming product is detected after delivery or use has begun, Nissha Medical Technologies will take all actions appropriate and necessary to correct known nonconformity through investigation and notification to any external party responsible for nonconformity, and negate potential for adverse effects.

Should analysis indicate notification to Regulatory Bodies is appropriate, action will be taken to notify applicable regulatory bodies by established procedures in a timely manner.

8.3.4 – Rework

Product may be reworked or reconfigured only if it can be determined that rework or reconfiguration does not compromise the integrity of the product, or present adverse effects. Reworked/Reconfigured products will be re-inspected prior to release to ensure all acceptance criteria are met. Determination of product disposition is documented, authorized and carried out only by those sanctioned to do so.

8.4 - ANALYSIS OF DATA

Nissha Medical Technologies Quality Management System decisions are based on market research, competitive analysis, and operation metrics. Appropriate methods, including statistical techniques and the extent of their use, are utilized to collect and analyze data for the ongoing verification of suitability, adequacy and effectiveness of the Quality Management System.

Data is generated as a result of monitoring and measurement as well as, at a minimum, through customer feedback, conformity to product requirements, system trends, audit results and service reports.

Results of analysis can be used to determine our ability to meet all quality system, product, customer, safety, statutory and applicable regulatory requirements through:

- Performance to Objectives
- Effectiveness and Efficiency of Processes
- Opportunities for Quality System Improvements
- Financial and Market Related Performances
- Competitive Strategies

8.5 - IMPROVEMENT

Nissha Medical Technologies senior management actively seeks opportunities to improve the efficiency and effectiveness of our Quality Management System. Opportunities for improvement are identified through use of our Quality Policy & Principles, Quality Objectives, Data Analysis, Internal Audits, Corrective and Preventive Actions and Management Reviews.

8.5.1 - Continual Improvement

Opportunities for continual improvement present themselves in different ways; improvement initiatives may be derived through highly visible strategic business projects or, as more often occurs, born through day to day business operations. At Nissha Medical Technologies it is our goal to cultivate opportunities for process improvements, while sustaining the effectiveness of our Quality Management System. Delivering quality products and meeting all customer, safety, statutory and applicable regulatory requirements is our competitive advantage in the marketplace.

8.5.2 - Corrective Action

Corrective Action is used as a tool for improvement. Corrective Actions are taken without undue delay to prevent re-occurrence of nonconformities and eliminate potential for deficiencies within our Quality Management System.

Corrective Action may be taken as the result of:

- Customer Complaints
- Process Measurements
- Management Review
- Internal Audits
- Data Analysis
- In-Process Inspections
- Surveillance Audits
- Process Measurements
- Data, Records and Statistics Collected
- Surveillance and Internal Audits
- Process and Capability Analysis

Reviewing nonconformities, determining their cause and evaluating the need for action to prevent recurrence is planned and documented. Verification of the corrective action and reviewing its effectiveness ensures the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device.

Should analysis indicate notification to Regulatory Bodies is appropriate, action will be taken to notify US FDA, Health Canada, the EU Competent Authority, and other applicable regulatory bodies by established procedures in a timely manner.

8.5.3 - Preventive Action

Nissha Medical Technologies takes preventive action to mitigate potential for nonconformities and losses. Planning for prevention is systematic, and based on data collected through evaluation of current performance, historical statistics and trend analysis.

Determining potential nonconformities and their causes and evaluating the need for action to prevent occurrence of nonconformities is planned and documented. Implementation of action plans, including update to documentation, verification that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device, and reviewing the effectiveness of the preventive action is documented and maintained.

Contributors to preventive action initiatives:

- Failure Mode and Effects Analysis (FMEA)
- Business Operation Metrics
- New Product Development/Design Control
- Review of Customer Requirements and Feedback
- Market Analysis
- Management Review

