

# Certificate

## Quality Management System

**EN ISO 13485:2016**

**EN ISO 13485:2016/AC:2018**

**EN ISO 13485:2016/A11:2021**

Registration No.: SX 2449171-1

Certificate Holder: Microgenics B.V. & Co. KG  
Neuendorfstr. 25  
16761 Hennigsdorf  
Germany

Scope: Sales, Distribution, Installation and Servicing of In-Vitro Diagnostic Instruments, Kits, and Reagents for Clinical Diagnostics.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1128378-40

Effective date: 2024-11-12

Expiry date: 2027-11-11

Issue date: 2024-11-12



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This certificate can be validated on <https://www.certipedia.com>

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Microgenics B.V. & Co. KG Neuendorfstr. 25 16761 Hennigsdorf Germany	Sales, Distribution, Installation and Servicing of In-Vitro Diagnostic Instruments, Kits, and Reagents for Clinical Diagnostics.
/02	c/o Microgenics B.V. & Co. KG Im Steingrund 4-6 63303 Dreieich Germany	Sales, Installation and Servicing of In-Vitro Diagnostic Instruments, Kits, and Reagents for Clinical Diagnostics.

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