

Certificate of Registration

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1690.240707

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A12312

Initial issue date

2018-07-07

Cycle start date

2024-07-07

Effective date

2024-07-07

Expiry date

2027-07-06

**Agilent Technologies Singapore (International) Pte Ltd.**No. 1 Yishun Avenue 7
768923 Singapore SINGAPORE

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, manufacture and distribution of antibodies, reagents and kits for in vitro diagnostics and research used in diagnosis and management of cancer, genetic testing, immune status, disease status, autoimmune status, protein metabolism, blood analytes, coagulation, transmissible agents, sexually transmissible agents and for immunological typing. The design, development, manufacture, distribution, installation and service of in vitro diagnostic instruments and software used in the diagnosis and management of cancer, genetic testing, immune status, disease status, autoimmune status, protein metabolism, blood analytes, coagulation, transmissible agents, sexually transmissible agents and for immunological typing.

Certificate with Addendum(s) totals 3 pages.

Authorized by:

A handwritten signature in black ink, appearing to read 'P. Daysh'.

Paul Daysh
Operations manager – Medical RegulatoryCheck certificate status: [here](#)

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, UL Solutions medical regulatory services
is an MDSAP Recognized Auditing Organization**UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

Addendum 1

Site	Company Name	Location	Performing
1-1	Agilent Technologies Singapore (International) Pte Ltd.	No. 1 Yishun Avenue 7 Singapore 768923 SINGAPORE Facility ID: F005192	corporate location
2-1	Agilent Technologies Denmark ApS	Produktionsvej 42 DK-2600 Glostrup DENMARK Facility ID: F001394	Design, Manufacturing, Distribution, QA, Logistics

Additional Regulatory Requirements

Agilent Technologies Singapore (International) Pte Ltd.

No. 1 Yishun Avenue 7
768923 Singapore SINGAPORE

Facility ID: F005192

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

Japan:

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act (,as applicable)

United States:

- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 821 (where applicable)