EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HX 1061883-1
Manufacturer:	Microgenics Corporation 46500 Kato Road Fremont CA 94538 USA
EUDAMED Single Registration No.:	US-MF-000030375
Products:	Products of Class B: IMMUNOCHEMISTRY (IMMUNOLOGY) IVR 0605: Devices intended to be used for monitoring of levels of medicinal products, substances or biological components. W01020901 - DRUGS OF ABUSE W01020902 - TOXICOLOGY W01021521 - MULTICOMPONENT IMMUNOCHEMISTRY CONTROLS Products of class C: IMMUNOCHEMISTRY (IMMUNOLOGY) IVR 0605: Devices intended to be used for monitoring of levels of medicinal products, substances or biological components. W01020407 - THYROXINE W01020801 - CARDIOVASCULAR TDM

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class D devices are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4 is required before placing them on the market.
If class B, C or D devices for self-testing or near-patient testing are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.1 is required before placing them on the market.
If companion diagnostics are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.2 is required before placing them on the market.

Report No.:	234205575-11
Effective date:	2023-12-12
Expiry date:	2028-12-11
Issue date:	2023-12-12

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/746 concerning medical devices with the identification number 0197.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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Registration No.:	HX 1061883-1
Manufacturer:	Microgenics Corporation 46500 Kato Road Fremont CA 94538 USA
EUDAMED Single Registration No.:	US-MF-000030375
	W01020802 - CENTRAL NERVOUS SYSTEMS TDM W01020803 - ANTIBIOTIC TDM / ANTIVIRUS TDM W01020806 - IMMUNOSUPPRESSANT TDM W01020901 - DRUGS OF ABUSE W01020902 - TOXICOLOGY W01021521 - MULTICOMPONENT IMMUNOCHEMISTRY CONTROLS W01021522 - STANDARDS AND CALIBRATORS IMMUNOCHEMISTRY GENETIC TESTING IVR 0302: Other devices intended to be used for markers of cancer and non-malignant tumours. W01060299 - TESTS FOR ACQUIRED GENETIC OR CHROMOSOMAL ALTERATIONS - OTHER
Authorized representative(s):	B·R·A·H·M·S GmbH Neuendorfstr. 25 16761 Hennigsdorf, Germany

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Fremont CA 94538
USA

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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-12-12

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