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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 109578 0005 Rev. 00

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. 00
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F008166**
Report No.: **721007706**
Effective Date: **2025-04-30**
Expiry Date: **2027-07-06**

Date of Issue: 2025-04-30

(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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CERTIFICATE

No. QS6 109578 0005 Rev. 00

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

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

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REPs Facility ID: F008117

Agilent Technologies Denmark ApS
Produktionsvej 42, 2600 Glostrup, DENMARK

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

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