

24 March 2009

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

Dear Mr. Jeff Wang:

I am writing to inform you that today, we have notified by registered mail the Competent Authority in the following countries:

Austria	Bulgaria	Cyprus	Czech Republic	Denmark	Estonia
Finland	France	Germany	Greece	Hungary	Iceland
Ireland	Italy	Latvia	Liechtenstein	Lithuania	Luxembourg
Malta	The Nether	lands	Norway	Poland	Portugal
Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland
United Kinad	om		250		

With this notification, LumiQuick Diagnostics, Inc. has met the requirements of the In-vitro Diagnostics Directive, 98/79/EC for the following devices:

- Adeno/Rota Virus
- Cardiac Marker
- Dengue IgG/IgM Combo (registered only in Italy and The Netherlands)
- Drugs of Abuse
- Fecal Occult Blood (registered only in Italy and The Netherlands)
- H. Pylori Ab/Ag
- HCG
- Legionella (registered only in Italy and The Netherlands)
- LH (registered only in Italy and The Netherlands)
- Strep A (registered only in Italy and The Netherlands)

As of today and without any further notice from the respective Competent Authorities, LumiQuick Diagnostics, Inc. can consider the respective devices and Authorized Representative as officially registered.

If you have any questions, please do not hesitate to contact me.

Yours sincerely,

Rene van de Zande President & CEO Emergo Europe



EmergoEurope.com



Declaration of Conformity

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

AUTHORIZED REPRESENTATIVE	建建筑 经 有效	人为"战争"的"
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

Infectious diseases	Model/number
HIV I&II Test Card 71002 HCV Antibody Test Card 71030	
HCV Antibody Test Card 71030	71001
	71002
HBsAg Test Card 71004	71030
	71004

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

dress	Telephone/email
lenstraat 15	+31.70.345.8570 - phone
13 BH	+31.70.346.7299 - fax
e Hague, Netherlands	service@emergogroup.com
)	dress blenstraat 15 13 BH e Hague, Netherlands

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COMPANY REPRESENTATIVE: Jeff C. Wang

TITLE: Quality Systems Manager SI

SIGNATURE:

Date: 2017.02.23 11:59:53 -08'00'

DATE: 23/02/2017





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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2011-10-20 Effective Date: 2020-10-20 Latest Revision Date: 2020-08-31 Expiry Date: 2023-10-19

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...making excellence a habit."



