



Declaration of Conformity

PRODUCT IDENTIFICATION

| Product name | Model/number |
|---|--------------|
| Adeno / Rota Virus Test Devices | |
| QuickProfile Rotavirus Antigen Test Card | 71029 |
| QuickProfile Adenovirus Antigen Test Card | 71032 |
| QuickProfile Adeno/Rota Combo Test Card | 71033 |
| QuickProfile Adeno/Rota Test Strip | 71051 |

MANUFACTURER

| Name of company | Address | Representative |
|-----------------------------|---|-----------------|
| LumiQuick Diagnostics, Inc. | 2946 Scott Blvd. Santa Clara, CA 95054 USA | Chih-Chieh 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 EmergoEurope@ul.com |

CONFORMITY ASSESSMENT

| Device classification | Route to compliance | Standards applied |
|-----------------------|---|-------------------|
| Class: Self-Certify | Annex III of IVDD 98/79/EC Council Directive | ISO 13485:2016 |

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: Chih-Chieh Wang

TITLE: Quality Systems Manager

SIGNATURE:

DATE: 26/07/2018



Declaration of Conformity

| PRODUCT IDENTIFICATION | |
|--|--------------|
| Product name | Model/number |
| Chikungunya Test Devices QuickProfile Chikungunya IgG/IgM Combo Test Card | 71031 |

| MANUFACTURER | | |
|-----------------------------|---|-----------------|
| Name of company | Address | Representative |
| LumiQuick Diagnostics, Inc. | 2946 Scott Blvd. Santa Clara, CA 95054 USA | Chih-Chieh Wang |

| AUTHORIZED REPRESENTATIVE | | |
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COMPANY REPRESENTATIVE: Chih-Chieh Wang

TITLE: Quality Systems Manager

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DATE: 26/07/2018



Declaration of Conformity

| PRODUCT IDENTIFICATION | |
|---|--------------|
| Product name | Model/number |
| Dengue IgG/M Ab and/or NS1 Ag Test Devices | |
| QuickProfile Dengue IgG/IgM Test Card | 71019 |
| QuickProfile Dengue IgG/IgM Test Strip | 71047 |
| QuickProfile Dengue NS1 Antigen Test Card | 71066 |
| QuickProfile Dengue NS1 Ag & IgG/IgM Ab Duo Test Card | 71087 |

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TITLE: Quality Systems Manager

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PRODUCT IDENTIFICATION

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

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TITLE: Quality Systems Manager

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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 Saliva THC Test Strip | 74035-SAL |
| 46 QuickProfile THC Test Card | 74036 |
| 47 QuickProfile TCA Test Strip | 74037 |
| 48 QuickProfile TCA Test Card | 74038 |
| 49 QuickProfile Ketamine Test Strip | 74039 |
| 50 QuickProfile Ketamine Test Card | 74040 |
| 51 QuickProfile Buprenorphine Test Strip | 74041 |
| 52 QuickProfile Buprenorphine Test Card | 74042 |
| 53 QuickProfile Oxycodone Test Strip | 74043 |
| 54 QuickProfile Oxycodone Test Card | 74044 |
| 55 QuickProfile Drug of Abuse Test Cup | 74046 |
| 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 |
| 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 (7-ACL) Test Strip | 74059 |
| 69 | QuickProfile Clonazepam (7-ACL) 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 |
| 74 | QuickProfile Ethyl Glucuronide (EtG) Test Strip | 74075 |
| 75 | QuickProfile Ethyl Glucuronide (EtG) Test Card | 74076 |

INITIAL:

[Handwritten Signature]
26/07/2018



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|---|----------------|
| Product name | Model/number |
| FLU A/B Test Devices QuickProfile Influenza A Antigen Test QuickProfile Influenza A+B Antigens Test | 71065 71067 |

| MANUFACTURER | | |
|-----------------------------|---|-----------------|
| Name of company | Address | Representative |
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| AUTHORIZED REPRESENTATIVE | | |
|---------------------------|---|---|
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| Emergo Europe | Prinsessegracht 20 2514 AP The Hague, Netherlands | +31.70.345.8570 - phone +31.70.346.7299 - fax EmergoEurope@ul.com |

| CONFORMITY ASSESSMENT | | |
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COMPANY REPRESENTATIVE: Chih-Chieh Wang

TITLE: Quality Systems Manager

SIGNATURE:

DATE: 26/07/2018



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 | | |
|-----------------------------|---|-----------------|
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TITLE: Quality Systems Manager

SIGNATURE:

