



Product Service

# Certificate

No. Q5 083013 0004 Rev. 03

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

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production, and Distribution of Microarrays, Reagents, Instruments and Software for In Vitro Diagnostics genetic testing; Installation and servicing of Instrument and Software for IVD Genetic testing.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 083013 0004 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_083013_0004_Rev.03)

**Report No.:** 721004669-SC, 721004669-SGP, 721004669-CN

**Valid from:** 2025-04-15  
**Valid until:** 2028-04-14

**Date,** 2025-02-14

Christoph Dicks  
Head of Certification/Notified Body



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**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **Affymetrix, Inc.**  
3450 Central Expressway, Santa Clara CA 95051, USA

Design and Development, Production and Distribution of  
Microarrays, Reagents, Instruments, and Software for In Vitro  
Diagnostics genetic testing; Installation and servicing of  
Instruments and software for IVD Genetic testing.

**Life Technologies Holdings Pte Ltd**  
7 Gul Circle, Level 2M-01/08, Keppel Logistic Building, Singapore  
629563, SINGAPORE

Production of Microarrays and Instruments for In Vitro Diagnostics  
Genetic Testing

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