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

Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapter I

Certificate No. V13 110139 0003 Rev. 01

Manufacturer:

Bosch Healthcare Solutions GmbH
Alte Bundesstraße 50
71332 Waiblingen
GERMANY

SRN Manufacturer - DE-MF-000024061

The quality management system has been evaluated in accordance with Regulation (EU) 2017/746, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class A devices in sterile conditions are covered by this certificate, the audit was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.
If class B or C excluding self-/near-patient-testing, or class C companion diagnostics devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class D devices, class B or C self-/near-patient testing, or class C companion diagnostics devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

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:V13 110139 0003 Rev. 01

Report No.:	713333126-06
Preceding Certificate No.:	V13 110139 0003 Rev. 00
Valid from:	2025-10-17
Valid until:	2027-10-20
Date of Initial Issuance:	2025-07-15

Marta Carnielli
Head of Certification IVD

Issue date: 2025-10-17

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EU Quality Management System Certificate

Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapter I

Certificate No. V13 110139 0003 Rev. 01

Classification:	Class B
Device Group:	IVR 0503 - Infectious agent detection: Presence of, or exposure to an infectious agent
Intended Purpose:	Devices intended to be used to detect the presence of, or exposure to an infectious agent
Classification:	Class B
Device Group:	IVR 0608 - Physiological status and therapeutic measures: General physiological markers
Device Properties:	IVS 1001 - Devices intended to be used for near-patient testing
Intended Purpose:	See product certificate
Classification:	Class C
Device Group:	W0105 + IVP 3011 - Infectious diseases
Intended Purpose:	IVD Reagents for Infectious diseases
Classification:	Class C
Device Group:	IVR 0503 - Infectious agent detection: Presence of, or exposure to an infectious agent
Device Properties:	IVS 1001 - Devices intended to be used for near-patient testing
Intended Purpose:	See product certificate
Classification:	Class C
Device Group:	IVR 0608 - Physiological status and therapeutic measures: General physiological markers
Device Properties:	IVS 1002 - Devices intended to be used for self-testing
Intended Purpose:	See product certificate
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2025-07-15	713374628	Amended: Change of certificate holder's data Administrative merge / transfer to new Certificate Type
01	2025-10-17	713333126-06	Supplemented: Device(s)/group of device(s) added

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