

QUALITY MANUAL

Value Plastics Fluid Management Product Line



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Introduction

Value Plastics, Inc., dba Nordson MEDICAL created a Quality Management System (QMS) to document the company's best business practices, better satisfy the requirements and expectations of its customers, and improve the overall management of the company. The company's QMS meets the requirements of the International Standards ISO 9001:2008 and 13485:2003.

This manual describes the company's QMS and delineates authorities and responsibilities of the personnel performing within the system. The manual also provides procedures or references for all activities comprising the QMS to describe the company's compliance to the standard.

This manual is used internally to guide the company's employees through the requirements of the ISO standards that must be met and maintained in order to ensure customer satisfaction, continuous improvement, and create an empowered work force.

This manual is used externally to introduce the QMS to customers and other external organizations or individuals. The manual familiarizes them with the controls that have been implemented, and assures them that the integrity of the QMS is maintained and is focused on customer satisfaction and continuous improvement.

Section 1: Purpose

The purpose of this quality manual is to establish and state the general policies governing the Quality Management System. These policies define management's intentional provision for managing our operations and activities in accordance with the framework established by ISO 9001:2008 and ISO13485:2003. These are the top-level policies representing the company's protocols for achieving quality assurance and customer satisfaction. All departmental policies and written procedures must conform to and parallel these top-level policies. All changes to policies and procedures are required to be reviewed to ensure that there are no conflicts with this Quality Manual.

Section 2: Scope

The policies stated in this manual apply to all operations and activities at Value Plastics, Inc., dba Nordson MEDICAL.



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The scope of activities under ISO 9001:2008

The design, manufacture, and sale of fluid management products and custom solutions.

The scope of activities under ISO 13485:2003

The design, manufacture, and sale of fluid management products and custom solutions for the medical market.

It is the responsibility of all department managers to help define, implement, and maintain the procedures required by this manual and to ensure all processes conform to these requirements. It is the responsibility of all employees to follow procedures that implement these policies.

2.1 Exclusions

- 2.1.1 Value Plastics does not have cleanliness of product and contamination and control (7.5.1.2.1)
- 2.1.2 Value Plastics does not perform installation (7.5.1.2.2) or servicing (7.5.1.2.3)
- 2.1.3 Value Plastics does not have particular requirements for sterile medical devices. (7.5.1.3 and 7.5.2.2)
- 2.1.4 Value Plastics does not have particular requirements for active implantable medical devices and implantable medical devices (7.5.3.2.2 and 8.2.4.2)

Section 3: General Information

3.1 Company Details

Value Plastics, Inc., dba Nordson MEDICAL
805 West 71st Street
Loveland, CO 80538
Phone: (970) 267-5200
Fax: (970) 223-0953
www.nordsonmedical.com

Value Plastics, Inc. is a corporation registered in Colorado. The organization is not debarred, suspended, or otherwise ineligible for Federal Programs as may be confirmed in General Services Administration's list of Parties Excluded from Federal Procurement or Non-procurement programs. Value Plastics complies with all applicable Colorado State and

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Federal laws, regulations regarding equal employment opportunities, non-segregated facilities as required by The Civil Rights Act of 1964, including its amendments. Value Plastics also complies as applicable with the Rehabilitation Act of 1973, Vietnam Era Veterans' Readjustment Act of 1974 and the Americans with Disabilities Act of 1990.

Colorado State Sales Tax License Number: 11-78110

Federal Employer Identification Number: 84-0700506

FDA Registration Number: 3003182071

3.2 Quality Policy

Value Plastics is committed to providing superior quality products and services that meet applicable regulatory, statutory, and customer requirements by adhering to an effective quality management system that benefits our customers, employees and shareholders.

3.3 Facility

State-of-the-art building in excess of 117,000 square feet, constructed in 2015.

- Product Development
- Engineering
- Tool Shop
- Maintenance
- Manufacturing
- Quality
- Warehouse
- Sales, Marketing, Customer Service
- Human Resources
- Finance
- Offices, Common area, Kitchen

3.4 Engineering and Product Development

The Engineering and Product Development departments support external and internal customers with timely response and innovative approaches to product line extensions and new product development, using the "nVision process". The nVision process is a specifically defined approach to ensure that all proposed new products follow a consistent system, to meet or exceed requirements. The nVision process is managed by trained engineers, who use state-of-the-art software (e.g. PDMworks, SolidWorks, solid modeling, FEA Analysis, solid

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surfacing, etc.), and an R&D lab that has mechanical, thermal and fluid flow analysis capability. All projects are tracked via Microsoft Project, and financial progress of all projects is reported to the finance department. All phases of nVision are tracked within the company's ERP System (IFS). Supporting procedures, work instructions, and data are also maintained within IFS. Our skilled team of Design Engineers, Project Engineers, Tooling Engineers, Engineering Technicians, and Mold Makers work together on product development efforts.

