MANUFACTURER’S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

Full Quality Assurance Procedures

This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the devices stated in the attached Schedule.

Reference: Schedule – Luminex Molecular Diagnostics, Inc. Class 3 IVD

Manufacturer’s Name: Luminex Molecular Diagnostics, Inc.

Business Address: Luminex Molecular Diagnostics, Inc.
439 University Avenue,
Toronto, Ontario
M5G 1Y8
Canada

IVD Medical Device(s): xTAG® Gastrointestinal Pathogen Panel (GPP)

Classification: Class 3 IVD

GMDN Code and Term: 61058, Multiple-viruses IVDs

Scope of Application: All Devices

Each kind of IVD medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable classification rules and essential principles, at each stage from the design of the device until its final inspection before being supplied.

This declaration is being made on the basis of the following certificates:

Full Quality Management System Certificate:
ISO 13485:2016 under MDSAP
Assessment Body: TUV Rhineland of North America
Certificate Number: MD 748849 156225-30

Design Examination Certificate: N/A

Conformity Assessment Standards Applied:

- EN ISO 13485:2016 - Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
- EN ISO 14971:2012 Medical Devices - Application of Risk Management to Medical Devices
- ISO 15223-1:2016 – Medical Devices Symbols to be used with Medical Devices Labels, Labeling and information to be supplied
- 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
- GHTF Design Control Guidance (SG3 99.9) - Biosafety in Microbiological and Biomedical Laboratories (BMBL) 4th Edn.
- MM17-A: Verification and Validation of Multiplex Nucleic Acid Assays
- CLSI Guidances:
  - EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices
  - EP14-A2: Evaluation of Matrix Effects; Approved Guideline
  - GP18-A: Laboratory Design; Approved Guideline

**Authorised Signatory:**

_________________________________________  ______________________________
Jennifer Grimes                             Date
Manager, Regulatory Affairs
MANUFACTURER’S DECLARATION OF CONFORMITY:

Luminex

Schedule - Luminex Molecular Diagnostics, Inc. Class 3 IVD

<table>
<thead>
<tr>
<th>Product Catalogue Number</th>
<th>Product Name</th>
<th>Class</th>
<th>GMDN Term:</th>
<th>GMDN Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>I032C0415</td>
<td>xTAG® Gastrointestinal Pathogen Panel (GPP)</td>
<td>3</td>
<td>Multiple-viruses IVDs</td>
<td>61058</td>
</tr>
</tbody>
</table>

Authorised Signatory:

______________________  __________________
Jennifer Grimes        Date
Manager, Regulatory Affairs