



Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model/number	
Infectious diseases		
HIV I&II Test Strip	71001	
HIV I&II Test Card	71002	
HCV Antibody Test Card	71030	
HBsAg Test Card	71004	

MANUFACTURER		
Name of company	Address	Representative
LumiQuick Diagnostics, Inc.	2946 Scott Blvd. Santa Clara, CA 95054 USA	Jeff C. Wang

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Molenstraat 15 2513 BH The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax service@emergogroup.com

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class: Self-Certify		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 C. Wang

TITLE: Quality Systems Manager

SIGNATURE:

Date:
2017.02.23
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DATE: 23/02/2017