



# Declaration of Conformity

## PRODUCT IDENTIFICATION

Product name	Model/number
2019-nCoV Test Devices Quick Profile™ COVID-19 IgG/IgM Test Card QuickProfile™ 2019-nCoV IgG/IgM Test Card	71108 71108B

## MANUFACTURER

Name of company	Address	Representative
LumiQuick Diagnostics, Inc.	2946 Scott Blvd. Santa Clara, CA 95054 USA	Chih-Chieh Wang

## AUTHORIZED REPRESENTATIVE

Name of company	Address	Telephone/email
Lotus NL B.V.	Koningin Julianaplein 10, 1e Verd 2595AA The Hague, Netherlands	+31.64.517.1879 - phone peter@lotusnl.com

## CONFORMITY ASSESSMENT

Device classification	Route to compliance	Standards applied
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	ISO 13485:2016

LumiQuick Diagnostics, Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

**COMPANY REPRESENTATIVE:** Chih-Chieh Wang

**TITLE:** Director, QA/RA

**SIGNATURE:** \_\_\_\_\_