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 010283 0641 Rev. 02

Manufacturer: **Roche Diagnostics GmbH**
Sandhofer Strasse 116
68305 Mannheim
GERMANY

SRN Manufacturer: DE-MF-000006260

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 010283 0641 Rev. 02

Report No.: 713231302-07

Preceding Certificate No.: V10 010283 0641 Rev. 01

Valid from: 2022-12-21

Valid until: 2026-09-23

Date of Initial Issuance: 2021-09-24

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-12-21

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:	C
Device Group:	W010302 - HAEMOSTASIS REAGENTS (COAGULATION)
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease
Classification:	C
Device Group:	W020206 - RAPID TEST HEMATOLOGY / HISTOLOGY / CYTOLOGY INSTRUMENTS
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease
Classification:	C
Device Group:	W010216 - IMMUNOCHEMISTRY - RAPID TESTS & POINT OF CARE
Intended Purpose:	IVR 0606 - Devices intended to be used for non-infectious disease staging
Classification:	B
Device Group:	W010106 - CLINICAL CHEMISTRY - RAPID TESTS & POC
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers
Classification:	C
Device Group:	W010216 - IMMUNOCHEMISTRY - RAPID TESTS & POINT OF CARE
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers
Classification:	C
Device Group:	W010216 - IMMUNOCHEMISTRY - RAPID TESTS & POINT OF CARE
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease
Classification:	D
Device Group:	W010504 - OTHER VIROLOGY TESTS (INFECT. IMMUNOLOGY/NAT)
Intended Purpose:	IVR 0504 - Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging

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No. V10 010283 0641 Rev. 02

Classification:	D
Device Group:	W010508 - CONTROLS/STANDARDS/CALIBRATORS - (INFECT. IMMUNOLOGY/NAT)
Intended Purpose:	IVR 0504 - Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging
Classification:	C
Device Group:	W020104 - BLOOD GAS ANALYSIS / ELECTROLYTE INSTRUMENTS
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers
Classification:	C
Device Group:	W010106 - CLINICAL CHEMISTRY - RAPID TESTS & POC
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report
00	2021-09-24	713209683_IVDR
01	2022-07-19	713231302-04

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