



DECLARATION OF CONFORMITY NEUMODX™ CMV QUANT ASSAY

MANUFACTURER

NeuMoDx Molecular, Inc.
1250 Eisenhower Place
Ann Arbor, MI 48108 USA
Tel: +1-734-477-0111 / Fax +1-734-477-0130
Website: www.neumodx.com

NOTIFIED BODY

BSI Group The Netherlands B.V., NB 2797
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Netherlands

AUTHORIZED REPRESENTATIVE



Emergo Europe B.V.
Prinsessegracht 20
2514 AP, The Hague
The Netherlands
Tel: +31 (0) 70 345 8570



RISK CLASSIFICATION

IVD Device under Annex II List B- Moderate Risk per IVD Directive 98/79/EC.

CONFORMITY ASSESSMENT ROUTE

IVD Directive 98/79/EC, Annex IV excluding Sections 4 and 6.

PRODUCTS

PRODUCT NAME:	CATALOG No.
NeuMoDx™ CMV Quant Test Strip	201400
NeuMoDx™ CMV Calibrators	800400
NeuMoDx™ CMV External Controls	900401

DECLARATION STATEMENT

I hereby declare that the above-mentioned products comply with the European In Vitro Diagnostic Directive (IVDD) 98/79/EC under Annex IV excluding Sections 4 and 6 and its relevant transposition into national laws of the member states into which NeuMoDx Molecular, Inc. is solely responsible for the placement of the above-mentioned products under CE# 687321.

AUTHORITY NAME(S) AND TITLE(S)

Name: Autumn Collasius	Title: VP, Head of Global Regulatory Affairs
Signature:	Date: 27 APRIL 2022

Addendum to the Original Declaration of Conformity

As of January 1, 2023, the address of the NeuMoDx Molecular, Inc. EU Authorized Representative as listed on the original DoC has changed as follows.

OLD ADDRESS AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

NEW ADDRESS AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

COMPANY REPRESENTATIVE: Autumn Collasius

TITLE: Vice President, Head of Global Regulatory Affairs

DATE: 14/04/2023

SIGNATURE:


