Declaration of Conformity

Product Identification

Product Name: Nxtag® Respiratory Pathogen Panel

Manufacturer

Name: Luminex Molecular Diagnostics, Inc.
Address: 439 University Avenue
          Toronto, ON, Canada M5G 1Y8
Country: Canada
Representative: Bojana Ilic, Manager, Regulatory Affairs

Authorised European Representative within European Union (EU)

Name: Winckels Medical Devices Expertise
Registered Address: WMDE B.V.
                  Bergerweg 18
                  6085 AT Horn
                  The Netherlands
EU Country: The Netherlands

Notified Body

Name: Not applicable (Self-Declaration)
EU Country: Not Applicable

Means of Conformity


Approval Signature

Bojana Ilic (Manager, Regulatory Affairs) 03/21/2022

PN: 89-30000-00-546 Rev. H  Effective Date: 03/21/2022
Description

NxTAG® Respiratory Pathogen Panel is a qualitative test intended for the simultaneous detection and identification of nucleic acids from multiple respiratory viruses and bacteria extracted from nasopharyngeal swabs, bronchoalveolar lavages (BALs), nasal and tracheal aspirates, nasal washes, sputum, and throat swabs collected from individuals with clinical signs and symptoms of respiratory tract infection. It incorporates multiplex Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) with the Luminex® proprietary universal tag sorting system on the Luminex® MAGPIX® instrument to easily detect respiratory pathogen targets.

Classification

General IVD

List of System Components

<table>
<thead>
<tr>
<th>Description</th>
<th>Format</th>
<th>Catalogue Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>NxTAG® Respiratory Pathogen Panel</td>
<td>Kit Reagents</td>
<td>I051C0449</td>
</tr>
<tr>
<td>NxTAG® RPP (Files)</td>
<td>Kit Software</td>
<td></td>
</tr>
<tr>
<td>SYNCT™</td>
<td>Software</td>
<td>CN-SW47</td>
</tr>
</tbody>
</table>

Applicable Standards

- EN ISO 13485: 2016 - Quality Management Systems: Medical Devices-System
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN ISO 14971:2019 - Medical Devices: Application of Risk Management to Medical Devices
- ISO 18113-1:2011 In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 1: Terms, definitions and general requirements
- ISO 18113-2:2011 In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 2: In vitro diagnostic reagents for professional use
- ISO 15223-1:2016 – Medical Devices Symbols to be used with Medical Devices Labels, Labeling and information to be supplied
- CLSI Guidances as listed in The Essential Requirements Checklist - TRR-732-045-001
- Other ancillary standards indicated in the Technical File – TRR-732-045-002

Applicable Regulations

- EU In Vitro Diagnostic Directive (98/79/EC)
- USA FDA 21 CFR 820
- Canadian Medical Device Regulations