

# 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

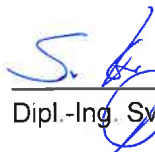
are fulfilled. The quality management system is subject to yearly surveillance.

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



Date 2018-11-29



Dipl.-Ing. Sven Hoffmann

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**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

**Certification Body**



**Date:** 2018-11-29



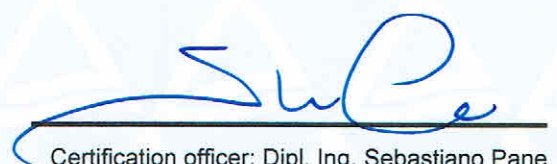
  
**Dipl.-Ing. Syen Hoffmann**

# Certificate

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



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.

# Certificate

Certificate No.: MD 50012645 158788-20

Manufacturer: Microgenics Corporation  
46500 Kato Road  
Fremont, CA 94538  
USA

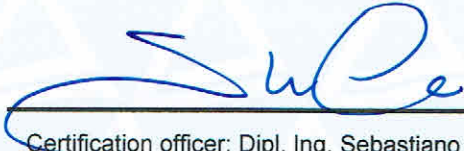
Scope: Design and development, manufacture and distribution of Immunodiagnostic reagents, calibrators and controls for drugs of abuse, therapeutic drug monitoring, calibration and linearity verification; Oncology markers and Quality control Reagents Used in the Detection of Genetic and Infectious Disease Testing status for next generation sequencing.

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