Certificate

TÜVRheinland®

Certificate No.:	MD 3200621 3228037-90
Manufacturer:	**QIAGEN Manchester Ltd.** Skelton House Lloyd Street North Manchester, M15 6SH United Kingdom
D-U-N-S No.:	22-141-1577
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
Scope:	The design and development and manufacture of molecular diagnostic reagents used in the field of human genetic analysis.

TUV Rheinland of North America, Inc., an MDSAP authorized 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.:	21277341 002
Issue Date:	2018-01-31
Effective Date:	2018-01-31
Expiry Date:	2020-12-07

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dr. H. Lüdemann
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified by calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, USA
Tel: (925) 249-9123, Fax: (925) 249-9124