9- STANDARDS TABLE

ISO 13485 STANDARD	21 CFR 820*	HC*	TGA*	ANVISA 665/2022*	MHLW MO169*	EU MDR*	1-42-01 Quality Manual Reference and Applicable SOPs
4.1 General Requirements	820.5		Sch3 P1 1.4(4)	Art 4, 106	5-1 - 5-6	Article 10 (1, 9, 15) Annex IX (1, 2.1, 2.2, 2.4)	1-42-01
4.2 Documentation Requirements						Annex IX (2.1, 2.2)	1-42-01
4.2.2 Quality Manual	820.186			Art 7	7-1		2-42-01
4.2.3 Medical Device File	820.181				7-2	Article 10 (4, 5, 9, 11, 15) Annex IX (2.2)	2-42-05 2-73-08
4.2.4 Control of Documents	820.40		Sch3 1.4(4)	Art 28-31, 34, 36-37	8	Article 10 (8,9) Annex IX (2.2)	2-42-01 2-42-04
4.2.5 Control of Records	820.180		Sch3 1.4(4)	Art 34, 36-37	9	Article 10 (8) Annex IX (2.2)	2-42-04 2-42-04-001
5.0 Management Responsibility	820.20						
5.1 Management Commitment	820.20			Art 5-7	10	Annex IX (2.1, 2.2)	2-56-01
5.2 Customer Focus				Art 5-7	11		1-42-01
5.3 Quality Policy	820.20 (a)		Sch3 1.4(5)(a)	Art 5-7	12	Annex IX (2.2)	1-42-01

5.4 Planning	820.20(d)						
5.4.1 Quality Objectives	820.20(a)		Sch3 1.4(5)(a)	Art 5	13	Annex IX (2.2)	2-56-01
5.4.2 Quality Management System Planning	820.20 (d)(e)		Sch3 P1 1.4(4)	Art 4, Art 106	14	Annex IX (2.1)	1-42-01
5.5.1 Responsibility and Authority	820.20 (b1)		Sch3 P1 1.4(5) (b)(ii)	Art 5-7	15	Annex IX (2.2)	1-42-01
5.5.2 Management Representative	820.20 (b3)		Sch3P1 1.4(5) (b)(ii)	Art 9	16		2-56-01
5.5.3 Internal Communication	820.20 (b1)				17		1-42-01
5.6 Management Review	820.20 (c)		Sch3 P1 1.4(5) (b)(iii)	Art 10-12		Annex IX (2.1, 2.2)	2-56-01
5.6.1 Management Review - General	820.20 (c)				18		2-56-01
5.6.2 Review Input	820.100 (a)(7)		Sch3 P1 1.4(5) (b)(iii)	Art 12, 120	19	Article 10 (9) Annex IX (2.2)	2-56-01
5.6.3 Review Output	820.20 (c)				20	Article 10 (9) Annex IX (2.2)	2-56-01
6.0 Resource Management						Article 10 (9) Annex IX (2.2)	
6.1 Provision of Resources	820.20 (b2)				21	Annex IX (2.1)	2-56-01
6.2 Human Resources	820.70 (d) 820.25			Art 15	22, 23		2-62-01
6.3 Infrastructure	820.70 (f)(g)	14		Art 35, 67, 78	24		2-63-01 2-75-01
6.4 Work Environment and Contamination Control	820.70 (c)(d)(e)		Sch1 P2 7.2, 8	Art 68, 71			2-64-01 2-64-02 2-64-03
6.4.1 Work Environment	820.70 (c)				25-1		2-64-01 2-64-03
6.4.2 Contamination Control	820.70 (d)(e)		Sch3 P1 Cl1.4(5)(d)	Art 69, 75, 79	25-2		2-64-01 2-83-01
7.0 Product Realization	820.30 (a)						
7.1 Planning of Product Realization	820.30 (g)	1, 34	Sch1 P1 2	Art 18-20	26	Article 10 (1, 2, 9,) Annex IX (2.2)	2-73-17 2-73-11
7.2 Customer Related Processes	820.30 (b)(c)						

