CERTIFICATE OF REGISTRATION

Agilent Technologies Singapore (International) Pte Ltd.

No. 1 Yishun Avenue 7
Singapore 768923 SINGAPORE

REPs Facility ID: F005192

UL Medical Regulatory Services of UL LLC®(UL) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

The design, development and manufacture 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, 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.

With additional locations listed on Addendum: 1

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Authorized by

Deborah Jennings-Conner
Global Regulatory Director
UL Life and Health Sciences
UL LLC

Check Certificate Status: here

File Number	A12312	Cycle Start Date	July 7, 2021
Certificate Number	1690.210528	Effective Date	May 28, 2021
Initial Issue Date	July 7, 2018	Expiry Date	July 6, 2022

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC.
Certificates may be verified by visiting the Online Certifications Directory on UL.com.

UL REGISTERED FIRM

UL Medical and Regulatory Services UL, LLC is an MDSAP Recognized Auditing Organization

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

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Addendum 1

2-1
REPs Facility ID: **F001394**

Agilent Technologies Denmark ApS
Produktionsvej 42
Glostrup DK-2600 DENMARK

Performing: Design, Manufacturing, QA, Logistics

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Singapore 768923 SINGAPORE

REPs Facility ID: **F005192**

Additional Regulatory Requirements

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

Brazil:
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- 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)

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