

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

NeuMoDx Molecular, Inc.

1250 Eisenhower Place
Ann Arbor
Michigan
48108
USA

Holds Certificate Number:

FM 675459

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design and development, production, installation, servicing, and distribution of in-vitro diagnostic analyzers/instruments, assay test reagents and consumables used in the detection of infectious diseases.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-11-17

Latest Revision Date: 2022-09-15

Effective Date: 2022-08-26

Expiry Date: 2024-11-16

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Certificate No: FM 675459

Location	Registered Activities
NeuMoDx Molecular, Inc. 1250 Eisenhower Place Ann Arbor Michigan 48108 USA	The design and development, production, installation, servicing, and distribution of in-vitro diagnostic analyzers/instruments, assay test reagents and consumables used in the detection of infectious diseases.
NeuMoDx Molecular, Inc. 1220 Eisenhower Place Ann Arbor Michigan 48108 USA	Production and Distribution of IVD instrumentation, assay test reagents and consumables.
NeuMoDx Molecular, Inc. 1100 Eisenhower Place Ann Arbor Michigan 48108 USA	Production and Distribution of IVD instrumentation, assay test reagents and consumables.
NeuMoDx Molecular, Inc. 1220 Victors Way Ann Arbor Michigan 48108 USA	Servicing of IVD instrumentation, assay test reagents and consumables.
NeuMoDx Molecular, Inc. 1320 Victors Way Ann Arbor Michigan 48108 USA	Administrative Support.

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

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Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.