ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.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 D Devices, Class C and B Devices for self-/near-patient testing, Class C Devices Companion Diagnostics)

No. V10 120353 0001 Rev. 00

Manufacturer:

Gesellschaft zur Forschung, Entwicklung und Distribution von Diagnostika im Blutspendewesen mbH
Altenhöferallee 3
60438 Frankfurt am Main
GERMANY

SRN Manufacturer - DE-MF-000025295

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 certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to the applicable Section(s) of Annex IX Chapter II is necessary in addition to this EU Quality Management System Certificate.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V10 120353 0001 Rev. 00

Report No.: 713297624

Valid from: 2024-06-19

Valid until: 2029-06-18

Marta Carnielli
Head of Certification IVD

Issue date: 2024-06-19

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	Class D
Device Group:	W010504 - OTHER VIROLOGY TESTS (INFECT. IMMUNOLOGY/NAT)
Intended Purpose:	IVR 0502 - Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration
Classification:	Class D
Device Group:	W010508 - CONTROLS/STANDARDS/CALIBRATORS - (INFECT. IMMUNOLOGY/NAT)
Intended Purpose:	IVR 0502 - Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2024-06-19	713297624	Initial issuance

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