Luminex®

Declaration of Conformity

Product Identification

Product Name: ARIES® SARS-CoV-2 Assay

Manufacturer

Name: Luminex Corporation

Address: 12212 Technology Blvd.
Austin, Texas 78727

Country: United States

Representative: Wendy Ricker, Director, 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

The undersigned declares that this product is designed, developed, and manufactured according to EN ISO 13485:2016, and fulfils 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 (Section 6 is not applicable).

Approval Signature

Wendy Ricker
Wendy Ricker (Director, Regulatory Affairs)

3/10/2021
Date

CE

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Description

ARIES® SARS-CoV-2 Assay is a Real-Time reverse-transcriptase polymerase chain reaction (RT-PCR) based qualitative in vitro diagnostic test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 (ORF1ab and N gene) in nasopharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider. The ARIES SARS-CoV-2 Assay is indicated for use with the ARIES Systems.

Classification

General IVD

List of System Components

Description	Format	Catalogue Number
ARIES® SARS-CoV-2 Assay Kit	Reagents	50-10051
ARIES® SARS-CoV-2 Assay Protocol File	USB	CN-0534-01

Applicable Standards

- EN ISO 13485:2016 - Quality Management Systems: Medical Devices-System
- EN ISO 23640:2015 - In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN ISO 14971:2012 - 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 - 03583
- Other ancillary standards indicated in the Technical File – 03741

Applicable Regulations

- EU In Vitro Diagnostic Directive (98/79/EC)
- Regulation 1272/2008 – Classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006