

EU Certificate

Quality Management System REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices Annex IX Chapters I and 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

The Notified Body hereby declares that the requirements of Annex IX, Chapter I 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.: 1209385-10
Effective date: 2026-06-30
Expiry date: 2031-06-29
Issue date: 2026-06-15



Katja Mierisch
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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 in vitro diagnostic medical devices with the identification number 0197.

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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zfg.de
BS-IVDR-097



TÜVRheinland®
Precisely Right.

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Products:

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
W01050702 - MULTIPLE BACTERIA/FUNGI PANELS

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



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Quality Management System

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Annex IX Chapters I and III

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Qiagen Str. 1
40724 Hilden
Germany

EUDAMED Single
Registration No.: DE-MF-000004949

Products:

Products of class C, companion diagnostics:

GENETIC TESTING

IVR 0302: Other devices intended to be used for markers of
cancer and non-malignant tumours
W01060299 - TESTS FOR ACQUIRED GENETIC OR
CHROMOSOMAL ALTERATIONS – OTHER

Authorized representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
8	Re-certification Replaces certificate HX 1782924-1 Rev. 7 issued 2026-03-17	2026-06-15

