



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

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™ 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: 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:


