



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 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 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

TITLE: Quality Systems Manager

SIGNATURE:

DATE: 24/09/2017

**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 Panel 2 Test (MET / THC)	74004-01
6	QuickProfile DOA Panel 2 Test (OPI / THC)	74004-02
7	QuickProfile DOA-2 Panel Test Card	74004-TC
8	QuickProfile DOA-3 Panel Test	74005
9	QuickProfile DOA Panel 3 Test (AMP / COC / THC)	74005-01
10	QuickProfile DOA-3 Panel Test Card	74005-TC
11	QuickProfile DOA-4 Panel Test	74006
12	QuickProfile DOA-4 Panel Test Card	74006-TC
13	QuickProfile DOA-5 Panel Test	74007
14	QuickProfile DOA Panel 5 Test (AMP / BZO / COC / OPI / THC)	74007-01
15	QuickProfile DOA Panel 5 Test (MET / BZO / COC / OPI / THC)	74007-02
16	QuickProfile DOA-5 Panel Test-24M	74007-24M
17	QuickProfile DOA-5 Panel Test Card	74007-TC
18	QuickProfile DOA-6 Panel Test	74008
19	QuickProfile DOA Panel 6 Test (AMP / BAR / BZO / COC / OPI / THC)	74008-01
20	QuickProfile DOA Panel 6 Test (AMP / BZO / COC / MET / OPI / THC)	74008-02
21	QuickProfile DOA Panel 6 Test (AMP / COC / MET / OPI / PCP / THC)	74008-03
22	QuickProfile DOA-6 Panel Test-24M	74008-24M
23	QuickProfile DOA-6 Panel Test Card	74008-TC
24	QuickProfile DOA-7 Panel Test	74009
25	QuickProfile DOA-7 Panel Test Card	74009-TC
26	QuickProfile DOA-8 Panel Test	74010
27	QuickProfile DOA-8 Panel Test Card	74010-TC
28	QuickProfile DOA-9 Panel Test	74011
29	QuickProfile DOA Panel 9 Test (AMP / BAR / BZO / COC / MET / MTD / OPI / PCP / THC)	74011-01
30	QuickProfile DOA-9 Panel Test Card	74011-TC
31	QuickProfile DOA-10 Panel Test	74012
32	QuickProfile DOA-10 Panel Test Card	74012-TC
33	QuickProfile Amphetamine Test Strip	74013
34	QuickProfile Amphetamine Test Card	74014
35	QuickProfile Barbiturate Test Strip	74015
36	QuickProfile Barbiturate Test Card	74016
37	QuickProfile Benzodiazepine Test Strip	74017
38	QuickProfile Benzodiazepine Test Card	74018
39	QuickProfile Cocaine Test Strip	74019
40	QuickProfile Cocaine Test Card	74020
41	QuickProfile EDDP Test Strip	74021
42	QuickProfile EDDP Test Card	74022
43	QuickProfile MDMA/Ecstasy Test Strip	74023
44	QuickProfile MDMA/Ecstasy Test Card	74024
45	QuickProfile Methadone Test Strip	74025
46	QuickProfile Methadone Test Card	74026
47	QuickProfile Methamphetamine Test Strip	74027
48	QuickProfile Methamphetamine Test Card	74028
49	QuickProfile Methamphetamine Test Card-24M	74028-24M
50	QuickProfile Morphine Test Strip	74029
51	QuickProfile Morphine Test Card	74030
52	QuickProfile Morphine Test Strip-(2000)	74031
53	QuickProfile Morphine Test Card-(2000)	74032
54	QuickProfile PCP Test Strip	74033
55	QuickProfile PCP Test Card	74034
56	QuickProfile THC Test Strip	74035
57	QuickProfile THC Test Card	74036
58	QuickProfile TCA Test Strip	74037
59	QuickProfile TCA Test Card	74038
60	QuickProfile Ketamine Test Strip	74039



61	QuickProfile Ketamine Test Card	74040
62	QuickProfile Buprenorphine Test Strip	74041
63	QuickProfile Buprenorphine Test Card	74042
64	QuickProfile Oxycodone Test Strip	74043
65	QuickProfile Oxycodone Test Card	74044
66	QuickProfile Drug of Abuse Test Cup	74046
67	QuickProfile DOA Test Cup - CYND	74046-II
68	QuickProfile Urine Alcohol Test Strip	74049
69	QuickProfile Urine Alcohol Test Card	74050
70	QuickProfile Propoxyphene Test Strip	74051
71	QuickProfile Propoxyphene Test Card	74052
72	QuickProfile DOA-11 Panel Test	74053
73	QuickProfile DOA-11 Panel Test Card	74053-TC
74	QuickProfile DOA-12 Panel Test	74054
75	QuickProfile DOA-12 Panel Test Card	74054-TC
76	QuickProfile Methylphenidate (MPD) Test Strip	74055
77	QuickProfile Methylphenidate (MPD) Test Card	74056
78	QuickProfile Fentanyl Test Strip	74057
79	QuickProfile Fentanyl Test Card	74058
80	QuickProfile Clonazepam (7-ACL) Test Strip	74059
81	QuickProfile Clonazepam (7-ACL) Test Card	74060
82	QuickProfile Cotinine Test Strip	74061
83	QuickProfile Cotinine Test Card	74062
84	QuickProfile K2 Test Strip	74065
85	QuickProfile K2 Test Card	74066
86	QuickProfile Ethyl Glucuronide (EtG) Test Strip	74075
87	QuickProfile Ethyl Glucuronide (EtG) Test card	74076

INITIAL:


24/09/2017