Validation Summary Report

Loveland Manufacturing Facility

Nordson MEDICAL
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nordsonmedical.com

Validation Summary Report

DATE: February 11th, 2016
SCOPE: **Loveland Manufacturing Facility**

Dear Valued Customer,

The purpose of this summary report is to communicate the qualification and validation activities that Nordson MEDICAL has performed during our transfer of manufacturing operations to our new Loveland, Colorado facility.

These activities were intended to provide assurance that the Value Plastics line of products manufactured by Nordson MEDICAL at our new facility will continue to meet all technical specifications and regulatory requirements. These manufacturing operations will continue to use the same quality system, materials, equipment, tools, manufacturing processes, and personnel as our previous facility.

The transfer of manufacturing operations will progress in a staged manner, with essential facilities being qualified, followed by the material handling systems, primary production equipment, and finally the supporting equipment and operations.

These activities were performed in accordance with Nordson MEDICAL corporate policy requirements as stated in the Validation Master Plan (VMP7.1), the Validation Master Plan for Value Plastics Facility Move (1034722), and all applicable regulatory requirements. Specific records of these activities are maintained by Nordson MEDICAL.

Please contact us with any further questions you may have. Thank you for your continued interest in Nordson MEDICAL's products.

Sincerely,

Robert Haynes
Regulatory Affairs

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Due to the thousands of catalog Value Plastics products Nordson MEDICAL offers, each of which can be produced on multiple machines and molds, it is not possible to conduct a part specific validation. Instead, the facility move validation is focused on the performance of equipment. The intent is to show that the new facility operates within designed parameters and that equipment transferred to this facility operates in a manner consistent and functionally equivalent with past operations.

The scope of this validation summary is limited to production machines that were purchased for the new facility, or equipment that was moved from our previous facility, and to processes that are used to produce catalog components. The primary focus of the facility validation is on the injection molding machines that produce the majority of our products. Validations for customer specific assemblies and processes are handled on an individual basis.

As always, Nordson MEDICAL's robust quality and inspection processes are used to ensure our products meet their specifications and requirements.

Facilities Qualifications			
Item	Summary	Date	Status
Certificate of Occupancy	Facility approved for occupancy	June 9, 2015	Issued
ISO 14644 Class 8 Clean Room Certification	Particle Count & Airflow Testing	July 9, 2015	Certified
Material Handling Systems	Operating Logic & Risk Assessment	July 14, 2015	Complete
Material Handling Systems	Vendor Installation Qualification	July 24, 2015	Complete
Material Handling Systems	Vendor Operational Qualification	August 26, 2015	Complete
Material Handling Systems	Vendor Performance Qualification	September 2, 2015	Complete
Material Handling Systems	Nordson MEDICAL Qualification	February 11, 2016	Complete
Compressed Air System	Installation Qualification	April 28, 2015	Complete
Chilled Water System	Verification	July 30, 2015	Complete
Air and Water systems	Balancing Report	September 21, 2015	Complete
Commissioning Report	Facilities Mechanical & Electrical	June 22, 2015	Complete
ISO 13485 certification*	Update Third Party Certification	October 13, 2015	Issued

*see www.nordsonmedical.com/tech/index.aspx for updated ISO certifications

Assembly, Packaging, & Quality Equipment Qualifications			
Item	Summary	Date	Status
Quality Inspection Equipment – CMM & Scope	Calibration	August 4, 2015	Complete
Packaging Equipment	IQ, PQ	September 30, 2015	Complete
Stopcock Assembly Automation	IQ, PQ	October 9th, 2015	Complete
Assembly Equipment	Ultrasonic welders, o-ring machine, automatic tubesetters	October 14th, 2015	Complete

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Injection Molding Machine Qualifications			
Item	Summary	Date	Status
Installation Qualification	Machine Installation	Final IQs – Complete 9/14/2015	Complete
Installation Qualification	Water Leak Detection Equipment		
Installation Qualification	Servo Robot / Sprue Picker		
Installation Qualification	Temperature Controller		
Operational Qualification	Injection Position Calibration	Final OQs – Complete 9/14/2015	Complete
Operational Qualification	Injection Velocity Calibration		
Operational Qualification	Injection Pressure Calibration		
Operational Qualification	Temperature Calibration		
Operational Qualification	Extruder RPMs Calibration		
Operational Qualification	Tonnage Calibration		
Process Qualification	Start up Dimensional Verification	Final PQs – Complete 10/5/2015	Complete
Process Qualification	Production Record Review		
Process Qualification	Historical Dimensional Comparison		
Process Qualification	Process Parameter Review		
Process Qualification	Review of any Deviations		
2 Shot Molding Machine	IQ,OQ, PQ	9/25/2015	Complete

Supporting Equipment			
Item	Summary	Date	Status
R & D Lab Equipment	Calibration	June 25, 2015	Complete
R & D Lab Equipment - 3D printer	Installation Qualification	June 15, 2015	Complete
Tool Room Equipment - CNCs, Lathes, EDMs	Verification	August 12, 2015	Complete
Mold transfer	Verification – as sent / as received	October 3, 2015	Complete

Please see http://www.nordsonmedical.com/news/mfg_facility_location.aspx for more information, including frequently asked questions, and the facility validation master plan.