7.2.1 Determination of Requirements Related to Product	820.30 (c)		Sch1 P1 2, Sch3 P1 Cl1.4(4), Sch3 P1 Cl1.4(5) (d)&(e)	Art 5-7, 44, 52, 64-66	27	Article 10 (1,9) Annex IX (2.2)	2-72-06
7.2.2 Review of Requirements Related to the Product	820.30 (e)				28	Article 10 (1)	2-72-06 2-73-17
7.2.3 Customer Communication	820.30 (b)				29	Article 10 (8, 9, 11, 14, 15) Annex IX (2.2, 2.4, 3.2)	2-72-06
7.3.1 General	820.30 (a)		Sch 3 P1 Cl 1.4(4) (5) (c)	Art 43	30	Article 10 (1) Annex IX (2.2)	2-73-17
7.3.2 Design and Development Planning	820.30 (b)	20	Sch 3 P1 Cl 1.4(4) (5)(c)	Art 44, 61	30	Article 10 (9)	2-73-17
7.3.3 Design and Development Inputs	820.30 (c)		Sch 3 Part 1.4(4)	Art 46	31	Article 10 (9, 11) Annex IX (2.2)	2-73-17
7.3.4 Design and Development Outputs	820.30 (d)		Sch 3 P1 Cl 1.4(5)(c)	Art 49, 61	32	Article 10 (9)	2-73-17
7.3.5 Design and Development Review	820.30 (e)		Sch 3 P1 C1.4(5)(c)(i)	Art 50	33	Article 10 (9) Annex IX (2.2)	2-73-17
7.3.6 Design and Development Verification	820.30 (f)	10, 11, 15, 16	Sch 1 P1 2, Sch 3 P1 Cl 1.4(5) (c)	Art 48	34		2-73-17
7.3.7 Design and Development Validation	820.30 (g)	10, 11, 12, 15, 16, 18, 19	Sch 1 P1 2, Sch 3 P1 Cl 1.4(5) (c) & (d), Sch 3 P8	Art 48-49, 53-58, 61	35-1		2-73-14 2-73-17
7.3.8 Design and Development Transfer	820.30 (h)			Art 52, 54-58, 61	35-2	Article 10 (9)	2-73-17
7.3.9 Control of Design and Development Changes	820.30 (i)	1, 34	P1 2	Art 60	36-1	Article 10 (9) Annex IX (2.2)	2-73-18
7.3.10 Design & Development Files	820.30 (j)	9, 10-20	Division 3.2, Sch 1 P1 2, Sch 1 EP12.1	Art 43, 52-58, 63	36-2		2-73-17
7.4 Purchasing	820.50					Article 10 (15)	

7.4.1 Purchasing Process	820.50		Sch 3 P1 Cl1.4(5)(d)(ii)	Art 21-23	37	Article 10 (9) Annex IX (2.2)	2-74-02 2-74-03 2-74-04
7.4.2 Purchasing Information	820.50 (b)		Sch 1 P1 2	Art 18, 24-26	38		2-74-02 2-74-07
7.4.3 Verification of Purchased Product	820.80 (b)(e) 820.86		Sch 1 P1 2, Sch3 1.4(5)(e)	Art 22, 41, 42, 89	39	Annex IX (2.2)	2-74-01 2-74-07
7.5 Production and Service Provision	820.70					Article 10(1)	
7.5.1 Control of Production and Service Provision	820.70(a) 820.181 820.184		Sch 1 P1 2, Sch 3 P1 Cl1.4(4), Sch 3 P1 CL1.4(5)(d) & (e)	Art 5-7, 44, 52, 64-66	40	Article 10 (9, 11) Annex IX (2.2)	2-75-01 2-75-02 2-75-07
7.5.2 Cleanliness of Product	820.70 (c) (e) (h)		Sch 3 P1 Cl 1.4(5)(d)	Art 69, 75, 79	41		2-64-03 2-75-02
7.5.3 Installation Activities - Not Applicable							
7.5.4 Servicing Activities - Not Applicable							
7.5.5 Requirements for Sterile Medical Devices - Not Applicable							
7.5.6 Validation of Processes for Production and Service Provision	820.75 820.70(i)	17	Sch 1 P2 8.2, 8.3; Sch 3 P1 1.4(5)(d)	Art 3, 103-106	45	Annex IX (2.2)	2-73-14
7.5.7 Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier System - Not Applicable							
7.5.8 Identification	820.86	21-23, 52-56, 66-68	Sch 1 EP 13, Sch 3 P1 1.4(5) (c), (d), (e), & 1.9	Art 108, 113	47	Annex IX (2.2)	2-75-01
7.5.9 Traceability	820.65	21-23, 52-56, 66-68	Sch 1 EP 13, Sch 3 P1 1.4(5) (c), (d), (e) & 1.9	Art 18-20, 63-64, 84-87	48	Annex IX (2.2)	2-75-01
7.5.9.2 Particular Requirements for Active Implantable Medical Devices and Implantable Medical Devices - Not Applicable							
7.5.10 Customer Property	N/A				51		