3.5 Equipment and Capacity

The company is equipped with all electric injection molding machines, supported by a central material handling and central monitoring system. Support equipment is utilized during the manufacturing processes. This automated equipment includes: robotic sprue pickers, automated bagging systems, and conveyor systems. The manufacturing process has the capacity to operate 24 hours a day, 7 days a week.

The Tool Room employs the latest technology in CAM software, CNC equipment including mills, grinders, lathes, and EDM equipment. The Quality department is equipped with several types of inspection equipment to ensure product conformance to documented specifications. Equipment utilized during our inspection processes include the following: vision, laser and probe CMM, calipers, gage pins, thread gages, luer gages, bore gages, optical scopes, surface analyzers, depth gages, and force gages.

3.6 Environmental and Chemical Issues

No Class I ozone-depleting chemicals (ODC) or any polybrominated biphenyl and polybrominated biphenyl oxide chemicals (PBB, PBBO, PBBE) of any type or class are intentionally introduced into our processes.

No mold release agents, CFC, or fluorocarbon-based chemicals, additives or agents are used in our processes unless prior approval is obtained from customers.

The injection molding processes and secondary operations operate in a Clean Room environment certified to ISO 14644-1 Class 8 (e.g. formerly known as Class 100,000).

None of our stock products are made with a resin, which, in its own manufacture, uses ODC's, PBB's, PBBO's, and PBBE's. We require our suppliers to provide evidence to this effect, and records are kept on file.

Careful measures are taken so that lubricants, cleaning solvents, water, etc. do not intentionally contact or otherwise contaminate the finished product. However, the production environment precludes our warranting that the finished products are totally free of contamination and thus cannot be certified to be non-pyrogenic.

Regarding latex content of our products: Letters from our vendors, who produce the resin used for our products, indicate that latex is not used or intentionally introduced in any

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formulation of or processing of the final resin material. Likewise, we do not intentionally introduce any form of latex into our own manufacturing processes.

Section 4: Quality Management System

4.1 General requirements

Value Plastics has established, documented, and implemented a Quality Management System in accordance with the requirements of ISO 9001:2008 and ISO 13485:2003. The system is maintained and continually improved through the use of the quality policy, quality objectives, internal & external audit results, analysis of data, corrective and preventive action and periodic management reviews.

4.1.1 To design and implement the QMS, we have:

- a) Identified the processes needed for the QMS and their application throughout the organization,
- b) Determined the sequence and interaction of these processes,
- c) Determined criteria and methods needed to ensure that the operation and control of the processes are effective,
- d) Ensured the continuing availability of resources and information necessary to support operation and monitoring of the processes,
- e) Established systems to monitor, measure and analyze these processes,
- f) Established processes to identify and implement actions necessary to achieve planned results and maintain effectiveness of these processes,
- g) Established control processes to identify and implement actions necessary to achieve planned results of outsourced processes, and
- h) Determined the criteria and information necessary to ensure that required regulations and standards are met.

4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

- a) Documented Quality Policy,
- b) Quality Manual,
- c) Documented Procedures,

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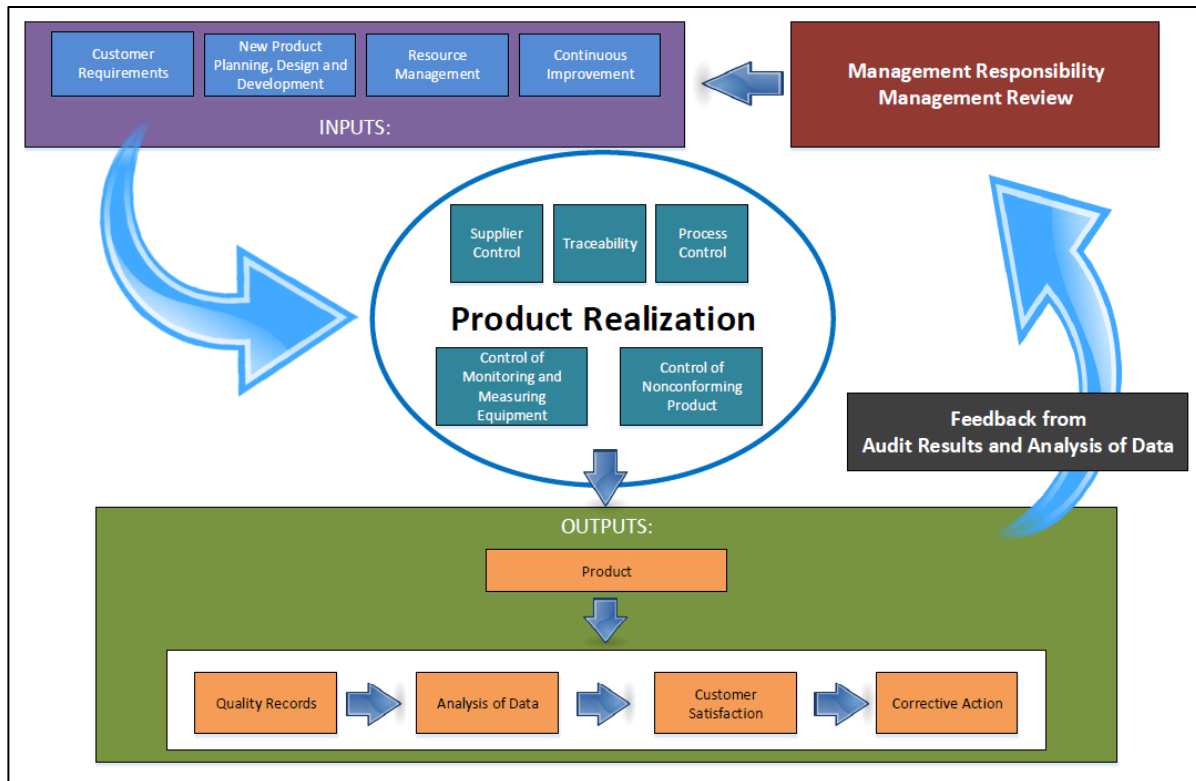
- d) Documents identified as needed for the effective planning, operation and control of our processes, and
- e) Quality Records.

