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

Digitally signed by Rodnițchii Andrei
Date: 2019.12.09 15:44:44 EET
Reason: MoldSign Signature
Location: Moldova

bsi.

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:

S M Brain

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

...making excellence a habit.™

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

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

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

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

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

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 **SIGNATURE:**

DATE: 28/04/2017

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

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

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		
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

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

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

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

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

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

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

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		
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

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

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

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

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 (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.co
Web: www.lumiquick.co

ATTACHMENT

	Product name	Model/number
1	QuickProfile Saliva Alcohol Test Strip	74001
2	QuickProfile Tramadol Test Card	74002
3	QuickProfile Tramadol Test Strip	74003
4	QuickProfile DOA-2 Panel Test	74004
5	QuickProfile DOA-2 Panel Test Card	74004-TC
6	QuickProfile DOA-3 Panel Test	74005
7	QuickProfile DOA-3 Panel Test Card	74005-TC
8	QuickProfile DOA-4 Panel Test	74006
9	QuickProfile DOA-4 Panel Test Card	74006-TC
10	QuickProfile DOA-5 Panel Test	74007
11	QuickProfile DOA-5 Panel Test Card	74007-TC
12	QuickProfile DOA-6 Panel Test	74008
13	QuickProfile DOA-6 Panel Test Card	74008-TC
14	QuickProfile DOA-7 Panel Test	74009
15	QuickProfile DOA-7 Panel Test Card	74009-TC
16	QuickProfile DOA-8 Panel Test	74010
17	QuickProfile DOA-8 Panel Test Card	74010-TC
18	QuickProfile DOA-9 Panel Test	74011
19	QuickProfile DOA-9 Panel Test Card	74011-TC
20	QuickProfile DOA-10 Panel Test	74012
21	QuickProfile DOA-10 Panel Test Card	74012-TC
22	QuickProfile Amphetamine Test Strip	74013
23	QuickProfile Amphetamine Test Card	74014
24	QuickProfile Barbiturate Test Strip	74015
25	QuickProfile Barbiturate Test Card	74016
26	QuickProfile Benzodiazepine Test Strip	74017
27	QuickProfile Benzodiazepine Test Card	74018
28	QuickProfile Cocaine Test Strip	74019
29	QuickProfile Cocaine Test Card	74020
30	QuickProfile EDDP Test Strip	74021
31	QuickProfile EDDP Test Card	74022
32	QuickProfile MDMA/Ecstasy Test Strip	74023
33	QuickProfile MDMA/Ecstasy Test Card	74024
34	QuickProfile Methadone Test Strip	74025
35	QuickProfile Methadone Test Card	74026
36	QuickProfile Methamphetamine Test Strip	74027
37	QuickProfile Methamphetamine Test Card	74028
38	QuickProfile Morphine Test Strip	74029
39	QuickProfile Morphine Test Card	74030
40	QuickProfile Morphine Test Strip-(2000)	74031
41	QuickProfile Morphine Test Card-(2000)	74032
42	QuickProfile PCP Test Strip	74033
43	QuickProfile PCP Test Card	74034
44	QuickProfile THC Test Strip	74035
45	QuickProfile THC Test Card	74036
46	QuickProfile TCA Strip	74037
47	QuickProfile TCA Test Card	74038
48	QuickProfile Ketamine Test Strip	74039
49	QuickProfile Ketamine Test Card	74040
50	QuickProfile Buprenorphine Test Strip	74041
51	QuickProfile Buprenorphine Test Card	74042
52	QuickProfile Oxycodone Test Strip	74043
53	QuickProfile Oxycodone Test Card	74044
54	QuickProfile Drug of Abuse Test Cup	74046
55	QuickProfile Drugs of Abuse Test Cup - CYND	74046-II
56	QuickProfile Urine Alcohol Test Strip	74049
57	QuickProfile Urine Alcohol Test Card	74050
58	QuickProfile Propoxyphene Test Strip	74051
59	QuickProfile Propoxyphene Test Card	74052

INITIAL:

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: 20/01/2014