



LumiQuick Diagnostics, Inc.
2946 Scott Blvd., Santa Clara, CA 95054, USA

Tel: 1-408-855-0061
Fax: 1-408-855-0063
E-mail: info@lumiquick.com
Website: www.lumiquick.com

STATEMENT

We, **LumiQuick Diagnostics Inc.** having a registered office at 2946 Scott Blvd, Santa Clara, CA 95054, USA assign **SRL Sanmedico** having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Signature:

A handwritten signature in black ink, appearing to read 'Charles Yu', written over a horizontal line.

Name: Charles Yu

Title: President

Date: March 4, 2020





By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

LumiQuick Diagnostics, Inc.
2946 Scott Blvd
Santa Clara
California
95054
USA

Holds Certificate No:

FM 574919

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development, manufacture and distribution of in vitro diagnostics test kits and reagents used in the diagnosis and management of disease status, including Infectious Diseases tests, Drugs of Abuse tests, Cardiac Monitor tests, Cancer Marker tests, Fertility Hormone tests, ELISA tests & Urine Chemistry tests.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2011-10-20

Latest Revision Date: 2018-11-21

Effective Date: 2017-10-20

Expiry Date: 2020-10-19



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...making excellence a habit.™

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.



Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model/number	
Legionella Test Devices		
QuickProfile Legionella Test Card	71034	
QuickProfile Legionella Test Strip	71035	
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



Declaration of Conformity

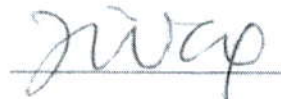
PRODUCT IDENTIFICATION		
Product name	Model/number	
Cardiac Marker Test Devices		
QuickProfile Troponin I Serum Test Card	75001	
QuickProfile Troponin I Whole Blood Test Card	75002	
QuickProfile Cardiac Panel Serum Test Card	75003	
QuickProfile Cardiac Panel Whole Blood Test Card	75004	
QuickProfile 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 europa@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

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COMPANY REPRESENTATIVE: Jeff Wang

TITLE: Quality Systems Manager

SIGNATURE:



DATE: 28/04/2017



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

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TITLE: Quality Systems Manager

SIGNATURE:

DATE: 28/04/2017



Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model/number	
H. Pylori Ab/Ag Test Devices		
QuickProfile H. Pylori Antigen Test Card	71020	
QuickProfile H. Pylori Antibody Test Card Whole Blood	71024	
QuickProfile H. Pylori Antibody Test Card-Serum	71046	
QuickProfile H. Pylori Antigen Test Strip	71061	
QuickProfile H. Pylori Antibody Serum Test Strip	71064	
QuickProfile H. Pylori Antibody WB Test Strip	71086	
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

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COMPANY REPRESENTATIVE: Jeff Wang

TITLE: Quality Systems Manager

SIGNATURE:

DATE: 28/04/2017



Declaration of Conformity

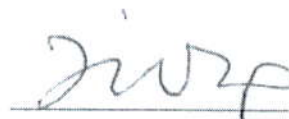
PRODUCT IDENTIFICATION		
Product name	Model/number	
Syphilis Test Devices		
QuickProfile Syphilis Test Strip (Serum)	71015	
QuickProfile Syphilis Test Card (Whole Blood)	71016	
QuickProfile Syphilis Test Card (Serum)	71057	
QuickProfile Syphilis Test Strip (Whole Blood)	71077	
MANUFACTURER		
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Name of company	Address	Telephone/email
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CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	ISO 13485:2003

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COMPANY REPRESENTATIVE: Jeff Wang

TITLE: Quality Systems Manager

SIGNATURE:



DATE: 28/04/2017



Declaration of Conformity

PRODUCT IDENTIFICATION

Product name	Model/number
Drugs of Abuse Test Devices See attachment for complete list of items in this family	

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	Annex III of IVDD 98/97/EC Council Directive	ISO 13485:2003

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COMPANY REPRESENTATIVE: Jeff Wang (a.k.a Chih-Chieh Wang)

TITLE: Quality Systems Manager

SIGNATURE:

PRINT DATE: 20/01/2014



LumiQuick Diagnostics, Inc.

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

Tel: 408-855-006
Fax: 408-855-006
E-mail: info@LumiQuick.com
Web: www.lumiquick.com

60	QuickProfile DOA-11 Panel Test	74053
61	QuickProfile DOA-11 Panel Test Card	74053-TC
62	QuickProfile DOA-12 Panel Test	74054
63	QuickProfile DOA-12 Panel Test Card	74054-TC
64	QuickProfile Methylphenidate (MPD) Test Strip	74055
65	QuickProfile Methylphenidate (MPD) Test Card	74056
66	QuickProfile Fentanyl Test Strip	74057
67	QuickProfile Fentanyl Test Card	74058
68	QuickProfile Clonazepam Strip	74059
69	QuickProfile Clonazepam Test Card	74060
70	QuickProfile Cotinine Test Strip	74061
71	QuickProfile Cotinine Test Card	74062
72	QuickProfile K2 Test Strip	74065
73	QuickProfile K2 Test Card	74066

INITIAL:

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20/01/2014