BUREAU VERITAS
Certification

Certification

Awarded to

QIAGEN GmbH

QIAGEN STRASSE 1, 40724 HILDEN
GERMANY

Bureau Veritas certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards indicated below

STANDARD

ISO 18385:2016

SCOPE OF SUPPLY

PRODUCTION OF REAGENTS AND CONSUMABLES USED IN THE PREPARATION AND ANALYSIS OF BIOLOGICAL MATERIAL FOR IDENTIFICATION AND FORENSIC DNA PURPOSES WHILST MINIMIZING THE RISK OF DETECTABLE HUMAN DNA CONTAMINATION

Original Approval Date: **17 April 2017**

Subject to the continued satisfactory operation of the organisation's Management System,

this certificate is valid until: **16 July 2026**

To check the validity of this certificate please call tel. **1800 855 190**

Further clarification regarding the scope of this certificate and the applicability of the Management System requirements may be obtained by consulting the organisation.

Certificate Number: **AU005482-1**

Date: **23 June 2023**

Andrew Mortimore
Vice President – I&F Pacific Region

Managing office: Bureau Veritas Pty Ltd, 3/435 Williamstown Road, Port Melbourne, Victoria, 3207

Issuing office: Bureau Veritas Pty Ltd, 3/435 Williamstown Road, Port Melbourne, Victoria, 3207

BUREAU VERITAS

EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HX 1782924-1
Manufacturer:	QIAGEN GmbH Qiagen Str. 1 40724 Hilden Germany
EUDAMED Single Registration No.:	DE-MF-000004949
Products:	Products of Class C: GENETIC TESTING IVR 0301 Devices intended to be used in screening, diagnosis, staging or monitoring of cancer W01060299 - TESTS FOR ACQUIRED GENETIC OR CHROMOSOMAL ALTERATIONS – OTHER INFECTIOUS DISEASES IVR 0503 Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents W01050107 - MYCOBACTERIA GENUS + SPECIES W01050705 - MULTIPLE PANELS FOR INFECTIONS - VARIOUS

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class D devices are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4 is required before placing them on the market.
If class B, C or D devices for self-testing or near-patient testing are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.1 is required before placing them on the market.
If companion diagnostics are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.2 is required before placing them on the market.

Report No.:	1148061-10
Effective date:	2024-09-13
Expiry date:	2026-06-29
Issue date:	2024-09-13

Dr. Volker Schlueter
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/746 concerning medical devices with the identification number 0197.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜVRheinland®
Precisely Right.

EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HX 1782924-1
Manufacturer:	QIAGEN GmbH Qiagen Str. 1 40724 Hilden Germany
EUDAMED Single Registration No.:	DE-MF-000004949

SAMPLES COLLECTION DEVICES
IVR 0503 Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
W05010101 - VENOUS OR ARTERIOUS BLOOD COLLECTION DEVICES

NUCLEIC ACID TESTING INSTRUMENTS
IVR 0302 Other devices intended to be used for markers of cancer and non-malignant tumours
IVR 0403 Other devices intended to be used for human genetic testing
W02050192 – NUCLEIC ACID TESTING INSTRUMENTS EXCEPT MICRO-ARRAYS - IVD MEDICAL DEVICE SOFTWARE

Products of Class D:

INFECTIOUS DISEASES
IVR 0503 Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
W01050705 - MULTIPLE PANELS FOR INFECTIONS - VARIOUS

Report No.:	1148061-10
Effective date:	2024-09-13
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EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
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Registration No.:	HX 1782924-1
Manufacturer:	QIAGEN GmbH Qiagen Str. 1 40724 Hilden Germany
EUDAMED Single Registration No.:	DE-MF-000004949
Authorized representative(s):	N/A

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2022-09-15
1	Scope extension	2023-02-09
2	Scope extension (new Product List and Application PDQ2_2023-12-12)	2024-04-26
3	Scope extension, based on Product List and Application PDQ2_2023 12-12_2024-07-30	2024-07-30
4	Scope extension, add class D products (based on Product List and Application PDQ2_2023 12-12_2024-09-13)	2024-09-13

Report No.:	1148061-10
Effective date:	2024-09-13
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BS-MDR-091

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Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810009**

Certificate Holder: **QIAGEN N.V.**
Hulsterweg 82
5912 PL Venlo
Netherlands

including the locations according to annex

Scope: Design and development, manufacture, distribution, installation and service of products and provision of customer services in the area of in vitro diagnostic medical devices and life science research

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2024-08-09 until 2027-08-08.
First certification 2018

2024-08-08

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

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Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810009**

No.	Location	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	Design and development, manufacture, distribution, marketing and servicing of products for the handling, stabilization, separation, purification, amplification and detection of nucleic acids and proteins and provision of services for RNA/DNA isolation, genome amplification, PCR-& sequencing-analysis including data interpretation in the area of in vitro diagnostic medical devices and life science research
/03	c/o QIAGEN Manchester Ltd. Citylabs 2.0 200 Hathersage Road Manchester M13 0BH United Kingdom	Design and development of molecular diagnostic reagents and instruments and the installation, service and distribution of molecular diagnostic and immunological reagents, instruments and software used in the area of in vitro diagnostic medical devices.
/04	c/o QIAGEN Ltd. Citylabs 2.0 200 Hathersage Road Manchester M13 0BH United Kingdom	Installation, service and distribution of molecular diagnostic and immunological reagents, instruments and software used in the area of in vitro diagnostic medical devices.
/05	c/o QIAGEN Redwood City Inc. 1001 Marshall Street 2nd Floor	Development of bioinformatics software for analyzing, interpreting and reporting on biological data

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810009**

	Redwood City CA 94063 USA	
/06	c/o QIAGEN Sciences LLC 19300 Germantown Road Germantown MD 20874 USA	Manufacture of Products for the Separation and Purification of Nucleic Acids and Proteins
/07	c/o QIAGEN Aarhus A/S Silkeborgvej 2 4. sal 8000 Aarhus C Denmark	Development and manufacturing of bioinformatics software for analyzing, interpreting and reporting on biological data and provisioning of bioinformatics services

2024-08-08

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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.

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

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.

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

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

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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

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.

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

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

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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

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.

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

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

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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Certificate

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

Registration No.: SX 1418003-1

Certificate Holder: QIAGEN N.V.
Hulsterweg 82
5912 PL Venlo
Netherlands

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.

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

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

TÜVRheinland® Precisely Right.

Validation Certificate

The following QIAGEN product is validated for use in your forensic applications:

QIAsymphony DNA Investigator Kit (192), cat. no. 931436

Our developmental validation study was based on the recommendations of:

The European Network of Forensic Science Institute (ENFSI)

The Revised Validation Guidelines of the Scientific Working Group on DNA Analysis Methods (SWGDAM)

The results of this study show that the kit is recommended for forensic casework, paternity testing, and other human identity testing applications.