

Certificate

Certificate No.: MD 3350838-510

Manufacturer: **QIAGEN GmbH**

Qiagen Str. 1
40724 Hilden
Germany

REPs Facility ID: F001091

Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure Australia Therapeutic Goods (Medical Devices)

Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC
ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282

Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD
Act

United States 21 CFR 820*, 21 CFR 803, 21 CFR 806, 21 CFR 807
– Subparts A to D

Scope: Design and development, manufacture, distribution, installation and service of in-vitro diagnostic systems used in the diagnosis, management and detection of cancer, compatibility testing, disease status, genetic testing, immune status, prenatal screening, sexually transmissible agents and transmissible agents

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 3350838-510

Issue Date: 2021-06-14

Effective Date: 2021-06-15

Expiry Date: 2022-06-14



Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/0000038303?locale=en
or calling 1-888-743-4652.

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The scope of certification includes the following additional locations:

No.	Location	Scope
/01	QIAGEN GmbH Qiagen Str. 1 40724 Hilden Germany	Design and development, manufacture
/02	QIAGEN GmbH Max-Volmer-Str. 1 40724 Hilden Germany	Design and development
/03	QIAGEN GmbH Max-Volmer-Str. 2 40724 Hilden Germany	Design and development
/04	QIAGEN GmbH Max-Volmer-Str. 3 40724 Hilden Germany	Service
/05	QIAGEN GmbH Max-Volmer-Str. 4 40724 Hilden Germany	Design and development

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No.	Location	Scope
/06	QIAGEN GmbH Max-Volmer-Str. 8 40724 Hilden Germany	Management
/07	STAT Dx Life S.L. Baldiri Reixac 4 08028 Barcelona Spain	Design and development, manufacture



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