



LumiQuick Diagnostics, Inc.

2946 Scott Blvd., Santa Clara, CA 95054, USA

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Web: www.lumiquick.com

Declaration of Conformity

PRODUCT IDENTIFICATION

Product name	Model/number
Cardiac Marker Test Devices	
QuickProfile Troponin I Serum Test Card	75001
QuickProfile Troponin I Whole Blood Test Card	75002
QuickProfile Cardiac Panel Serum Test Card	75003
QuickProfile Cardiac Panel Whole Blood Test Card	75004
QuickProfile Myoglobin Serum Test card	75005
QuickProfile Myoglobin Whole Blood Test Card	75006
QuickProfile CK-MB Serum Test Card	75007
QuickProfile CK-MB Whole Blood Test Card	75008
QuickProfile Troponin I Strip	75009
QuickProfile CK-MB Strip	75010
QuickProfile Myoglobin Strip	75011

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

SIGNATURE:

DATE: 26/07/2018

EC_Declaration_Letter_Emergo_E3R0_Iso2016+NewEuRepEmail

