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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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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 094600 0010 Rev. 01

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 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.All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12 094600 0010 Rev. 01

Report No.:	713330013_CN
Preceding Certificate No.:	V12 094600 0010 Rev. 00
Valid from:	2024-07-02
Valid until:	2027-10-20
Date of Initial Issuance:	2024-05-15

Marta Carnielli
Head of Certification IVD

Issue date: 2024-07-02

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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No. V12 094600 0010 Rev. 01

Classification:	Class B
Device Group:	W0105 - INFECTIOUS DISEASES
Intended Purpose:	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

Classification:	Class C
Device Group:	W0105 - INFECTIOUS DISEASES
IVP Code:	IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
Intended Purpose:	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

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

Revision History:

Rev.	Dated	Report	Description
00	2024-05-15	713283653_CN	Initial issuance
01	2024-07-02	713330013_CN	Supplemented: Device(s)/group of device(s) added

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