Certificate

Certificate No.:	MD 1782924-1-2
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

Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, 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

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.:	1157094-230
Issue Date:	2024-06-06
Effective Date:	2024-06-15
Expiry Date:	2027-06-14

MDSAP
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Certification officer: M.Sc. Irene Carraretto
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

Certificate No.: MD 1782924-1-2

Manufacturer:

QIAGEN GmbH

Qiagen Str. 1
40724 Hilden
Germany

Scope:

The design and development, manufacture, distribution, installation, and servicing of in-vitro diagnostic analyzers, in-vitro diagnostic reagents and in-vitro diagnostic test kits used in the diagnosis, management and detection of cancer, disease status, immune status, sexually transmissible agents and transmissible agents.
The design and development, manufacture, distribution, installation, and servicing of in-vitro diagnostic analyzers, in-vitro diagnostic reagents and in-vitro diagnostics medical devices used for clinical specimen collection and isolation and purification of nucleic acids from human samples.

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Certificate

Certificate No.: MD 1782924-1-2

Manufacturer:

QIAGEN GmbH

Qiagen Str. 1
40724 Hilden
Germany

The scope of certification also covers the following sites:

No.	Location	Scope
/01	QIAGEN GmbH Qiagen Str. 1 40724 Hilden Germany	Manufacture, installation, administration REPs Facility ID: F001091
/02	QIAGEN GmbH Max-Volmer-Str. 1 40724 Hilden Germany	Design and development, administration REPs Facility ID: F001091
/03	QIAGEN GmbH Max-Volmer-Str. 2 40724 Hilden Germany	Design and development, administration REPs Facility ID: F001091
/04	QIAGEN GmbH Max-Volmer-Str. 3 40724 Hilden Germany	Service REPs Facility ID: F001091
/05	QIAGEN GmbH Max-Volmer-Str. 4 40724 Hilden Germany	Design and development, administration REPs Facility ID: F001091
/06	QIAGEN GmbH Max-Volmer-Str. 8 40724 Hilden Germany	Manufacture REPs Facility ID: F001091

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Certificate

Certificate No.: MD 1782924-1-2

Manufacturer: **QIAGEN GmbH**

Qiagen Str. 1
40724 Hilden
Germany

The scope of certification also covers the following sites:

/07	QIAGEN GmbH Max-Volmer-Str. 9a 40724 Hilden Germany	Manufacture REPs Facility ID: F001091
/08	STAT Dx Life S.L. Baldiri Reixac 4 08028 Barcelona Spain	Design and development, manufacture of in-vitro diagnostic analyzers, in-vitro diagnostic reagents and in-vitro diagnostic test kits used in the detection of transmissible agents. REPs Facility ID: F004285
/09	QIAGEN Manchester Ltd. 200 Hathersage Road Manchester M13 0BH United Kingdom	Design and development, administration REPs Facility ID: F001105

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

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