Certificate

Certificate No.:	MD 1061883-1-1
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. 665/2022, RDC ANVISA n. 551/2021, 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, Development, Manufacture, and Distribution of Immunodiagnostic Reagents, Calibrators and Controls for Drugs of Abuse, Therapeutic Drug Monitoring, Calibration and Linearity Verification. Design, Development, Manufacture, and Distribution of Oncology Markers and Quality Control Reagents for immunoassay, clinical

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.:	234218243-12
Issue Date:	2024-10-18
Effective Date:	2024-11-16
Expiry Date:	2027-11-15

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Melissa Di Buono-Russo
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com
or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

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Manufacturer:

Microgenics Corporation

46500 Kato Road
Fremont, CA 94538
USA

chemistry, serological assays and molecular testing for oncology and infectious diseases.

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