

# Certificate of Registration

**Certificate number**

1880.240628

**File number**

A28261

**Initial issue date**

2018-08-27

**Cycle start date**

2024-08-27

**Effective date**

2024-06-28

**Expiry date**

2027-08-26

**Agappe Diagnostics Ltd.**

Agappe Hills, Pattimattom P.O.  
Ernakulam, Kerala 683562 INDIA

UL LLC, UL Solutions medical and regulatory services issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in conformance per the defined scope with respect to:

**ISO 13485:2016  
EN ISO 13485:2016 + A11:2021**

The design, development and manufacture of in-vitro diagnostic reagents, test kits used in the diagnosis and detection of clinical chemistry, immunology, blood grouping, coagulation, microbiology, hematology, serology and molecular biology.

The design, development and manufacture of biochemistry analyzers, nephelometers, hematology analyzers, sample processing equipment and vein detecting equipment.

Manufacturing of immunoassay analyzers.

Purchase for resale of hematology analyzers, bio-chemistry analyzers, coagulation analyzers, urine chemistry analyzers, electrolyte analyzers, microbiology analyzers, molecular biology analyzers, immunoassay analyzers and its allied reagents.

Installation and servicing of biochemistry analyzers, nephelometers, hematology analyzers, sample processing equipment, vein detecting equipment, coagulation analyzers, urine chemistry analyzers, electrolyte analyzers, microbiology analyzers, molecular biology analyzers, and immunoassay analyzers.

Certificate with Addendum(s) totals 3 pages.

Authorized by:

Paul Daysh

Operations manager – Medical Regulatory



Check certificate status: [here](#)

# Addendum 2

This quality system registration is included in UL's Product iQ directory and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown. By issuance of this certificate, the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferrable and remains the property of UL Solutions.

UL LLC  
333 Pfingsten Road  
Northbrook, IL 60062-2096 USA

# Addendum 1

Site	Company Name	Location	Performing
1-1	Agappe Diagnostics Ltd.	Agappe Hills Pattimattom P.O Ernakulam Kerala 683562 INDIA	Management, regulatory affairs, design, development, purchasing, manufacture of in-vitro diagnostic reagents, test kits used in the diagnosis and detection of clinical chemistry, immunology, blood grouping, coagulation, microbiology, hematology, serology, molecular biology, installation and servicing.
1-2	Agappe Diagnostics Ltd.	Central Warehouse, Agappe Hills Pattimattom P.O Ernakulam Kerala 683562 INDIA	Storage and delivery
2-1	Agappe Diagnostics Ltd.	X/588-Cb Block No 32, Kinfra Small Industrial Park Nellad, Mazhuvannur Ernakulam Kerala 686721 INDIA	Manufacture of biochemistry analyzers, nephelometers, hematology analyzers, sample processing equipment, vein detecting equipment, coagulation analyzers, urine chemistry analyzers, molecular biology analyzers and immunoassay analyzers.