

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1545122-1

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

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.: 1114937-40
Effective date: 2022-07-22
Expiry date: 2025-07-21
Issue date: 2022-07-08



D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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Organization: QIAGEN Sciences LLC
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Scope: Design, development and manufacture of in vitro diagnostic lateral flow testing for detection of placental alpha macroglobulin-1 (PAMG-1), ELISA-based in vitro diagnostic kits used in the detection of transmissible agents, sexually transmissible agents, the determination of disease status and in the detection of immune responses to infectious diseases, cervical specimen collection kits and in vitro diagnostic systems used in the detection of transmissible agents and sexually transmissible agents and the determination of disease status.

Installation and service of in vitro diagnostic laboratory equipment and instrumentation used in the diagnosis, management and detection of cancer, compatibility testing, disease status, genetic testing, immune status, prenatal screening, sexually transmissible agents and transmissible agents.

Distribution of in vitro diagnostic systems used in the diagnosis, management and detection of cancer, compatibility testing, disease status, genetic testing, sexually transmissible agents, transmissible agents and transmissible agents and detection of placental alpha macroglobulin-1 (PAMG-1).

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The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o QIAGEN Sciences LLC 19300 Germantown Road Germantown MD 20874 USA	Design, development and manufacture
/02	c/o QIAGEN LLC 19300 Germantown Road Germantown MD 20874 USA	Distribution, installation and service
/03	c/o QIAGEN Sciences LLC 12920 Cloverleaf Center Drive Germantown MD 20874 USA	Service

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