Certificate

TÜV Rheinland®

Certificate No.:	MD 1061883-1
Manufacturer:	**Microgenics Corporation** 46500 Kato Road Fremont, CA 94538 USA
REPs Facility ID:	F001111
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 United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
Scope:	Design and Development, Manufacture, and Distribution of Immunodiagnostic Reagents, Calibrators and Controls for Drugs of Abuse, Therapeutic Drug Monitoring, Calibration and Linearity Verification; Oncology Markers and Quality Control Reagents Used in the Detection of Genetic and Infectious Disease Testing status for Next Generation Sequencing

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.:	234176132-12
Issue Date:	2021-11-15
Effective Date:	2021-11-16
Expiry Date:	2024-11-11

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: S. Liu
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000009953?locale=en or calling 1-888-743-4652.

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