CERTIFICATE

Number: 3822461

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Nordson MEDICAL (CA), LLC

7612 Woodwind Drive Huntington Beach, CA 92647 United States of America

including the implementation meets the requirements of the standard:

ISO 13485:2016

Scope:

Contract manufacturing of medical products with contract engineering services. Contract manufacturing processes include polymer solution casting, assembly, kitting, and packaging operations for catheters, cannulae, and tubing for applications such as cardiovascular, cardiopulmonary, peripheral access, neurovascular and gastrointestinal access. Additional processes include ultrasonic welding, injection molding, assembly and packaging for fluid management fittings, connectors, applicators and regulators used in the delivery of bone-graft and other biomaterials.

Certificate expiry date: 23 November 2025
Certificate effective date: 31 January 2023
Certified since: 15 September 2011

This certificate is valid for the organization(s) and/or locations mentioned on/the addendum.

DEKRA Certification B.V.

B.T.M. Holtus Managing Director J.M.A. McKenzie Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 3822461

The management system of the organization(s) and/or location(s) of:

Nordson MEDICAL (CA), LLC

7612 Woodwind Drive Huntington Beach, CA 92647 United States of America

Certified organization(s) and/or locations:

Different scope

Nordson MEDICAL (CA), LLC Carretera International KM129, Salida Norte, Sin Numero Parque Industrial Roca, Fuerte Guaymas, Sonora Mexico C.P 85400 Mexico Contract manufacturing of medical products with contract engineering. Contract manufacturing processes include polymer solution casting, assembly, kitting, and packaging operations for catheters, cannulae, and tubing for applications such as cardiovascular, cardiopulmonary, peripheral access, neurovascular and gastrointestinal access. Additional processes include ultrasonic welding, injection molding, assembly and packaging for fluid management fittings, connectors, applicators and regulators used in the delivery of bone-graft and other biomaterials.

Addendum expiry date: 23 November 2025
Addendum effective date: 31 January 2023