

STATE OF CALIFORNIA
DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH
MEDICAL DEVICE MANUFACTURING LICENSE

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

LICENSE NUMBER: 50940
EXPIRATION DATE: 2/18/2026

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

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 Number:

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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2011-10-20

Latest Revision Date: 2023-08-21

Effective Date: 2023-10-20

Expiry Date: 2026-10-19

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Certificate No. 5430-2-2024-1

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Two Pages)

Name of Manufacturer/Distributor, Address

Name of Manufacturer

LUMIQUICK DIAGNOSTICS, INC.
2946 SCOTT BLVD.
SANTA CLARA, CA USA 95054

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from February 23, 2024 to February 22, 2026.



To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.



Certificate No. 5430-2-2024-1

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2

Name of Manufacturer

LUMIQUICK DIAGNOSTICS, INC.
2946 SCOTT BLVD.
SANTA CLARA, CA
USA 95054

Name of Product(s)

Catalog no. A / B	Product Name
07RD7014 / 74014	- Amphetamine (AMP) Urine Test Card
07RD7013 / 74013	- Amphetamine (AMP) Urine Test Strip
07RD7016 / 74016	- Barbiturate (BAR) Urine Test Card
07RD7015 / 74015	- Barbiturate (BAR) Urine Test Strip
07RD7018 / 74017	- Benzodiazepine (BZD) Urine Test Card
07RD7017 / 74017	- Benzodiazepine (BZD) Urine Test Strip
07RD7106 / 74042	- Buprenorphine (BUP) Urine Test Card
07RD7105 / 74041	- Buprenorphine (BUP) Urine Test Strip
07RD7007 / 74019	- Cocaine (COC) Urine Test Strip
07RD7008 / 74020	- Cocaine (COC)Urine Test Card
07RD7069 / 74022	- EDDP Urine Test Card
07RD7068 / 74021	- EDDP Urine Test Strip
07RD7010 / 74036	- Marijuana (THC) Urine Test Card
07RD7009 / 74035	- Marijuana (THC) Urine Test Strip
07RD7020 / 74026	- Methadone (MTD) Urine Test Card
07RD7019 / 74025	- Methadone (MTD) Urine Test Strip
07RD7006 / 74028	- Methamphetamine (M-AMP)Urine Test Card
07RD7005 / 74027	- Methamphetamine (M-AMP)Urine Test Strip
74024	- MDMA Urine Test Card
74023	- MDMA Urine Test Strip
07RD7012 / 74030	- Opiate (OPI) Urine Test Card - 300ng/ml cutoff
07RD7011 / 74029	- Opiate (OPI) Urine Test Strip - 300ng/ml cutoff
07RD7040 / 74032	- Opiate-2000 (OPI-2000) Urine Test Card - 2000ng/ml cutoff
07RD7039 / 74031	- Opiate-2000 (OPI-2000) Urine Test Strip - 2000ng/ml cutoff
07RD7101 / 74044	- Oxycodone (OXY) Urine Test Card
07RD7100 / 74043	- Oxycodone (OXY) Urine Test Strip
07RD7022 / 74034	- Phencyclidine (PCP) Urine Test Card
07RD7021 / 74033	- Phencyclidine (PCP) Urine Test Strip
07RD7170 / 74052	- Propoxyphene (PPX) Urine Test Card
07RD7169 / 74051	- Propoxyphene (PPX) Urine Test Strip
74038	- Tricyclic antidepressant (TCA) Urine Test Card
74037	- Tricyclic antidepressant (TCA) Urine Test Strip
07RD7061 / 74004	- Multiple Drug Panel 2 Urine Test
07RD7062 / 74005	- Multiple Drug Panel 3 Urine Test
07RD7063 / 74006	- Multiple Drug Panel 4 Urine Test
07RD7064 / 74007	- Multiple Drug Panel 5 Urine Test
07RD7065 / 74008	- Multiple Drug Panel 6 Urine Test
07RD7070 / 74009	- Multiple Drug Panel 7 Urine Test
07RD7071 / 74010	- Multiple Drug Panel 8 Urine Test
07RD7072 / 74011	- Multiple Drug Panel 9 Urine Test
07RD7073 / 74012	- Multiple Drug Panel 10 Urine Test
07RD7093 / 74005-TC	- Multiple Drug -3 Combo Urine Test Card
07RD7094 / 74006-TC	- Multiple Drug -4 Combo Urine Test Card
07RD7095 / 74007-TC	- Multiple Drug -5 Combo Urine Test Card
07RD7183 / 74008-TC	- Multiple Drug -6 Combo Urine Test Card
07RD7184 / 74009-TC	- Multiple Drug -7 Combo Urine Test Card
07RD7185 / 74010-TC	- Multiple Drug -8 Combo Urine Test Card
07RD7202 / 74046	- Multiple Drug -2 Urine Test Cup
07RD7203 / 74046	- Multiple Drug -3 Urine Test Cup
07RD7204 / 74046	- Multiple Drug -4 Urine Test Cup





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- 07RD7205 / 74046 - Multiple Drug -5 Urine Test Cup
- 07RD7206 / 74046 - Multiple Drug -6 Urine Test Cup
- 07RD7207 / 74046 - Multiple Drug -7 Urine Test Cup
- 07RD7208 / 74046 - Multiple Drug -8 Urine Test Cup
- 07RD7209 / 74046 - Multiple Drug -9 Urine Test Cup
- 07RD7210 / 74046 - Multiple Drug -10 Urine Test Cup
- 07RD7211 / 74046 - Multiple Drug -11 Urine Test Cup
- 07RD7002 / 73002 - HCG pregnancy Urine Test Card
- 07RD7001 / 73006 - HCG pregnancy Urine Test Strip
- 07RD7004 / 73004 - LH Ovulation Urine Test Card
- 07RD7003 / 73007 - LH Ovulation Urine Test Strip
- 78052 - Estradiol Enzyme Immuno Assay Kit
- 78049 - Ferritin Enzyme Immuno Assay Kit
- 78045 - FSH Enzyme Immuno Assay Kit
- 78044 - HCG Enzyme Immuno Assay Kit
- 78050 - HGH Enzyme Immuno Assay Kit
- 78057 - High Sensitivity CRP Enzyme Immuno Assay Kit
- 78051 - IgE Enzyme Immuno Assay Kit
- 78046 - LH Enzyme Immuno Assay Kit
- 78056 - Myoglobin Enzyme Immuno Assay Kit
- 78053 - Progesterone Enzyme Immuno Assay Kit
- 78047 - Prolactin Enzyme Immuno Assay Kit
- 78026 - Sensitive TSH Enzyme Immuno Assay Kit
- 78054 - Testosterone Enzyme Immuno Assay Kit
- 78027 - Total T3 Enzyme Immuno Assay Kit
- 78029 - Total T4 Enzyme Immuno Assay Kit
- 78055 - Troponin I Enzyme Immuno Assay Kit
- 78025 - TSH Enzyme Immuno Assay Kit
- 78024 - β -2 Microglobulin Enzyme Immuno Assay Kit

-----END OF PRODUCT LIST-----

