



LumiQuick Diagnostics, Inc.
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Declaration of Conformity

PRODUCT IDENTIFICATION

Product name	Model/number
2019-nCoV Test Devices QuickProfile 2019-nCoV IgG/IgM Duo Test Card QuickProfile 2019-nCoV IgG/IgM Combo 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
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax EmergoEurope@ul.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

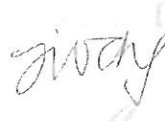
LumiQuick Diagnostics, Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Chih-Chieh Wang

TITLE: Quality Systems Manager

DATE: 17/03/2020

SIGNATURE:


Digitally signed by Jeff Wang
DN: cn=Jeff Wang,
o=LumiQuick Diagnostics, Inc.,
ou=Quality Systems Manager,
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Date: 2020.03.17 15:29:14
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