4.2.1.1 For each type or model of medical device, Value Plastics maintains a Device Master Record , which documents product specifications and QMS requirements. Device history records are maintained for each lot. Records of medical device product that Value Plastics distributes, are kept with the suppliers of the product.

4.2.2 Quality Manual

The Quality Manual is maintained, and includes reference to the following:

- a) The scope and permissible exclusions (in Section 2)
- b) The documented procedures
- c) The interaction between the processes of the QMS

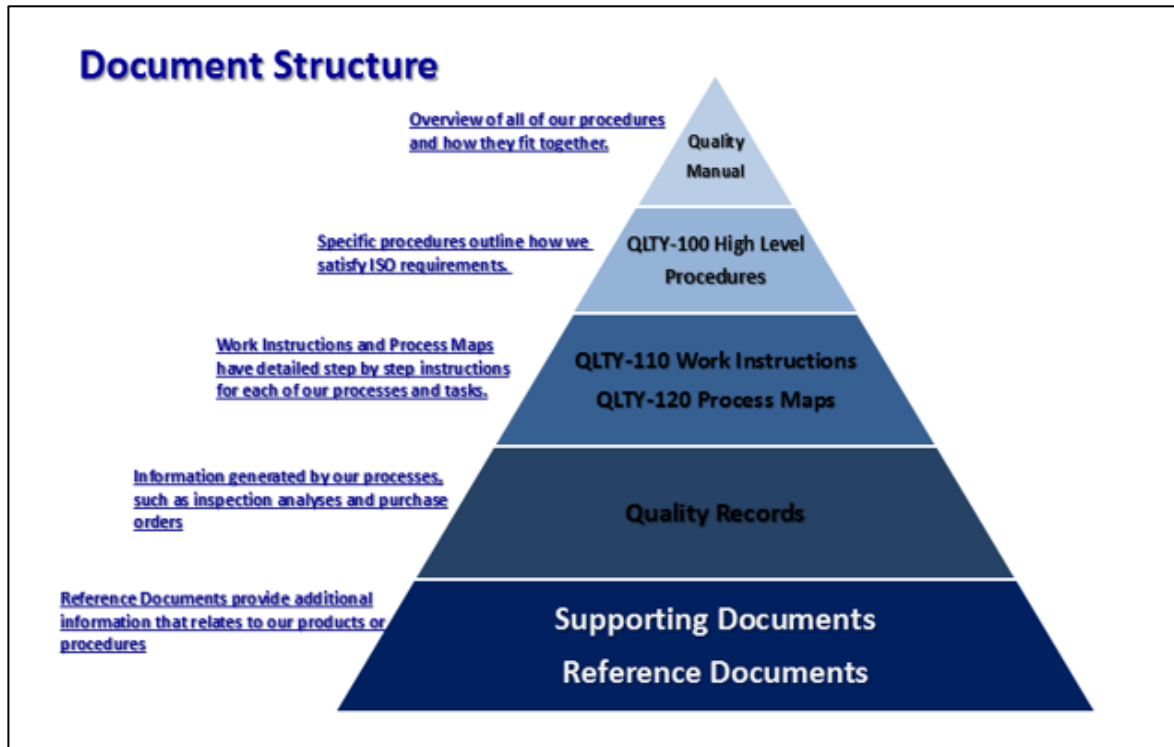


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d) The structure of documentation used in the QMS



4.2.3 Control of Documents

All of the QMS documents are controlled according to the Document Control procedure. This procedure defines the process for:

- a) Approving documents for adequacy prior to issue,
- b) Reviewing and revising as necessary and ensuring proper approval of new revisions,
- c) Ensuring that changes and current revision status of documents are identified,
- d) Ensuring that relevant versions of applicable documents are available at points of use,
- e) Ensuring that documents remain legible and readily identifiable,
- f) Ensuring proper access control,
- g) Identifying the retention period of quality records,

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- h) Ensuring that documents of external origin are identified and their distribution controlled,
- i) Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose,
- j) Ensuring that changes to documents are reviewed and approved by appropriate personnel, and
- k) Defining the retention period for obsolete controlled documents, specific to the lifetime of medical devices.

