



Declaration of Conformity

PRODUCT IDENTIFICATION

Product name	Model/number
Fecal Occult Blood Test Devices QuickProfile Fecal Occult Blood Test Card QuickProfile Fecal Occult Blood Test Strip	72001 72006

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

SIGNATURE:

DATE: 28/04/2017