



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

Date: February 13, 2018

LETTER OF AUTHORIZATION

To whom it may concern:

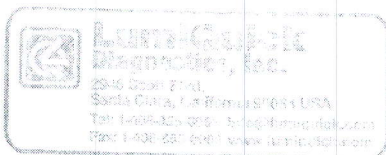
We, LumiQuick Diagnostics Inc. having a registered office at 2946 Scott Blvd, Santa Clara, CA 95054, USA, assign Sanmedico SRL having a registered office at str. A. Corobceanu 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 98/79/EEC.

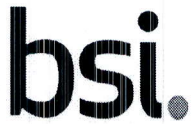
We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This authorization letter is valid until February 28, 2020.

Best regards,

Charles Yu
President





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



Page: 1 of 1

...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.



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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



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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

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

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CONFORMITY ASSESSMENT

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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	72001
QuickProfile Fecal Occult Blood Test Strip	72006

MANUFACTURER		
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Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	ISO 13485:2003

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TITLE: Quality Systems Manager

SIGNATURE: 

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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		
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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
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

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CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
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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

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

AUTHORIZED REPRESENTATIVE

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CONFORMITY ASSESSMENT

Device classification	Route to compliance	Standards applied
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COMPANY REPRESENTATIVE: Jeff Wang (a.k.a Chih-Chieh Wang)

TITLE: Quality Systems Manager

SIGNATURE:

PRINT DATE: 20/01/2014



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Web: www.lumiquick.com

- 60 QuickProfile DOA-11 Panel Test
- 61 QuickProfile DOA-11 Panel Test Card
- 62 QuickProfile DOA-12 Panel Test
- 63 QuickProfile DOA-12 Panel Test Card
- 64 QuickProfile Methylphenidate (MPD) Test Strip
- 65 QuickProfile Methylphenidate (MPD) Test Card
- 66 QuickProfile Fentanyl Test Strip
- 67 QuickProfile Fentanyl Test Card
- 68 QuickProfile Clonazepam Strip
- 69 QuickProfile Clonazepam Test Card
- 70 QuickProfile Cotinine Test Strip
- 71 QuickProfile Cotinine Test Card
- 72 QuickProfile K2 Test Strip
- 73 QuickProfile K2 Test Card

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INITIAL:

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20/01/2014