



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 094600 0007 Rev. 00

Manufacturer: **Bosch Healthcare Solutions GmbH**
Stuttgarter Strasse 130
71332 Waiblingen
GERMANY

SRN Manufacturer: DE-MF-000024061

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_094600_0007_Rev_00

Report No.: 713226555-IVDR

Valid from: 2022-10-21

Valid until: 2027-10-20

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-10-21



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 BS-IVDR-099



Product Service

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No. V10 094600 0007 Rev. 00

Classification: B
Device Group: W02010199 - CHEMISTRY INSTRUMENTS - OTHER
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-