ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
Medical Device Single Audit Program

America

CERTIFICATE

No. QS6 113968 0011 Rev. 00

Certificate Holder: **Agilent Technologies, Inc.**
5301 Stevens Creek Boulevard
Santa Clara CA 95051
USA

Certification Mark:

Scope of Certificate: **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**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 113968 0011 Rev. 00
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F006136**
Report No.: **721012586**
Effective Date: **2025-10-27**
Expiry Date: **2027-01-27**

Date of Issue: 2025-10-27

(Renee Walker)
Director, US Certification Body, MHS

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Regulatory Requirements: **Audit/Certification Criteria**

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 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

Agilent Technologies, Inc.
5301 Stevens Creek Boulevard, Santa Clara CA 95051, USA

Agilent Technologies, Inc.
6392 Via Real, Carpinteria CA 93013, USA

Agilent Technologies, Inc.
1170 Mark Ave., Carpinteria CA 93013, USA

Date of Issue: 2025-10-27

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No. QS6 113968 0011 Rev. 00

Facility Scopes:

Agilent Technologies, Inc.
5301 Stevens Creek Boulevard, Santa Clara CA 95051, USA

Management of Design and Development, Manufacture, of In-Vitro Diagnostics Test Kits and Reagents, Sales, Customer Service, and Design Changes

REPs Facility ID: F006136

Agilent Technologies, Inc.
6392 Via Real, Carpinteria CA 93013, USA

Design and Development of In-Vitro Diagnostic Test Kits and Reagents

REPs Facility ID: F008533

Agilent Technologies, Inc.
1170 Mark Ave., Carpinteria CA 93013, USA

Manufacture In-Vitro Diagnostic Test Kits and Reagents, Sales, Customer Service, and Design Changes

REPs Facility ID: F008533

Date of Issue: 2025-10-27

(Renee Walker)
Director, US Certification Body, MHS

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