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DECLARATION OF CONFORMITY

Legal Manufacturer's Name: Luminex Corporation
Legal Manufacturer's Address:
12212 Technology Blvd
Austin, TX 78727
USA

Single Registration Number:
Not Yet Issued

Declares under our sole responsibility that the product

Basic UDI: 0840847ARIES
Product Name: ARIES SARS-CoV-2 Assay
(24 Cassettes)
Risk Class: General IVD
GMDN Code: 64747

Code Number: 50-10051

Basic UDI:0840847ARIES
Protocol File Kit, ARIES SARS-CoV-2
Assay (CE-IVD)
Risk Class: General IVD
GMDN Code: 64747

Code Number: CN-0534-01

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:

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

Luminex Corporation

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Revision: C

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Notified Body Details: Not Applicable – Self Certified

EC Certificate Number: N/A

European Authorized Representative:
DiaSorin Italia S.p.A.
Via Crescentino,snc
13040 Saluggia (VC)
Italy

Single Registration Number:
IT-AR-000029423

Person Keeping the Technical Documentation:

Place and Date: Agile NOV/16/2023, 89-30000-00-797, Rev C

Electronically signed by: Jack Hartnett
Reason: By entering my electronic signature
I acknowledge this to be the legally binding
equivalent of my handwritten signature.
Date: Nov 16, 2023 13:57 CST

Jack Hartnett, Sr. Manager of Quality
Person Responsible for Regulatory
Compliance

Electronically signed by: Jack Hartnett
Reason: By entering my electronic signature
I acknowledge this to be the legally binding
equivalent of my handwritten signature.
Date: Nov 16, 2023 13:57 CST

Jack Hartnett, Sr. Manager of Quality
Site General Manager