



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 113968 0005 Rev. 00

Manufacturer:

Agilent Technologies, Inc.

5301 Stevens Creek Boulevard
Santa Clara CA 95051
USA

SRN Manufacturer - US-MF-000009385

Authorized Representative:

Agilent Technologies Denmark ApS
Produktionsvej 42, 2600 Glostrup, DENMARK

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. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V12 113968 0005 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:V12_113968_0005_Rev.00)

Report No.: 72185439

Valid from: 2023-08-16

Valid until: 2028-08-15

Marta Carnielli
Head of Notified Body IVD

Issue date: 2023-08-16



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Classification: Class C
Device Group: W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code: IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose: IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer

Classification: Class C
Device Group: W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code: IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose: IVR 0701 - Devices which are controls without a quantitative assigned value

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

Revision History:

Rev.	Dated	Report	Description
00	2023-08-16	72185439	Initial issuance