4.2.4 Control of Quality Records

Quality records are maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. The records are maintained according to the Control of Quality Records Procedure. This procedure requires that quality records remain legible, readily identifiable and retrievable. The procedure defines the controls needed for identification, storage, protection, retrieval, retention time and disposition of quality records.

Quality records for medical devices are maintained for at least the lifetime of the medical device, and not less than two years from the product release date.

Section 5: Management Responsibility

5.1 Management Commitment

Top management has been actively involved in implementing the Quality Management System. It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

5.1.1 To continue to provide leadership and show commitment to the improvement of the QMS, management has done the following:

- a) Communicated the importance of meeting customer, statutory, and regulatory requirements,
- b) Established quality objectives,
- c) Ensured that the quality policy is communicated throughout the organization,
- d) Conducted periodic management reviews, and
- e) Ensured the availability of resources.

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5.2 Customer Focus

Value Plastics strives to identify current and future customer needs, to meet customer requirements and exceed customer expectations.

- 5.2.1 Top management ensures that customer requirements are understood and met. Customer requirements are determined, understood, converted into internal requirements, and communicated to the appropriate personnel in our organization.

5.3 Quality Policy

- 5.3.1 Top management ensures that the quality policy is appropriate to the purpose of the organization, and is communicated to all employees. It is included in new employee training and training on the QMS. It is posted on the organization intranet to maintain high standards within our organization. It includes a commitment to comply with requirements and to maintain the effectiveness of the QMS.
- 5.3.2 Management reviews the quality policy during management review meetings to determine the policy's continuing suitability for our organization, and its relevance to the quality objectives.

5.4 Planning

5.4.1 Quality Objectives

Quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed annually for suitability. Quality objectives are measurable, and reviewed against performance goals during periodic management reviews.

5.4.2 Quality Management System Planning

The quality system has been planned and implemented to meet our quality objectives and the requirements of the ISO standards. Quality planning takes place as changes that affect the quality system are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

An organizational structure has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions. Job descriptions and the organizational structure are reviewed and approved by top management for adequacy. These documents are available to the employees to help them understand responsibilities and authorities. Top management ensures that the personnel who manage, perform and assess work affecting quality have sufficient independence and authority necessary to perform these tasks. The

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most current organizational structure is available in the corporate human capital management system.

5.5.2 Management Representative

Top Management appoints the ISO Management Representative. The Management Representative has the following responsibility and authority to:

- a) Ensure that processes needed for the quality management system are established and implemented,
- b) Report to top management on the performance of the quality management system, and note needed improvements,
- c) Promote awareness of regulatory and customer requirements throughout the organization, and
- d) Act as a liaison with external parties such as customers or auditors on matters relating to the QMS.

5.5.3 Internal Communication

Top management ensures communication throughout the organization regarding the effectiveness of the QMS using several methods, including: email, intranet resources, signage within the building, and all-company meetings held periodically as deemed necessary.

5.6 Management Review

5.6.1 General

Top management reviews the QMS at management review meetings held at a minimum of twice per year. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes. Records for each management review meeting are maintained.

5.6.2 Review Input

Assessment of the QMS is based on a review of information inputs to management review. These inputs include the following:

- a) Results of audits,
- b) Customer feedback,
- c) Process performance and product conformity,
- d) Status of preventive and corrective actions,
- e) Follow-up actions from previous management reviews,

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- f) Changes that could affect the quality management system,
- g) Recommendations for improvement, and
- h) New or revised regulatory requirements.

5.6.3 Review Output

During these review meetings, management will identify appropriate actions to be taken regarding the following issues:

- a) Improvements needed to maintain the effectiveness of the quality management system and its processes,
- b) Improvement of product related to customer requirements, and
- c) Resource needs.

Responsibilities for required actions are assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded.

Section 6: Resource Management

6.1 Provision of Resources

During planning and budgeting processes and as needed throughout the year, Top Management will determine and ensure that appropriate resources are available to implement and maintain the QMS, and continually improve its effectiveness and enhance customer satisfaction by meeting regulatory and customer requirements.

6.2 Human Resources

6.2.1 General

Qualifications for personnel are defined in job descriptions, which include requirements for education, skills and experience. Appropriate qualifications, along with required training, provide the competence required for each position.

6.2.2 Competence, Awareness and Training

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. Human Resources maintain records of employee qualifications. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the

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employee with the necessary competence for the job. The results are then evaluated to determine if they were effective. Training and evaluation are conducted according to the training procedure.

