Nordson MEDICAL
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DOCUMENTED ASSURANCE OF QUALITY

Document: 1036619	Revision: G	Effective Date: March 7, 2017

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 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 9001:2008 and ISO 13485:2003.
The Quality Policy, the Quality Manual and our current ISO certificates are available for download: http://www.nordsonmedical.com/default.aspx

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

- Document Control
- Quality Records
- Management Responsibility
- Training, Competence, and Awareness
- Infrastructure and Work Environment
- Product Planning, Design and Development
- Validation Master Plan
- Customer Related Processes
- Supplier Evaluation
- Identification and Preservation of Product
- Control of Monitoring and Measuring Equipment
- Customer Satisfaction
- Internal and External Audit
- Control of Nonconforming Products
- Customer Complaint Handling
- Corrective and Preventive Actions

Procedure/Topic Summary:

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, and vigorous data recovery tests 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 at least 7 years.

Management Responsibility – Management is committed to ensuring adequate resources are provided and implementing methods to accomplish the defined Quality Objectives. Management Reviews 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.

Infrastructure and Work Environment – A maintenance program is in place for the preventive and reactive work required to keep the building and production equipment in proper working order. Environmental conditions in the workplace are properly maintained.

Product Planning, 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. 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 and FDA 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.

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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 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 – Satisfaction is measured and monitored to ensure customer requirements are being met.

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.

Unannounced Notified Body Audits: Nordson MEDICAL understands that unannounced audits by our customers' Notified Body 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 a MRB investigation, including potential quarantine, and the disposition is documented. If a

nonconformance is discovered after product has already shipped 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 a recall will be borne by Nordson MEDICAL if the recall is due to a manufacturing issue caused by Nordson MEDICAL.

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 nonconforming 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.

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.

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.

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.

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Changes are also posted on the Nordson MEDICAL website
http://www.nordsonmedical.com/tech/product_changes_notification.aspx

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.

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.

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.

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. Additionally, customer part numbers can be provided on custom labels, if requested at the time of order placement (fees apply).

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, please contact our Design Center at designcenter@nordsonmedical.com and we will be happy to get started on your project.

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

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website, catalog, and current part drawings at www.nordsonmedical.com/default.aspx. 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. An example of our Certificate of Conformance and Certificate of Origin can be viewed at http://www.nordsonmedical.com/tech/product_certification.aspx

Environmental Controls:

Cleanroom Operations: The manufacturing operations at our Loveland, CO facility take place in a cleanroom environment certified to ISO 14644 Class 8 (formerly Class 100,000) standards. These manufacturing operations include the processes of injection molding, assembly, inspection, packaging and finished goods inventory storage. Prior to shipment, products are also double-bagged inside the cleanroom. All personnel working inside the cleanroom are first required to don proper cleanroom garments while in the transitional gowning room.

ISO 14644 Class 8 Certified: Our cleanroom is annually recertified by a licensed 3rd party certification vendor. We also perform regular self-monitoring of cleanroom pressure and particulate levels to confirm compliance through the year.

Air Control System: 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.

Housekeeping: Regular cleaning of the cleanroom is performed according to specified requirements, using a 3rd party, contracted janitorial vendor. Records of the cleaning activities are reviewed and maintained.

Pest Control: Regular inspections/service visits for pest control are performed 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.

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.

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.

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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: http://www.nordsonmedical.com/tech/quality_system.aspx

Product Information: http://www.nordsonmedical.com/products/fm_index.aspx

Product Changes, Notification: http://www.nordsonmedical.com/tech/product_changes_notification.aspx

Regulatory, Safety and Material Info: http://www.nordsonmedical.com/tech/material_information.aspx

Ordering FAQ's: http://www.nordsonmedical.com/orders/order_faqs.aspx

Technical FAQ's: http://www.nordsonmedical.com/tech/technical_faqs.aspx

General Conditions of Sale: http://terms.nordson.com/GCOS/NordsonMED-US.pdf

This Documented Assurance of Quality will remain in effect until it is superseded.

Regards,

Jordan Berkel
Quality and Regulatory Manager

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REVISION HISTORY		
DATE	**REV**	**DESCRIPTION OF CHANGE**
–	–	Reference IFS document history for prior changes
03/7/2017	G	Initial website release