

DECLARATION OF CONFORMITY

Legal Manufacturer's Name:

Luminex Molecular Diagnostics, Inc.

Legal Manufacturer's Address:

439 University Avenue

Toronto, ON, Canada M5G 1Y8

Single Registration Number:

Not Available

Declares under our sole responsibility that the product

Basic UDI: 0840847NxTAGRPPX2

Product Name: NxTAG[®] Respiratory Pathogen Panel

Code Number: I051C0449

Risk Class: General IVD

GMDN: 47922

The undersigned declares that this product is designed, developed, and manufactured according to EN ISO 13485:2016, and fulfills the obligations imposed by "Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on in vitro diagnostic medical devices" in accordance with Annex I: Essential Requirements and Annex III: EC Declaration of Conformity (Article 6 is not applicable).

Applied Common Specifications: Not Applicable

Reference to the applied harmonized standards is listed in the Technical Documentation.

Conformity Assessment Procedure: Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on in vitro diagnostic medical devices

Notified Body Details: Not applicable – Self Certified

EC Certificate Number: N/A

European Authorized Representative: Single Registration Number: IT-AR-000029423

DiaSorin Italia S.p.A.

Via Crescentino, snc

13040 Saluggia (VC) – Italia

Person keeping the Technical Documentation: TRR-732-045-002, CE Technical File for NxTAG Respiratory Pathogen Panel, Bojana Ilic, Manager, Regulatory Affairs, Phone +1437-371-5458

Place and Date Toronto, Canada: Agile 10/19/2023, 89-30000-00-546 Rev K

Electronically signed by: Maria
McChesney
Reason: By entering my electronic
signature I acknowledge this to be
the legally binding equivalent of
my handwritten signature.
Date: Oct 19, 2023 12:54 EDT

Maria McChesney

Maria McChesney
Personal Responsible for Regulatory Compliance

Electronically signed by: Duff Ying
Reason: By entering my electronic
signature I acknowledge this to be
the legally binding equivalent of
my handwritten signature.
Date: Oct 19, 2023 13:20 EDT



Duff Ying
Site General Manager

I051C0449– Rev K










89-30000-00-546

Final Audit Report

2023-10-19

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By:	Maria McChesney (mmcchesney@luminexcorp.com)
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