EU Declaration of Conformity

as per ANNEX IV of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices

NeuMoDx molecular

NeuMoDx Molecular, Inc.
1250 Eisenhower Place
Ann Arbor, MI 48108, USA

SRN / Single Registration Number
US-MF-000009823

EC REP Emergo Europe B.V.
Westervoortedijk 60;
6827 AT, Arnhem, The Netherlands

SRN / Single Registration Number
NL-AR-000000116

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the below mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives:

Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Product Name	REF	Basic UDI-DI
NeuMoDx™ 288 Molecular System	500100	0814278025001009P
NeuMoDx™ 96 Molecular System	500200 500201	0814278025002009U 4053228IMOLSYSNMX000001V9

Intended Purpose

The NeuMoDx™ 288 Molecular System is intended for in vitro diagnostic (IVD) use in performing NeuMoDx validated nucleic acid testing in clinical laboratories. The NeuMoDx 288 Molecular System is capable of automated extraction and isolation of nucleic acids from multiple specimen types, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The system is capable of providing functionality to enable laboratories to develop qualitative and quantitative tests, which use NeuMoDx-provided consumables and reagents.

The NeuMoDx™ 96 Molecular System is intended for in vitro diagnostic (IVD) use in performing NeuMoDx validated nucleic acid testing in clinical laboratories. The NeuMoDx 96 Molecular System is capable of automated extraction and isolation of nucleic acids from multiple specimen types, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The system is capable of providing functionality to enable laboratories to develop qualitative and quantitative tests, which use NeuMoDx-provided consumables and reagents.

RISK CLASS ☒ A ☐ B ☐ C ☐ D

CONFORMITY ASSESSMENT PROCEDURE
ANNEX II+III Conformity Assessment

Digitally signed by Ceaicovschi Tudor
Date: 2024.02.19 15:39:56 EET
Reason: MoldSign Signature
Location: Moldova

On behalf of NeuMoDx Molecular, Inc.

Ann Arbor, 2024-01-09

Autumn Collasius
VP, Head of Global Regulatory Affairs

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