Nordson MEDICAL
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DOCUMENTED ASSURANCE OF QUALITY

DOCUMENT NUMBER:	1036619	EFFECTIVE DATE:	11 APRIL 2023	REV	L	PAGE	1 of 9

Scope:

Value Plastics Inc., dba Nordson MEDICAL ("Nordson MEDICAL") understands that many of our customers require a documented assurance of quality from critical suppliers. Oftentimes, the need is requested in the form of a "Supplier Quality Agreement" or a "Supplier Quality Requirements" document or acknowledgement, or a "Change Notification Agreement", for example. However, Nordson MEDICAL does not enter into Quality Agreements or sign Quality Requirements/Change Notification documents for our standard, off-the-shelf products, because our procedures apply. Therefore, this **Assurance of Quality** document provides a brief summary of our routine procedures, and is presented with the intent to provide you with the assurances needed in order to do business with Nordson MEDICAL.

Please note that all products we sell are offered according to Nordson MEDICAL drawings, specifications, quality system, change control, etc.

Below is an overview of our standard processes, which we guarantee for all customers.

Quality Management System ("QMS"):

We operate a QMS registered under ISO 13485.
Copies of our Quality Manual and our current ISO certificate are available on our website:
https://www.nordsonmedical.com/Resources

Electronic documented procedures exist (and are available upon request) for the following:

- Document Control
- Quality Records
- Management Responsibility
- Training, Competence, and Awareness
- Preventive and Corrective Maintenance
- Infrastructure and Work Environment
- Design and Development
- Validation Master Plan
- Customer Related Processes
- Change Management
- Supplier Evaluation
- Identification and Preservation of Product
- Control of Monitoring and Measuring Equipment
- Customer Satisfaction
- Internal and External Audit
- Control of Nonconforming Products
- Analysis of Data
- Customer Complaint Handling
- Corrective and Preventive Action
- Environmental Controls of the Cleanroom
- Risk Management

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Procedure Summaries:

Document Control – Documents are appropriately controlled, stored, revised, distributed (and as needed, obsoleted) electronically, using our fully integrated and validated ERP system. Document access is controlled and restricted according to each employee's specific job function, and only the currently Released revisions of work instructions are made available to operators at points of use. Good Documentation Practices ("GDP") are utilized, and employees are trained accordingly.
Data Integrity: Access to the ERP system is tightly controlled, including compliance with Sarbanes-Oxley ("SOX") requirements. Additionally, a robust system exists to regularly backup all electronic data, consisting of daily, weekly and monthly backup procedures, regularly transporting backups to a secure offsite location. Vigorous data recovery tests are performed annually to verify the backup system is functioning as expected. Aside from the description provided here, further details about the status of our data integrity will not be disclosed.

Quality Records – Nordson MEDICAL maintains records electronically via our ERP system indefinitely. Retained samples are kept for 3 years.

Management Responsibility – Management is committed to ensuring adequate resources are provided and implementing methods to accomplish the defined Quality Objectives. Management Review Meetings are held twice per year.

Training – A program is in place to ensure that all personnel are adequately trained to perform their job functions, including awareness of potential defects resulting from errors, and awareness of current Good Manufacturing Practices ("cGMP"). Evidence of training is recorded.

Preventive and Corrective Maintenance – A program is in place for the preventive and corrective work required to maintain the manufacturing equipment, ensuring it continues to produce product that meets specifications. Periodic inspections of the PM schedules confirm the on-time PM performance. Unscheduled maintenance (repairs) are performed as needed. Records of maintenance schedules and activities are documented in the ERP system.

Infrastructure and Work Environment– The infrastructure (including the building, equipment, security, lighting, cleanliness, computer systems, etc.) is monitored, controlled and supported to ensure conformity to product requirements and prevent product mix-up. The work environment (both inside the certified Class 8 cleanrooms, and the supporting environments outside the cleanroom) is controlled to ensure personnel safety and comfort, as well as compliance with requirements. Contamination control measures are in place to prevent risk to conforming product.

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Design and Development – New product development engineers and marketing solutions teams work together to follow Nordson MEDICAL protocol for designing and launching products in the marketplace. The phase-gated "nVision Nordson Product Development Process" is used to plan and control the design and development of new standard products and custom products, including defined processes for transfer to manufacturing, and design changes. Applicable U.S. laws and standards are incorporated into the process, to ensure that products are compliant with current U.S. federal laws and requirements.

Validation – In compliance with ISO requirements, Nordson MEDICAL has implemented a validation protocol necessary for any production processes where the resulting output cannot be verified by subsequent monitoring or measurement.

Customer Related Processes – Contract review, receiving and confirming customer purchase orders for specified Nordson MEDICAL part numbers, online order processes, as well as product labeling, bagging, boxing and shipping processes are performed according to standard Nordson MEDICAL procedures. The Sales, Customer Service, and Marketing departments manage/delegate customer communication regarding product information, custom options, fees and pricing, estimated delivery dates and/or lead times, complaints and other customer feedback.

Change Management – Documented procedures are in place to assess proposed changes to our Quality Management System, to our products, and to our processes. The change assessments are documented, and determine the necessary actions, which are commensurate with risk.

Supplier Evaluation – Nordson MEDICAL monitors our critical suppliers (vendors, subcontractors, secondary operations) through the Approved Supplier List (ASL). The required criteria are documented for inclusion in (and removal from) the ASL, as well as for scoring and auditing these suppliers. All incoming materials are subject to applicable incoming inspection processes.

ID & Preservation Of Product – Material Control: We use only 100% virgin, lot traceable resins in our production activities. Material certifications from resin suppliers are scanned and stored for every lot received. All material lots are inspected, received and tracked via barcodes in our ERP system to ensure full traceability of every production shop order. Runners, scrap and regrind material are stored in segregated and clearly identified containers. Nordson MEDICAL does not use regrind, mold release or other processing aids in any production operations.

Barcode Tracking and Labeling: Our barcode tracking system is fully integrated into our ERP system. Barcoded labels identify the product throughout the entire process – from incoming raw material all the way through final packaging and customer order

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shipping. Full traceability is ensured and documented via certifications. Shop Order numbers are used as Lot/Batch numbers, to simplify traceability.

Control of Monitoring and Measuring Equipment – Calibration is required, performed and recorded for all equipment used to measure finished product and/or make quality decisions about finished product. Certificates of calibration are recorded. Impact analysis investigations are performed if any out-of-calibration, or out-of-tolerance conditions are discovered.

Customer Satisfaction – Customer Satisfaction measurement methods are in place to ensure customer requirements are being met. These methods include trending real-time key metrics, complaint record reviews, customer scorecard reviews, and proactive surveys sent to customers annually, requesting direct feedback rating satisfaction.

Audits – Internal Audits: Nordson MEDICAL performs regular internal audits to confirm compliance to QMS requirements. Internal auditors are trained per our procedure, their training is documented, and they cannot audit their own work.
Customer Audits: Nordson MEDICAL welcomes mutually beneficial customer audits at agreed upon times scheduled in advance. Nordson MEDICAL agrees to provide a written response to audit findings as soon as possible after receipt of the customer's audit report.
Notified Body / Competent Authority Audits: Nordson MEDICAL understands that announced and unannounced audits by our customers' Notified Body or Competent Authority may occur. Nordson MEDICAL will host such audits and notify the affected customer as soon as possible after an unannounced audit occurs.

Control of Non-Conforming Products – Nordson MEDICAL follows established procedures to control nonconforming product. Discovery of nonconforming product generates an MRB (Material Review Board) investigation, including potential quarantine, and the disposition is documented. If a nonconformance is discovered after delivery to customers, Nordson MEDICAL will notify the affected customers as soon as possible, with information and instructions about resolution.
Product Recalls: All costs associated with an FDA recall will be borne by Nordson MEDICAL if the FDA recall is due to a manufacturing issue caused by Nordson MEDICAL.

Analysis of Data – Data (from such sources as production feedback, conformity trending, supplier performance, and audit results) is gathered and analyzed to ensure the suitability, adequacy and effectiveness of the Quality Management System. The analysis is used as an input to risk management, and to determine actions for improvement.

