

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**QIAGEN Sciences LLC**  
19300 Germantown Road  
Germantown MD 20874  
USA

has established and applies a quality management system for medical devices  
for the following scope:

**(see attachment for scope definition)**

Proof has been furnished that the requirements specified in

## EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-07-22  
Certificate Registration No.: SX 60140871 0001  
An audit was performed. Report No.: 21249753 010  
This Certificate is valid until: 2022-07-21

Certification Body



Date 2019-07-16



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60140871 0001

**Report No.:** 21249753 010

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

**Scope:**

Design, development, manufacture and distribution 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.

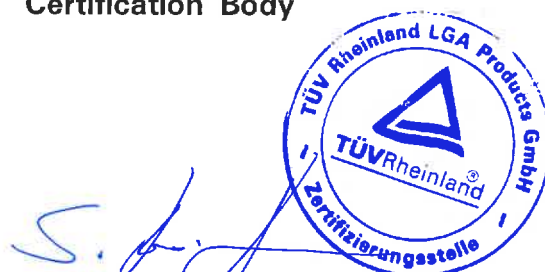
Installation and service of in vitro diagnostic laboratory equipment and instrumentation used in the diagnosis, management and detection of cancer, compatibility testing, disease status, genetic testing, immune status, prenatal screening, sexually transmissible agents and transmissible agents.

Distribution of in vitro diagnostic systems used in the diagnosis, management and detection of cancer, compatibility testing, disease status, genetic testing, sexually transmissible agents and transmissible agents.

**Certification Body**



**Date:** 2019-07-16



**Dipl.-Ing. Sven Hoffmann**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60140871 0001

**Report No.:** 21249753 010

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

**Scope:**

Site included:

QIAGEN LLC  
19300 Germantown Road,  
Germantown, MD 20874  
USA

Activities: distribution, installation and service



**Date:** 2019-07-16

**Certification Body**



  
**Dipl.-Ing. Sven Hoffmann**