



# CERTIFICATE

**No. QS6 109578 0005 Rev. 01**

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

**Certification Mark:**

**Scope of Certificate:** **See Page 2 for Overall Scope Statement.**

**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\\_109578\\_0005\\_Rev\\_01](http://www.tuvsud.com/ps-cert?q=cert:QS6_109578_0005_Rev_01)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F008117**  
**Report No.:** **721007706**  
**Effective Date:** **2025-10-22**  
**Expiry Date:** **2028-10-21**

( 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

**Overall Scope Statement:**

**Design, Development, Manufacture and Distribution of Antibodies, Reagents and Kits for In-Vitro Diagnostics and Research used in Diagnoses 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**

**Design, Development, Manufacture and 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**

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Date of Issue: 2025-10-22

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**Facility(ies):**

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

**Agilent Technologies Denmark ApS**  
Produktionsvej 42, 2600 Glostrup, DENMARK

**Facility Scopes:**

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

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REPs Facility ID: F008117

**Agilent Technologies Denmark ApS**  
Produktionsvej 42, 2600 Glostrup, DENMARK

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REPs Facility ID: F008166

( Renee Walker )  
Director, US Certification Body, MHS