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

6.3 Infrastructure

Value Plastics provides the infrastructure necessary to achieve conformity to product requirements. During the budgeting and strategic planning processes, buildings, equipment, workspace, and associated utilities are evaluated and provided. When new personnel are added, hiring managers coordinate activities to ensure appropriate process equipment including hardware and software if required and supporting services such as telephones etc. are available based on information provided on the Personnel Requisition. Requirements for maintenance activities, and their frequency, are documented and maintained, if product quality could be affected.

6.4 Work Environment

A safe work environment suitable for achieving product conformance is maintained. Requirements are determined during quality planning.

- 6.4.1 The work environment is managed for continuing suitability, and is properly controlled by the following activities
- a) Requirements for health, cleanliness and clothing of personnel (if contact with the product or work environment could affect product quality) are documented
 - b) Data from the quality system is evaluated to determine if the work environment is sufficient for achieving product conformance, or if preventive or corrective action related to the work environment is required.
 - c) Value Plastics ensures that personnel who are required to work temporarily under special environmental conditions within the work environment are either trained or supervised by a trained person.
 - d) In order to prevent contamination of other product, the work environment, or personnel, special arrangement to control contaminated or potentially contaminated product is a documented process.

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Section 7: Product Realization

7.1 Planning of Product Realization

- 7.1.1 Quality planning is required before new products or processes are implemented. During this planning, management or assigned personnel identify:
- The quality objectives and requirements for the product are developed during the Product Development “nVision” Process
 - Processes, documentation and resources required and stored in IFS,
 - Verification, validation, monitoring, inspection and test requirements,
 - Criteria for product acceptance,
 - Necessary records to provide evidence that the realization process and resulting product meet requirements, and
 - Requirements and records for applicable risk management during product realization.
- 7.1.2 The output of quality planning includes documented quality plans, resource requirements, processes, equipment requirements, procedures, test data, and design outputs.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

Customer requirements are determined according to the Customer Related Processes Procedure. Before acceptance of an order, customer requirements are determined, including the following:

- Previous customer requirements which pertain to current part numbers being ordered,
- Required for delivery and post-delivery activities,
- Not stated by the customer but necessary for specified or intended use,
- Statutory and regulatory requirements related to the product, and
- Additional requirements determined by Value Plastics

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7.2.2 Review of Requirements Related to the Product

Value Plastics has a process in place for the review of requirements related to the product. The review is conducted before the order is accepted. The process ensures that:

- a) Product requirements are defined and documented,
- b) Contract or order requirements differing from those previously expressed are resolved, and
- c) Value Plastics has the ability to meet the defined requirements.

Records are maintained showing the results of the review and any actions arising from the review.

Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance.

Where product requirements are changed, Value Plastics communicates changes to relevant personnel and amends relevant documents.

7.2.3 Customer Communication

In keeping with our commitment to customer satisfaction, Value Plastics views effective customer communication as an essential element of customer satisfaction.

Appropriate handling of communications can reduce customer dissatisfaction in situations and in many cases turn a dissatisfying scenario into a satisfying experience.

Value Plastics has implemented procedures for communicating with customers, including:

- a) Marketing, Sales and Customer Service handle external communications, and are the primary contacts for product information.
- b) Sales and Customer Service are responsible for ensuring that customer inquiries, contracts and order handling, including amendments, are managed expeditiously and professionally. Sales and Customer Service also receive customer feedback, including customer complaints. All customer complaints are processed as Support Issues within IFS.
- c) QA is committed to addressing all documented customer inquiries/complaints. The QA department has the primary responsibility to address all customer related issues regarding the quality of our products and services. QA is the key contact for questions pertaining to the company's QMS.
- d) The QA and Marketing departments are responsible for issuing advisory notices as necessary.

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7.3 Design and Development

The nVision process is a multi-phased product development process which was developed to ensure consistency between projects. By following the nVision process, products can be developed and launched to the market with fewer errors and in a timely fashion. The nVision process is designed to be highly flexible to ensure processes can be worked in parallel while ensuring steps are not skipped. This allows a quicker timeframe as opposed to traditional linear product development processes. The phases in the nVision process allow checkpoints along the way to ensure all the required steps are completed prior to spending large amounts of capital or making commitments that are difficult to return from. The phases are as follows:

1. Phase 0 – Opportunity Discovery
2. Phase 1 – Project Planning and Feasibility
3. Phase 2 – Project Definition & Product Requirements
4. Phase 3 – Product Feasibility
5. Phase 4 – Product Development & Project Execution
6. Phase 5 – Commercialization
7. Phase 6 – Sales Acceleration / Project Review

Between each phase are hand-off meetings called phase gates. These are the points in time where the project requirements are completed and presented to upper management for approvals to proceed with the next phase activities. This is the most important part of the nVision process, in that these checkpoints help to prevent incomplete or not fully evaluated projects from launching.

