



America

CERTIFICATE

No. QS6 083013 0007 Rev. 04

Certificate Holder: **Affymetrix, Inc.**
3450 Central Expressway
Santa Clara CA 95051
USA

Certification Mark:



Scope of Certificate: **Design, Development and Production of Microarrays, Reagents, Instruments and Software for use in Medical Diagnostics**

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

Regulatory Authority(ies): **Australia TGA, 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_083013_0007_Rev.04

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

REPs Facility ID: **F003982**
Report No.: **721004669**
Effective Date: **2025-05-16**
Expiry Date: **2028-05-15**

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Date of Issue: 2024-12-30

(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

United States

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

Facility(ies):

Affymetrix, Inc.

3450 Central Expressway, Santa Clara CA 95051, USA

Life Technologies Holdings Pte Ltd

7 Gul Circle, Level 2M-01/08, Keppel Logistic Building, Singapore 629563, SINGAPORE

Facility Scopes:

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Design, Development and Production of Microarrays, Reagents, Instruments and Software for use in Medical Diagnostics
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Production of Microarrays and Instruments for use in Medical Diagnostics
 REPs Facility ID: F003994

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