

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

Authorised
representative(s): N/A

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. 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. If class D devices are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.10 is required before placing them on the market.

Report No.: 3350838-60

Effective date: 2022-09-15

Expiry date: 2026-06-29

Issue date: 2022-09-15

A blue ink signature of Dipl.-Ing. Sven Hoffmann over a horizontal line.

Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2022-09-15

Report No.: 3350838-60
Effective date: 2022-09-15
Expiry date: 2026-06-29
Issue date: 2022-09-14





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