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Customer Complaint Handling – Customer complaints are documented within the Support Center in our ERP system and are assigned to the Quality Department for investigation and resolution. A response is provided to the complainant right away, confirming that the complaint was received and requesting any further details that may be needed to investigate the concern, and provide appropriate resolution. Any resulting corrective actions or nonconformance reports, and photos or other details, can be attached to the support issue record so resolution information is cohesive and retrievable.

Corrective/Preventive Action – Instances of non-conformance (in procedure or product) are documented and tracked through to resolution within the ERP system. The disposition/correction for the concern could be recorded within Fault Reports, MRB records, Support Issues (customer complaints), Supplier NCMR, the NCR module, the CAPA module, or otherwise within the document management system. Corrective or Preventive Actions require a plan, a target due date, an assigned owner, an effectiveness verification step, and a closure date.

Environmental Controls of the Cleanroom – Nordson MEDICAL has various processes in place for monitoring and controlling its' certified Class 8 cleanroom environments. Processes include controlling: personnel access and training, cleanroom garments, equipment and materials, maintenance access, cleaning protocol, air pressure differential, air particulate levels, and pest prevention. Annual recertification testing of cleanrooms to ISO 14644 Class 8 standards is conducted by a licensed 3rd party vendor. Monthly self-sampling tests of air particulate levels are performed to verify continued compliance to the Class 8 requirements. Additional specific details are shown below:

Manufacturing operations inside the cleanroom include: injection molding, assembly, inspection, packaging and finished goods inventory storage. Prior to shipment, products are double-bagged inside the cleanroom.

The cleanroom air management system is integrated into the building facility. Air controls include rooftop air handling units, fan filter units (using HEPA filters) and transfer fan return systems accessible via the walkable ceiling plenum space - all of which coordinate together to filter and automatically monitor the cleanroom air. The building management systems also monitors and controls air pressure, ensuring that positive pressure is maintained in the cleanroom. If any air control failures occur, the system automatically implements correction measures such as surrounding fan ramp-up, or alarms sent to the facilities department for investigation.

Pest Control is managed using a 3rd party, contracted pest control vendor. Inspections/service visits include insect and rodent control, and pesticide use according to specified requirements. Use of insecticide sprays is not allowed inside the cleanroom. Records of the pest control service activities are reviewed and maintained.

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Risk Management – Nordson MEDICAL uses a risk-based approach for managing various processes in the QMS, such as: Design and Development, Supplier Management, Incoming Inspection, Product Realization/Production Controls, Training, and Measurement, Analysis and Improvement.

Compliance with Laws and Regulatory Requirements:
Nordson MEDICAL complies with all applicable federal and environmental laws and ordinances. Procedures and work instructions are designed to comply with cGMP.

Code of Ethics:
Nordson MEDICAL's parent company, Nordson Corporation, defines its commitment to ethical behavior in the Nordson Code of Ethics and Business Conduct. Ethical behavior is expected both within the workplace among our employees, and as a business working in the marketplace with other businesses. For example, we do not condone or tolerate any kind of harassment, discrimination, bribes or involuntary/underage labor, and the company will not allow retaliation when employees report a concern in good faith. The Code of Ethics applies to all Nordson employees.

Current copies of the Nordson Code of Ethics and Business Conduct are available on our website: https://nordson.sharepoint.com/sites/Legal/Governance/default.aspx.

Product Change Notification Policy for Standard Products:
Nordson MEDICAL's policy is to notify customers for changes related to a product's form, fit or function. We endeavor to communicate proposed changes 90 days before implementation. Sometimes shorter notification times are unavoidable, and we ask for your understanding in such cases.

Customers who have purchased an affected standard part directly from Nordson MEDICAL within the previous 24 months are notified by email of the proposed change. No action by the customer is required to receive the email notifications regarding affected products purchased directly from Nordson MEDICAL.

Nordson MEDICAL's products are our proprietary designs with which we serve many diverse customers and markets. Therefore, we will not withhold changes to standard parts pending customer approval. However, in the event that any change we propose causes you concern, we will work closely with you to minimize or alleviate any negative impact.

Please note that this change notification policy does not apply to custom products (those products generally offered for sale to only one customer, and for which Nordson MEDICAL requires a signed drawing prior to initial manufacturing). All custom product changes are managed on a case by case basis, and in general, must be approved by the individual customer prior to implementation.

