

Certificate


Certificate No.: MD 1545122 3280422-600
Manufacturer: **QIAGEN Sciences LLC**
19300 Germantown Road
Germantown MD 20874
USA

D-U-N-S No.: 197294564
Certification criteria ISO 13485:2016
Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure
Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC
ANVISA n. 67/2009
Canada Medical Devices Regulations – Part 1 – SOR 98/282
Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD
Act (as applicable)
United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 21249753 010
Issue Date: 2020-05-27
Effective Date: 2020-05-27
Expiry Date: 2021-07-12




Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on www.certipedia.com, via the QR code or calling 1-888-743-4652.

Certificate

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Manufacturer: **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, immune status, prenatal screening, sexually transmissible agents and transmissible agents.

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Scope: The scope of Certification also includes the following additional sites:

QIAGEN Sciences LLC
19300 Germantown Road
Germantown MD 20874, USA
D-U-N-S No.: 197294564

Scope: Distribution, Installation and Service


Project No.: 21249753 010

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