

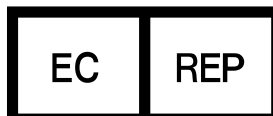
MANUFACTURER

NeuMoDx Molecular, Inc.
 1250 Eisenhower Place
 Ann Arbor, MI 48108 USA
 Tel: 734-477-0111 / Fax 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 A- High Risk per IVD Directive 98/79/EC.

CONFORMITY ASSESSMENT ROUTE

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

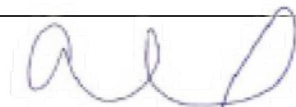
PRODUCTS

PRODUCT NAME:	CATALOG No.
NeuMoDx™ HCV Quant Test Strip	300300
NeuMoDx™ HCV Calibrators	800202
NeuMoDx™ HCV External Controls	900202
NeuMoDx™ HCV Calibrators	800200
NeuMoDx™ HCV External Controls	900201

DECLARATION STATEMENT

I hereby declare that the above-mentioned products comply with the European In Vitro Diagnostic Directive (IVDD) 98/79/EC 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# 699735. We also certify that the Essential Requirements of Annex I of IVDD 98/79/EC and its associated Common Technical Specifications (CTS)-2002/364/EC and amending decision (2009/108/EC) have been met and documented.

AUTHORITY NAME(S) AND TITLE(S)

Name: Autumn Collasius	Title: VP, Head of Global Regulatory Affairs
Signature: 	Date: 05May2022

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:

