EU Certificate

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

Registration No.:	HX 1545122-1
Manufacturer:	QIAGEN Sciences LLC 19300 Germantown Road Germantown MD 20874 USA
EUDAMED Single Registration No.:	US-MF-000014502

Products:

Product Class C:

IMMUNOCHEMISTRY (IMMUNOLOGY)

IVR 0608 Devices intended to be used for screening, determination or monitoring of physiological markers

W01020190 - SPECIFIC PROTEINS

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.:	1166920-40
Effective date:	2025-11-10
Expiry date:	2029-09-09
Issue date:	2025-11-10

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-IVDR-097

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Precisely Right.

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Manufacturer: QIAGEN Sciences LLC
19300 Germantown Road
Germantown MD 20874
USA

EUDAMED Single Registration No.: US-MF-000014502

Products:

Product class C, Near-Patient Testing:

IMMUNOCHEMISTRY (IMMUNOLOGY)

IVR 0608 Devices intended to be used for screening, determination or monitoring of physiological markers

W01020190 – OTHER SPECIFIC PROTEINS

Authorized representative(s): QIAGEN GmbH
QIAGEN Strasse 1, 40724 Hilden, Germany
DE-AR-000004971

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-09-10
1	Scope extension: Products of Class C, Near-Patient Testing	2025-11-10

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