To ensure that specified requirements are met, the following activities as applicable for the design project will be performed:

7.3.1 Design and Development Planning

The design and development procedures are documented and the process flow outlines the process for controlling the design and development process. The Product Development Department ensure that the product specification requirements are clear, creates the necessary planning tools, identifies all necessary resources, oversees designs and testing activities, and coordinates all internal activities according to this procedure. The design plan includes:

- a) Overall Project Management,
- b) Design and development stages,
- c) Required design reviews,
- d) Customer reviews,

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- e) Verification, validation, and design transfer methods appropriate to each design and development stage,
- f) Responsibilities and authorities for design and development,
- g) Identification of the technical interfaces required for the project, and
- h) Updating and documenting of the design plan as the project progresses.

7.3.2 Design and Development Inputs

Inputs relating to product requirements are determined and documented according to the nVision process. All inputs are reviewed for adequacy and completeness and are approved to resolve any ambiguity. Inputs include:

- a) Functional, performance, and safety requirements according to intended use,
- b) Applicable statutory and regulatory requirements,
- c) Where applicable, information derived from previous similar designs,
- d) Other requirements essential for design and development, and
- e) Outputs from applicable risk management.

7.3.3 Design and Development Outputs

Outputs of concepts and/or detailed designs and development activities are documented according to the nVision process. They are documented in a format that enables verification against the inputs, are approved prior to release, *and are retained*.
Outputs:

- a) Meet the input requirements,
- b) Provide appropriate information for engineering, materials management, manufacturing and for service provision,
- c) Contain or reference product acceptance criteria,
- d) Specify the characteristics of the product that are essential for its safe and proper use, and
- e) Review of initial development and manufacturing costs.

7.3.4 Design and Development Review

The design plan specifies suitable stages of the project to conduct design and development reviews (phase gate reviews). Results of phase gate reviews are recorded and are maintained as a quality record. Design reviews:

- a) Evaluate the results of design and development activities and determine if they fulfill requirements,

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- b) Identify any problems and propose necessary actions, and
- c) Include representatives of functions concerned with the design and development stage being reviewed, as well as other specialist personnel as required.

7.3.5 Design and Development Verification

Design verification is planned and performed to ensure that the design and development outputs have satisfied the design and development input requirements. Initial tooling and manufacturing costs may also be reviewed at this time as well. Records of the results of the verification and any necessary actions are maintained.

7.3.6 Design and Development Validation

Design and development validation is performed according to the design plan to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application. All pertinent tooling and manufacturing costs are reviewed and approved at this point as well. Validation is completed prior to delivery whenever practicable. Records of the validation activities are maintained according to the design and development procedure.

7.3.7 Control of Design and Development Changes

The change control procedure defines a process for identifying, recording, verifying, validating and approving design changes. The review of design and development changes includes an evaluation of the effect of the changes on constituent parts and delivered product (i.e. schedule cost, etc.). Records are maintained to show the results of the review and any necessary actions identified during the review.

7.4 Purchasing

7.4.1 Purchasing Process

The purchasing process is essential to Value Plastics' ability to provide our customers with products that meet their requirements. Value Plastics has documented procedures to ensure that purchased product conforms to specified purchase requirements. Value Plastics works closely with our supplier base (i.e. audits, scorecards, surveys) and inspecting purchased product as required. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

It is the responsibility of QA, Supply Chain and Buyers to evaluate suppliers based on their ability to supply product in accordance with specified requirements. Additionally, other internal resources may be called on to assist as required. Criteria for selection,

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evaluation and re-evaluation are defined in the Supplier Evaluation procedure. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained within the ERP system.

7.4.2 Purchasing Information

Value Plastics uses purchase orders (PO's) to describe the product or services to be purchased. PO's are created by designated individuals, within the ERP system. Purchase orders include where appropriate:

- a) Requirements for approval of product, services, or equipment,
- b) Identification of product or service to be delivered, quantity, delivery date, and cost,
- c) Quality management system requirements, and
- d) Applicable regulatory requirements

The PO originator is responsible for ensuring the adequacy of specified purchase requirements prior to their communication to the supplier. PO's are maintained within the company's ERP system.

Materials used in the manufacture of finished product have traceable identification which is maintained and controlled in the company's ERP system and is included on the PO.

7.4.3 Verification of Purchased Product

The Receiving Personnel, Material Handler, QC department, and/or Purchaser verify purchased items and materials for correctness. Verification records are maintained.

Should Value Plastics or any of our customers decide to perform verification at the supplier's premises, the verification arrangements and method of product release shall be stated in the purchasing information.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

7.5.1.1 Value Plastics plans and carries out production and service provisions under controlled conditions. Controlled conditions include, as applicable:

- a) The availability of information that describes the characteristics of the product,
- b) The availability of work instructions, documented procedures, documented requirements, reference materials, and reference measurement procedures as necessary,

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- c) The use of suitable equipment,
- d) The availability and use of monitoring and measuring devices,
- e) The implementation of monitoring and measurement processes,
- f) The implementation of release, delivery and post-delivery activities, and
- g) The implementation of defined operations for labeling and packaging.

