

DECLARATION OF CONFORMITY NEUMODX™ HBV QUANT ASSAY

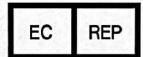
MANUFACTURER

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

AUTHORIZED REPRESENTATIVE

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



Emergo Europe B.V. Prinsessegracht 20 2514 AP, The Hague The Netherlands Tel: +31 (o) 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™ HBV Quant Test Strip	201300
NeuMoDx™ HBV Calibrators	800102
NeuMoDx™ HBV External Controls	900102
NeuMoDx™ HBV Calibrators	800100
NeuMoDx™ HBV External Controls	900101

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# 687320. 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: 27APRIL2022

NeuMoDx Molecular, Inc.

CONFIDENTIAL

P/N DOC-201300 (v2.0)_Rev C April 2022 TMP-1453 A



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	+31.70.345.8570 - phone	
	2514 AP The Hague	EmergoEurope@ul.com	
	The Netherlands	100 1000	

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

COMPANY REPRESENTATIVE: Autumn Collasius

TITLE: Vice President, Head of Global Regulatory Affairs

DATE: 14/04/2023

SIGNATURE:

