





Product Service

Certificate

No. Q5 083013 0004 Rev. 02

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

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 and certification regulation of 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.02

Report No.: 72172719

 Valid from:
 2022-04-15

 Valid until:
 2025-04-14

Date, 2022-04-04 Christoph Dicks

Head of Certification/Notified Body





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Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies): Affymetrix, Inc.

3380 Central Expressway, Santa Clara CA 95051, USA

Design and Development of Microarrays, Reagents, Instruments

and Software for In Vitro Diagnostics.

Affymetrix, Inc.

3450 Central Expressway, Santa Clara CA 95051, USA

Design and Development of Microarrays, Reagents, Instruments

and Software for In Vitro Diagnostics.

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
