CERTIFICATE OF REGISTRATION

Agilent Technologies, Inc.

5301 Stevens Creek Boulevard
Santa Clara, California 95051 UNITED STATES

Facility ID: F005193

UL Medical Regulatory Services of UL LLC® (UL Solutions) 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
EN ISO 13485:2016

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

The design, development, and manufacture of in-vitro diagnostic test kits and reagents used in the diagnosis and/or management of cancer, immune status, disease status, autoimmune status, blood analytes, immunological typing and disease management.

With additional locations listed on Addendum: 1

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Authorized by

Paul Hilgeman
Senior Business Manager - Medical
CMIT – Medical Regulatory

Check Certificate Status:
here

File Number	A12643	Cycle Start Date	January 28, 2024
Certificate Number	1073.240128	Effective Date	January 28, 2024
Initial Issue Date	January 28, 2018	Expiry Date	January 27, 2027

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® (UL Solutions). Certificates may be verified by visiting the Online Certifications Directory on UL.com.

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

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

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Addendum 1

1-1
Facility ID: **F005193**

Agilent Technologies Inc.
5301 Stevens Creek Boulevard
Santa Clara, California 95051 UNITED STATES

Performing: Corporate affairs

2-1
Facility ID: **F001395**

Agilent Technologies, Inc.
6392 Via Real
Carpinteria, California 93013 UNITED STATES

Performing: Design and development of in-vitro diagnostic test kits and reagents.

2-2
Facility ID: **F001395**

Agilent Technologies, Inc.
1170 Mark Ave.
Carpinteria, California 93013 UNITED STATES

Performing: Manufacture in-vitro diagnostic test kits and reagents, sales, customer service, and design changes.

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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. 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)

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