



America

# CERTIFICATE

No. QS6 098002 0008 Rev. 00

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

**Certification Mark:**



**Scope of Certificate:** Design, Development of Analytical Instruments, Microarrays, Reagents, Software and Accessories used in the Diagnosis, Detection and / or Management of Molecular Genetic Testing; Manufacture of Microarrays, Software, Reagents and Accessories used in the Diagnosis, Detection and / or Management of Molecular Genetic Testing

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

**Regulatory Authority(ies):** Australia TGA, Health Canada, USA FDA, MHLW / PMDA.  
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. Validity of this certificate can be obtained by visiting the website [www.tuvsud.com/ps-cert](http://www.tuvsud.com/ps-cert)

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

**REPs Facility ID:** F005558

**Effective Date:** 2021-11-17

**Expiry Date:** 2024-11-16

Page 1 of 3

**Date of Issue:** 2021-11-17

( Michael Ogunleye )  
Manager, US Certification Body,  
Medical and Health Services

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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

**Canada**

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

**Japan**

- MHLW Ministerial Ordinance 169, Article 4 to Article 68  
 - PMD Act

**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 Blvd, Santa Clara CA 95051, USA

Agilent Technologies, Inc.  
 1834 State Highway 71 West, Cedar Creek TX 78612, USA

Page 2 of 3

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**Agilent Technologies, Inc.**

1834 State Highway 71 West, Cedar Creek TX 78612, USA

Design, Development of Microarrays, Reagents, and Accessories used in the Diagnosis, Detection and / or Management of Molecular Genetic Testing; Manufacture of Reagents, Distribution of Reagents, Microarrays, and Accessories used in the Diagnosis, Detection and / or Management of Molecular Genetic Testing

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Page 3 of 3

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