DATE: 26/07/2018



Declaration of Conformity

| PRODUCT IDENTIFICATION | |
|--|--------------|
| Product name | Model/number |
| HCG Test Devices | |
| QuickProfile HCG Mid-Stream test | 73001 |
| QuickProfile HCG Urine Test Card - 25 mIU/mL | 73002 |
| QuickProfile HCG Serum/Urine Test Card | 73005 |
| QuickProfile HCG Serum/Urine Test Strip | 73011 |

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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 |

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TITLE: Quality Systems Manager

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Declaration of Conformity

PRODUCT IDENTIFICATION

| Product name | Model/number |
|--|----------------|
| Legionella Test Devices QuickProfile Legionella Test Card QuickProfile Legionella Test Strip | 71034 71035 |

MANUFACTURER

| Name of company | Address | Representative |
|-----------------------------|---|-----------------|
| LumiQuick Diagnostics, Inc. | 2946 Scott Blvd. Santa Clara, CA 95054 USA | Chih-Chieh Wang |

AUTHORIZED REPRESENTATIVE

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COMPANY REPRESENTATIVE: Chih-Chieh Wang

TITLE: Quality Systems Manager

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DATE: 26/07/2018



Declaration of Conformity

| PRODUCT IDENTIFICATION | |
|---|-------------------------|
| Product name | Model/number |
| LH Test Devices QuickProfile LH Mid-Stream test QuickProfile LH Test Card QuickProfile LH Test Strip | 73003 73004 73007 |

| MANUFACTURER | | |
|-----------------------------|---|-----------------|
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Declaration of Conformity

PRODUCT IDENTIFICATION

| Product name | Model/number |
|---|--------------|
| Malaria Test Devices | |
| QuickProfile Malaria pf Antigen Test Card | 71049 |
| QuickProfile Malaria pf/pv Antigen Test Card | 71050 |
| QuickProfile Malaria pan Antigen Test Card | 71053 |
| QuickProfile Malaria pf/pan Antigen Test Card | 71063 |
| QuickProfile Malaria pan Test Strip | 71074 |

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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 |

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TITLE: Quality Systems Manager

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Declaration of Conformity

PRODUCT IDENTIFICATION

| Product name | Model/number |
|--|--------------|
| Salmonella Antigen / Antibody Test | |
| QuickProfile Salmonella typhi Antigen Test Card | 71028 |
| QuickProfile Salmonella typhi/paratyphi Antigen Test | 71054 |
| QuickProfile Salmonella Typhi IgG/IgM Duo Test | 71055 |
| QuickProfile Salmonella Typhi IgG/IgM Combo Test | 71055B |

MANUFACTURER

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COMPANY REPRESENTATIVE: Chih-Chieh Wang

TITLE: Quality Systems Manager

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Declaration of Conformity

PRODUCT IDENTIFICATION

| Product name | Model/number |
|---|--------------|
| Saliva Drugs of Abuse Test Devices QuickProfile Saliva DOA-6 Panel Test Card | 74074 |

MANUFACTURER

| Name of company | Address | Representative |
|-----------------------------|---|-----------------|
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PRODUCT IDENTIFICATION

| Product name | Model/number |
|--|--------------------------|
| Strep A Test Devices QuickProfile Strep A Test Card QuickProfile Strep A Rapid Test QuickProfile Strep A Test Strip | 71048 71048B 71052 |

MANUFACTURER

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| 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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COMPANY REPRESENTATIVE: Chih-Chieh Wang

TITLE: Quality Systems Manager

SIGNATURE:

DATE: 26/07/2018



Declaration of Conformity

PRODUCT IDENTIFICATION

| Product name | Model/number |
|---|--------------|
| Vitamin D Test Device QuickProfile Vitamin D Test Card | 83001 |

MANUFACTURER

| Name of company | Address | Representative |
|-----------------------------|---|-----------------|
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DATE: 26/07/2018



Declaration of Conformity

| PRODUCT IDENTIFICATION | |
|--|----------------|
| Product name | Model/number |
| Zika IgG/M Ab and/or NS1 Ag Test Devices QuickProfile Zika Virus IgG/IgM Antibody Combo Test QuickProfile Zika NS1 Antigen Test Card | 71090 71093 |

| MANUFACTURER | | |
|-----------------------------|---|-----------------|
| Name of company | Address | Representative |
| LumiQuick Diagnostics, Inc. | 2946 Scott Blvd. Santa Clara, CA 95054 USA | Chih-Chieh 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 EmergoEurope@ul.com |

| CONFORMITY ASSESSMENT | | |
|-----------------------|---|-------------------|
| Device classification | Route to compliance | Standards applied |
| Class: Self-Certify | Annex III of IVDD 98/79/EC Council Directive | ISO 13485:2016 |

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: Chih-Chieh Wang

TITLE: Quality Systems Manager

SIGNATURE:

DATE: 26/07/2018