



EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and
Companion Diagnostics)

No. V12 083013 0046 Rev. 00

Manufacturer:

Affymetrix, Inc.

3450 Central Expressway
Santa Clara CA 95051
USA

SRN Manufacturer - US-MF-000028847

Authorized Representative:

Life Technologies Europe B.V
2 Kwartsweg, 2665 NN Bleiswijk, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).

The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:V12 083013 0046 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:V12_083013_0046_Rev._00)

Report No.:

72193346

Valid from:

2024-04-25

Valid until:

2029-04-24

Marta Carnielli

Issue date: 2024-04-25

Head of Certification IVD



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Classification: Class C
Device Group: W0106 - GENETIC TESTING
IVP Code: IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
Intended Purpose: IVR 0401 - Devices intended to be used in screening/confirmation of congenital/inherited disorders

Classification: Class C
Device Group: W02079092 - VARIOUS GENERAL PURPOSE IVD INSTRUMENTS - IVD MEDICAL DEVICE SOFTWARE
IVP Code: IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
Intended Purpose: IVR 0401 - Devices intended to be used in screening/confirmation of congenital/inherited disorders

The validity of this certificate depends on conditions and/or is limited to the following: -

Revision History:

Rev.	Dated	Report	Description
00	2024-04-25	72193346	Initial issuance