7.5.11 Preservation of Product	820.120 820.130 820.140 820.150 820.160	14	Sch 1 P1 4&5	Art 84, 107, 111	52		2-75-03 2-75-04
7.6 Control of Monitoring and Measuring Devices	820.70(g) 820.72		Sch 3 p1 1.4(5)(e)	Art 93-95, 102, 104	53	Annex IX (2.2)	2-73-15 2-76-01 2-76-02
8.0 Measurement Analysis, and Improvement						Article 10 (9) Annex IX (2.1, 2.2)	
8.1 General	820.250				54	Annex IX (2.1, 2.2)	2-84-01
8.2 Monitoring and Measurement						Article 10 (9)	
8.2.1 Feedback	820.198	57-58, 61.4-61.6	Sch 1 P1 2, Sch 3 P1 1.4(3), 1.4(5)(b)(iii) & 1.4(5)(f)	121	55-1	Article 10 (9, 10) Annex IX (2.1, 2.2)	2-56-01 2-84-01 2-85-10
8.2.2 Complaint Handling	820.198	57-58, 61.4-61.6	Sch 1 P1 2, Sch 3 P1 1.4(3), 1.4 (5)(b)(iii) & 1.4 (5)(f)	121	55-2	Article 10 (9, 11)	2-85-01 2-85-10
8.2.3 Reporting to Regulatory Authorities	820.198 (d) 803	59-61.1	Sch 3 P1 1.4(3)(c)	Art 120	55-3	Article 10 (9, 11, 13)	2-85-05 2-85-06 2-85-09
8.2.4 Internal Audit	820.22		P1 1.4(5)(b)(iii)	Art 122-124	56	Annex IX (2.2)	2-82-02
8.2.5 Measurement and Monitoring of Processes	820.70(a) 820.250		Sch 3 P1 Cl 1.4(5)(d)&(e)	Art 30, 62-66, 84, 88	57	Article 10 (9) Annex IX (2.2)	2-56-01 2-84-01
8.2.6 Monitoring and Measurement of Product	820.80		Sch 3 P1 Cl 1.4(5)(d)& (e)	Art 30, 62-66, 84, 88	58, 59	Article 10 (9) Annex IX (2.2)	2-56-01 2-73-16 2-74-01 2-75-07 2-76-01
8.3 Control of Nonconforming Product						Annex IX (2.2)	
8.3.1 Management Commitment to Quality Products	820.90		P1 1.4(5)(b)(iii)	Art 117, 118, 120	60-1		2-83-01

8.3.2 Actions in Response to Nonconforming Product Detected Before Shipment	820.90		P1 1.4(5)(b)(iii)	Art 117, 118, 120	60-2		2-83-01
8.3.3 Actions in Response to Nonconforming Product Detected After Delivery	820.100	63-65.1	P1 1.4(3) (a),(b),(5)(b) (iii),(f) P1 2	Art 18-20, 120	60-3	Article 10 (9m 11)	2-83-01, 2-85-01, 2-85-05, 2-85-09
8.3.4 Rework	820.90 (b)			Art 119	60-4		2-83-02
8.4 Analysis of Data	820.100			Art 120	61	Article 10 (9) Annex IX (2.2)	2-84-01
8.5 Improvement							
8.5.1 General	820.198	57-58, 61.4-61.6	Sch 1 P1 2, Sch 3 P1 1.4(3), 1.4(4)(b)(iii) & 1.4(5)(f)	121	62	Article 10 (9, 10) Annex IX (2.1)	8.5.1
8.5.2 Corrective Action	820.100		P1 1.4(3)(a),(b), (5)(b)(iii), (f) P1 2	Art 116, 120	63	Article 10 (9)	8.5.2, 2-85-02
8.5.3 Preventive Action	820.100		P1 1.4(3)(a),(b), (5)(b)(iii), (f) P1 2	Art 120	64	Article 10 (9)	8.5.3, 2-85-02

Reference MDSAP Audit Approach P0002.

Nissha Medical Technologies devices are classified as Class 1 and Class 1M. Nissha Medical Technologies holds an MDD CE Certificate expiring in 2024 for all Class 1M products. In regards to European Medical Device Regulation (2017/745 MDR), Nissha is compliant as per Article 120(3). Class 1 self declared products fall under jurisdiction of applicable sections of (EU) MDR 2017/745.

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