Manufacturing Procedures, Routers, Inspection Control Plans, and Service Procedures define our company's plan for manufacturing and service, and provide detailed planning for all phases including the methods and equipment to be used and workmanship criteria. This detailed planning will be documented for each product and/or process in the form of work instructions, drawings or specifications. Value Plastics maintains a record for each batch of product and of medical devices that provides traceability and identifies the amount manufactured and released for distribution. This record is verified and approved.

7.5.1.2 Control of production and service provision - Specific Requirements

7.5.1.2.1 Cleanliness of product and contamination control. (EXCLUDED)

Requirements for cleanliness are documented if:

- a) Product is cleaned prior to use, or
- b) Product is supplied non-sterile, to be subjected to a cleaning process prior to use, or
- c) Product is supplied to be used non-sterile, and its cleanliness is of significance in use, or
- d) Process agents are to be removed from product during manufacture.

7.5.1.2.2 Installation activities (EXCLUDED)

Requirements containing acceptance criteria for installing and verifying the installation of medical device are documented.

7.5.1.2.3 Servicing activities (EXCLUDED)

Procedures for performing and verifying servicing activities are recorded and maintained.

7.5.1.3 Particular requirements for sterile medical device (EXCLUDED)

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

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7.5.2 Validation of Processes for Production and Service Provision

7.5.2.1 General requirements

Value Plastics validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results.

Value Plastics has documented the process for validation including:

- a) Tooling validation,
- b) Defined criteria for review and approval of the processes,
- c) Approval of equipment and qualification of personnel,
- d) Use of specific methods and procedures,
- e) Requirements for records, and
- f) Revalidation as necessary

Value Plastics has documented procedures for the validation of processes that include software and computer applications that affect the ability of the product to conform to specified requirements. Where such software is identified in a work instruction or procedure, the validation of the procedure or work instruction includes the software, and is maintained as a record.

7.5.2.2 Particular requirements for sterile medical devices (EXCLUDED)

Procedures for the validation of sterilization processes are documented, and sterilization processes are validated prior to initial use.

7.5.3 Identification and Traceability

7.5.3.1 Identification

Select personnel are responsible for identifying the product by suitable means throughout the process from receipt of material through shipment of the final product. Product identification will be provided by using the company's part numbering system to assign unique identification for all components and internally manufactured parts. Tags, labels, and routers are used as appropriate to clearly identify products and materials throughout the manufacturing process and in storage.

Documented procedures are in place for ensuring that any product (or medical device) that is returned to Value Plastics is identified and distinguished from conforming product.

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7.5.3.2 Traceability

7.5.3.2.1 In products where component traceability is a requirement, a unique identification will be used to identify the product. Product traceability will be provided by this unique identifier for all completed products.

Documented procedures define the extent of product traceability and the records maintained.

7.5.3.2.2 Particular requirements for active implantable medical devices and implantable medical devices (EXCLUDED)

Records of all components, materials and work environment conditions include traceability

Any agents or distributors are required to maintain records of the distribution of medical devices to allow traceability and those records are available for inspection.

7.5.3.3 Status Identification

Personnel performing monitoring and measuring activities are responsible for clearly identifying the product status with respect to monitoring and measurement requirements. To ensure that only items, assemblies or final products that have passed required tests and/or inspections proceed to the next operation or process, all products or assemblies will be appropriately labeled, tagged, stamped, or accompanied by routers or check-out sheets to properly indicate their inspection status. The inspection status shall clearly indicate pass or fail as appropriate.

7.5.4 Customer Property

Value Plastics rarely deals with customer-supplied materials or intellectual property; however should the situation arise, Value Plastics shall exercise care with customer property while it is under our control or being used. The receiving personnel shall identify customer-supplied product upon receipt and verify it is correct and not damaged. Warehouse and manufacturing personnel shall protect and safeguard customer property provided for use or incorporation into the product while it is in Value Plastics' possession.

Customer property and customer samples provided to Value Plastics are identified, verified, and protected within specified customer sample library. A record is maintained to track and safeguard customer samples. Appropriate personnel may contact the customer directly if the customer property is lost, damaged, or found to be unsuitable. Records of these situations are maintained.

7.5.5 Preservation of Product

Value Plastics has documented procedures for preserving the conformity of product during internal processing and delivery to the intended destination. This preservation

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includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

If applicable, documented procedures or work instructions are in place for the control of product with a limited shelf-life or requiring special storage conditions.

7.6 Control of Monitoring and Measuring Equipment

The organization has determined the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. A documented procedure outlines the processes used to control monitoring and measurement; the processes are carried out in a manner that is consistent with the monitoring and measurement requirements.

7.6.1 Where necessary to ensure valid results, measuring equipment is:

- a) Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards,
- b) Adjusted or re-adjusted as necessary,
- c) Identified to enable the calibration status to be determined,
- d) Safeguarded from adjustments that would invalidate the measurement result, and
- e) Protected from damage and deterioration during handling, maintenance and storage.

