



LumiQuick Diagnostics, Inc.

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

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E-mail: info@LumiQuick.com

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## 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	Jeff 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 europe@emergogroup.com

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	ISO 13485:2003

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:** Jeff Wang

**TITLE:** Quality Systems Manager

**DATE:** 28/04/2017

**SIGNATURE:**