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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zflg.de
BS-IVDR-099



Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and
Companion Diagnostics)

No. V12 097102 0003 Rev. 00

Manufacturer:

Proteomedix AG

Wagistrasse 23
8952 Schlieren
SWITZERLAND

SRN Manufacturer:

CH-MF-000028322

**Authorized
Representative:**

Emergo Europe B.V.
Prinsessegracht 20, 2514 AP The Hague, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).

The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12_097102_0003_Rev_00

Report No.:

713225022_IVDR

Valid from:

2022-10-07

Valid until:

2027-10-06

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-10-07



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Classification: C
Device Group: W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code: IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose: IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer

Classification: C
Device Group: W0201 - CHEMISTRY / IMMUNOCHEMISTRY INSTRUMENTS
IVP Code: IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose: IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer

The validity of this certificate depends on conditions and/or is limited to the following: -none-