In addition, the Quality Department assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. The Quality Department takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained.

Section 8: Measurement, Analysis and Improvement

8.1 General

8.1.1 Value Plastics has planned and implemented the monitoring, measurement, analysis and improvement processes needed to:

- a) demonstrate conformity of the product,
- b) ensure conformity of the quality management system, and
- c) maintain and continually improve the effectiveness of the quality management

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system.

This includes determination of applicable methods, statistical techniques, and the extent of their use.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the QMS, the Marketing Department monitors information relating to customer perception and satisfaction as part of a feedback system to demonstrate whether the organization has fulfilled customer requirements. The method for obtaining this information is identified in the Customer Related Processes, Customer Satisfaction, the Management Responsibility and Customer Complaint Handling procedures, and is used to provide early warning of possible quality problems and to provide input for corrective and preventive actions.

8.2.2 Internal Audit

Value Plastics conducts internal audits at planned intervals to determine whether the quality management system:

- a) conforms to the planned arrangements for product realization, to the requirements of the ISO 9001:2008 and ISO 13485:2003, and to the quality management system requirements; and
- b) is effectively implemented and maintained.

The Internal and External Audit Procedure details the requirements for the audit program. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records are detailed in the procedure.

Management is responsible for the area being audited, to ensure that actions are taken without delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken, and the reporting of verification results.

8.2.3 Monitoring and Measurement of Processes

Value Plastics applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective action is taken, as appropriate, to ensure conformity of the product.

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8.2.4 Monitoring and Measurement of Product

8.2.4.1 The organization monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process in accordance with documented procedures.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of product.

Product release and service delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

8.2.4.2 Particular requirement for active implantable medical devices and implantable medical devices (EXCLUDED)

The identity of personnel performing any inspection or testing shall be recorded.

8.3 Control of Nonconforming Product

Value Plastics ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in the Control of Nonconforming Product procedure.

8.4 Analysis of Data

Value Plastics has documented procedures to identify, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the QMS can be made.

8.4.1 The process for determining, collecting and analyzing this data is defined in the Customer Satisfaction and Management Responsibility procedures. Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

- a) Customer feedback
- b) Conformance to product and/or process requirements
- c) Characteristics and trends of processes and products including opportunities for preventive action
- d) Suppliers

Results from the analysis of data are recorded and maintained.

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8.5 Improvement

8.5.1 Continual Improvement

Value Plastics shall identify and implement any changes necessary to ensure and maintain the continued suitability and continually improve effectiveness of the quality management system through the use of the quality policy, quality objectives, employee training, audit results, analysis of data, corrective and preventive actions and management review.

Records of all customer complaint investigations are maintained; all corrective actions or lack thereof will be authorized and recorded. If a customer complaint is not followed by a corrective/preventive action, the reason shall be authorized and recorded.

Issuing and implementing advisory notices is a documented procedure, and can occur at any time.

Value Plastics will notify applicable regulatory authorities of adverse events that meet specified reporting criteria.

8.5.2 Corrective Action

Value Plastics takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure defines requirements for:

- a) Reviewing nonconformities (including customer complaints),
- b) Determining the causes of nonconformities,
- c) Evaluating the need for action to ensure that nonconformities do not recur,
- d) Determining and implementing action needed including updating documentation if appropriate,
- e) Records of the results of any investigation and action taken and
- f) Reviewing corrective action taken and verifying its effectiveness.

8.5.3 Preventive Action

Value Plastics determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure defines requirements for:

- a) Determining potential nonconformities and their causes,

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- b) Evaluating the need for action to prevent occurrence of nonconformities,
- c) Determining and implementing action needed,
- d) Records of results of investigations and any action taken, and
- e) Reviewing preventive action taken and verifying its effectiveness.

REVISION HISTORY		
DATE	REV	DESCRIPTION OF CHANGE
		Reference document history for prior changes
9/11/2015	O	Updated cover page to reflect Nordson MEDICAL and Loveland address, added Nordson MEDICAL logo, Effective Date and Rev Level to header, revised address in section 3 from FTC to Loveland, corrected minor formatting issues, condensed Introduction verbiage, added subset numbering to Section 3, removed outdated verbiage in sections 5.2.1, 6.2.1, 7.2.3, 7.5.3.1 and 8.2.2, added Revision History table to the end.
2/3/2017	P	Revised 13485 Scope in section 2 to include Design, proprietary and custom. Updated Quality Policy in section 3.2 to correct the company name. Simplified the appointment process in section 5.5.2.
5/30/2017	Q	Section 2: revised scope statements for both 9001 and 13485. Section 3.1: removed reference to ISO certificate ID numbers. Section 4.2.2: revised to include images of the interaction between the processes of the QMS, and the structure of documentation used in the QMS. Section 3.4, 7.1 and 7.3: revised to reflect the nVision process Removed italics (no longer relevant) throughout document.