

# 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

Facility ID Number: F005708

Holds Certificate No:

**MDSAP 755013**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Brazil:** RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

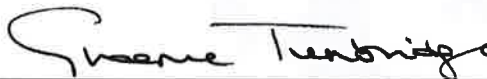
**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

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: 2022-08-26

Effective Date: 2022-08-26

Expiry Date: 2024-11-16



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 755013**

Location	Registered Activities
NeuMoDx Molecular, Inc. 1250 Eisenhower Place Ann Arbor Michigan 48108 USA Facility ID Number: F005708	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 Facility ID Number: F005708	Production and Distribution of IVD instrumentation, assay test reagents and consumables.
NeuMoDx Molecular, Inc. 1100 Eisenhower Place Ann Arbor Michigan 48108 USA Facility ID Number: F005708	Production and Distribution of IVD instrumentation, assay test reagents and consumables.
NeuMoDx Molecular, Inc. 1220 Victors Way Ann Arbor Michigan 48108 USA Facility ID Number: F005708	Servicing of IVD instrumentation, assay test reagents and consumables.
NeuMoDx Molecular, Inc. 1320 Victors Way Ann Arbor Michigan 48108 USA Facility ID Number: F005708	Administrative Support.

Original Registration Date: 2022-08-26

Effective Date: 2022-08-26

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This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](https://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.