EU Certificate

Technical Documentation Assessment
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter II

Registration No.:	IX 1782924-1
Manufacturer:	QIAGEN GmbH Qiagen Str. 1 40724 Hilden Germany
EUDAMED Single Registration No.:	DE-MF-000004949
Classification:	D
General product group name:	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
Product name:	QIAstat-Dx® Respiratory SARS-CoV-2 Panel
Models and types:	REF: 691215
Basic UDI-DI:	4053228RRPSC2QST0000001PM
Authorized representative(s):	N/A

The Notified Body hereby declares that the requirements of Annex IX, Chapter II, Section 4 and 5.1 / 5.2 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and maintains a technical documentation defined by Annex IX, Chapter II, Section 4 and 5.1 / 5.2 of the aforementioned regulation. In addition to this certificate an EU quality management system certificate and for class D devices a batch verification is required before placing the listed products on the market.

Report No.:	1148061-30
Effective date:	2024-09-13
Expiry date:	2029-09-12
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
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Intended use:	The QIAstat-Dx® Respiratory SARS-CoV-2 Panel is used as qualitative test intended for analyzing nasopharyngeal swab (NPS) samples taken from symptomatic patients suspected of respiratory infection for the presence of viral or bacterial nucleic acids. The intended use is defined in the information of the QIAstat-Dx® Respiratory SARS-CoV-2 Panel labeling.

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-09-13

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