Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.:	SX 1418003-1
Certificate Holder:	QIAGEN N.V. Hulsterweg 82 5912 PL Venlo Netherlands
Scope:	The design and development, manufacture, distribution, installation, and servicing of in-vitro diagnostic instruments, in-vitro diagnostic reagents, in-vitro diagnostic test kits and in-vitro diagnostic software used in the diagnosis, management and detection of cancer, disease status, immune status, sexually transmissible agents, transmissible agents and detection of placental alpha macroglobulin- 1 (PAMG-1). The design and development, manufacture, distribution, installation, and servicing of in-vitro diagnostic instruments, 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.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	1157452-40
Effective date:	2024-08-15
Expiry date:	2027-08-14
Issue date:	2024-08-08

Replaces certificate SX 1418003-1 issued 2023-02-14

This certificate can be validated on https://www.certipedia.com

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland®
Precisely Right.

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Hulsterweg 82
5912 PL Venlo
Netherlands

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o QIAGEN N.V. Hulsterweg 82 5912 PL Venlo Netherlands	Management of the global QM System and administration.
/02	c/o QIAGEN GmbH Qiagen Str. 1 40724 Hilden Germany	The manufacture, distribution, installation, servicing and administration of in-vitro diagnostic instruments, in-vitro diagnostic reagents, 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 manufacture, distribution, installation, servicing and administration of in-vitro diagnostic instruments, 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.
/03	c/o QIAGEN GmbH Max-Volmer Str. 1 40724 Hilden Germany	The design and development of in-vitro diagnostic instruments, in-vitro diagnostic reagents, 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 of in-vitro diagnostic instruments, 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.
/04	c/o QIAGEN GmbH Max-Volmer Str. 2 40724 Hilden Germany	The design and development of in-vitro diagnostic instruments, in-vitro diagnostic reagents, 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 of in-vitro diagnostic instruments, 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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The scope of certification also covers the following sites:

/05	c/o QIAGEN GmbH Max-Volmer Str. 3 40724 Hilden Germany	The servicing of in-vitro diagnostic instruments used in the diagnosis, management and detection of cancer, disease status, immune status, sexually transmissible agents, transmissible agents and detection of placental alpha macroglobulin- 1 (PAMG-1). The servicing of in-vitro diagnostic instruments used for clinical specimen collection and isolation and purification of nucleic acids from human samples.
/06	c/o QIAGEN GmbH Max-Volmer Str. 4 40724 Hilden Germany	The design and development of in-vitro diagnostic instruments, in-vitro diagnostic reagents, 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 of in-vitro diagnostic instruments, 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.
/07	c/o QIAGEN GmbH Max-Volmer Str. 8 40724 Hilden Germany	The manufacture of in-vitro diagnostic reagents, in-vitro diagnostic test kits used in the diagnosis, management and detection of cancer, disease status, immune status, sexually transmissible agents and transmissible agents.
/08	c/o QIAGEN GmbH Max-Volmer Str. 9a 40724 Hilden Germany	The manufacture of in-vitro diagnostic reagents, 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 manufacture of in-vitro diagnostic instruments, 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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The scope of certification also covers the following sites:

/09	c/o QIAGEN Wrocław Sp. z.o.o. Powstańców Śląskich 95 53-332 Wrocław Poland	The design and development of in-vitro diagnostic instruments and distribution In-vitro diagnostic software used in the diagnosis, management and detection of cancer, disease status, immune status, sexually transmissible agents and transmissible agents. The design, development of in-vitro diagnostic instruments used for isolation and purification of nucleic acids from human samples. Administration for manufacture, distribution, installation and service.
/10	c/o QIAGEN Manchester Ltd. Citylabs 2.0 200 Hathersage Road Manchester M13 0BH United Kingdom	The design, development and administration of in-vitro diagnostic instruments, 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, development and administration of in-vitro diagnostic instruments used for clinical specimen collection and isolation and purification of nucleic acids from human samples.
/11	c/o QIAGEN Ltd. Citylabs 2.0 200 Hathersage Road Manchester M13 0BH United Kingdom	The distribution, installation, and servicing of in-vitro diagnostic instruments, in-vitro diagnostic reagents, in-vitro diagnostic test kits and In-vitro diagnostic software used in the diagnosis, management and detection of cancer, disease status, immune status, sexually transmissible agents, transmissible agents and detection of placental alpha macroglobulin- 1 (PAMG-1). The distribution, installation and servicing of in-vitro diagnostic instruments, 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.
/12	c/o STAT DX LIFE S.L. Calle Baldiri Reixac 4 08028 Barcelona Spain	The design and development and manufacture of in-vitro diagnostic instruments, in-vitro diagnostic reagents, in-vitro diagnostic test kits used in the diagnosis, management and detection of cancer, disease status, immune status, sexually transmissible agents and transmissible agents.

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The scope of certification also covers the following sites:

/13	c/o QIAGEN Sciences LLC 19300 Germantown Road Germantown MD 20874 USA	The design, development, manufacture and administration of in-vitro diagnostic instruments, 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, transmissible agents and detection of placental alpha macroglobulin- 1 (PAMG-1). The design and development, manufacture and administration of in-vitro diagnostic instruments, 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.
/14	c/o QIAGEN LLC 12920 Cloverleaf Center Drive Germantown MD 20874 USA	The servicing of in-vitro diagnostic instruments used in the diagnosis, management and detection of cancer, disease status, immune status, sexually transmissible agents, transmissible agents and detection of placental alpha macroglobulin- 1 (PAMG-1). The servicing of in-vitro diagnostic instruments used for clinical specimen collection and isolation and purification of nucleic acids from human samples.
/15	c/o QIAGEN LLC 19300 Germantown Road Germantown MD 20874 USA	The distribution, installation, and servicing of in-vitro diagnostic instruments, 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, transmissible agents and detection of placental alpha macroglobulin- 1 (PAMG-1). The distribution, installation, and servicing of in-vitro diagnostic instruments, 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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The scope of certification also covers the following sites:

/16	c/o Qiagen Beverly LLC 100 Cummings Center, Suite 407j Beverly MA 01915 USA	The design and development, manufacture and administration of in-vitro diagnostic reagents used in the diagnosis, management and detection of cancer, disease status, immune status, sexually transmissible agents and transmissible agents. The design and development, manufacture and administration of in-vitro diagnostic reagents used for isolation and purification of nucleic acids from human samples.
/17	c/o QIAGEN Aarhus A/S Silkeborgvej 2 4. sal 8000 Aarhus C Denmark	The design, development and manufacture of In-vitro diagnostic software used in the diagnosis, management and detection of cancer, disease status, immune status, sexually transmissible agents and transmissible agents.
/18	c/o QIAGEN Redwood City Inc. 1001 Marshall Street, Suite 200 Redwood City CA 94063 USA	The design, development and manufacture of In-vitro diagnostic software used in the diagnosis, management and detection of cancer, disease status, immune status, sexually transmissible agents and transmissible agents.

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