Changes are posted on the Nordson MEDICAL website:
https://www.nordsonmedical.com/Components-and-Technologies/Fluid-Management-Components/Support/Product-Change-Notifications/

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Product Specifications:

Nordson MEDICAL's standard products are designed and manufactured to proprietary specifications developed, maintained, and controlled under our certified Quality Management System. We do not verify any customer-supplied documents, dimensions, or specifications against our own controlled documentation for standard products; nor will we store, reference, or maintain any customer-specific information for use in our manufacturing, inspection, or packaging processes, other than those required for custom products or custom assemblies.

For the purpose of processing orders, no proprietary information is required from the buyer, and we specifically request that buyers refrain from including any information in their purchase orders which may be considered proprietary.

Upon customer request, we are glad to maintain and update customer part numbers for cross-referencing on order confirmations, packing slips, and invoices, as a courtesy and convenience for our customers. Nordson MEDICAL sends order confirmations for all orders processed; it is the customer's responsibility to review the confirmation and verify the cross-reference information for accuracy.

If a customer is seeking something other than what our standard products offer, Nordson MEDICAL does have the ability to provide custom components and assemblies to address your unique application and product requirements, through our Design Center. To discuss your custom request today, or to request changes to your current custom products, please contact our Sales Department at sales@nordsonmedical.com and we will be happy to work with you.

Certification of Conformance:

Certification of Conformance and Certificate of Origin statements are included with every shipped order. Nordson MEDICAL certifies that our products comply with all technical specifications stated on our website, catalog, and current part drawings at https://www.nordsonmedical.com/Resources/Part-Drawings. Products are dimensionally verified, and visually inspected to a 0.65 AQL. Certification documents include the order lot numbers and the material lot numbers used, providing full traceability of materials. Standard products are shipped bulk, non-sterile.

Confidentiality Agreements:

Typically, no exchange of confidential information occurs during the process of purchasing our standard products, and it is our practice that we do not enter into confidentiality agreements/non-disclosure agreements without specific intentions of pending confidential discussions.

Business Continuity and Disaster Recovery:

Nordson MEDICAL has an established program for maintaining continuity of production in case a disastrous event disrupts the business.

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Insurance:

Nordson MEDICAL procures and maintains liability insurance with a limit of not less than $5,000,000, and confirms the policy is reviewed on an annual basis.

Website Resources:

Nordson MEDICAL provides a wealth of information on our website, allowing customers to access our most current documentation at any time. Below are links to some commonly used webpages:

- Documented Assurance of Quality: https://www.nordsonmedical.com/Resources/Assurance-of-Quality
- FAQ's:https://www.nordsonmedical.com/Components-and-Technologies/Fluid-Management-Components/Support/FAQs/
- Product Information: https://www.nordsonmedical.com/Shop/Fluid-Management
- Product Changes, Notification: https://www.nordsonmedical.com/Components-and-Technologies/Fluid-Management-Components/Support/Product-Change-Notifications/
- General Conditions of Sale: http://www.nordson.com/en/our-company/resources/globalcos

This revision of our Documented Assurance of Quality will remain in effect until it is superseded. Please check our website for the most current revision.

Regards,

Brian Benton
Manufacturing and Quality Manager

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REVISION HISTORY		
DATE	**REV**	**DESCRIPTION OF CHANGE**
–	–	Reference IFS document history for prior changes
03/07/2017	G	Initial website release
05/02/2018	H	Removed the ISO year designations and reference to QP in the QMS section. Corrected all website links. Added descriptions of the new and revised QMS procedures. Updated contact email address in Product Specifications section. Updated header formatting.
06/04/2019	I	Removed reference to ISO 9001
07/10/2020	J	Modified retained sample duration. Added website link for Nordson Code of Ethics and Business Conduct.
08/28/2020	K	Including “Notified Body” in authorized Competent Authority Audits section
04/11/2023	L	Updated and/or removed obsolete website links. Updated retained sample duration. Updated Infrastructure section for multiple cleanrooms. Removed reference to FDA in Validation section. Removed reference to custom labels. Updated Quality Manager signature block.