TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Microgenics Corporation
46500 Kato Road
Fremont CA 94538
USA

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

(see attachment)

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:	2018-11-30
Certificate Registration No.:	SX 60134720 0001
An audit was performed. Report No.:	31891238 002
This Certificate is valid until:	2021-11-29

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-11-29

Dipl.-Ing. Sven Hoffmann

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

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60134720 0001
Report No.: 31891238 002

Organization:
Microgenics Corporation
46500 Kato Road
Fremont CA 94538
USA

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

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TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2018-11-29

Dipl.-Ing. Sven Hoffmann

Certificate

TÜVRheinland®

Certificate No.:	MD 50012645 158788-20
Manufacturer:	Microgenics Corporation 46500 Kato Road Fremont, CA 94538 USA
D-U-N-S No.:	122153799
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

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.:	31891238 002
Issue Date:	2018-12-21
Effective Date:	2018-12-21
Expiry Date:	2021-11-16

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl. Ing. Sebastiano Pane
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

Certificate

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