BOSCH
Healthcare Solutions

EU DECLARATION OF CONFORMITY
EU-KONFORMITÄTSERKLÄRUNG

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:
Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller:

Bosch Healthcare Solutions GmbH
Stuttgarter Strasse 130
71332 Waiblingen, Germany

SRN: (Single Registration Number)	DE-MF-000024061

We declare under our sole responsibility that the product(s) classified as follows:
Wir erklären in alleiniger Verantwortung, dass das/die Produkt(e) mit folgender Klassifizierung:

Name: Name:	**Article no(s).:** Artikelnummer(n):	**Classification, incl. Rule:** Klassifizierung, inkl. Rule:	**Basic UDI-DI:** Basis UDI-DI:	**Contents of package:** Packungsinhalt:
Vivalytic Bacterial Meningitis	F09G301118	**C** **According to Rule 3b** Gemäß Regel 3b	4059233BAM000CK	15 Cartridges/ Kartuschen

Short Intended Purpose: Kurzer Verwendungszweck:	**PCR test for pathogens related to Bacterial Meningitis** PCR Test für relevante Pathogene für Bakterielle Meningitis
Meet(s) all the provisions of the directive(s)/regulation(s) on: allen Anforderungen der Richtlinie(n)/Verordnung(en) über:	**In vitro diagnostic medical devices regulation 2017/746** In-vitro-Diagnostik Verordnung 2017/746

which apply to it.
entspricht/entsprechen, die anwendbar sind.

Conformity assessment procedure: Konformitätsbewertungsverfahren:	**ANNEX IX Conformity assessment based on a quality management system and on assessment of technical documentation of the In Vitro Diagnostic Medical Devices Regulation 2017/746** **- Chapters I and III** **- Chapter II Sections 4** Anhang IX Konformitätsbewertung auf der Grundlage eines Qualitätsmanagementsystems und einer Bewertung der technischen Dokumentation - Kapitel I und III - Kapitel II Abschnitt 4
Name, address and identification number of Notified Body: Name, Adresse und Kennnummer der Benannten Stelle:	**TÜV SÜD Product Service GmbH** Ridlerstraße 65 80339 München, Germany Nr.0123
Valid until: Gültg bis:	**20-October-2027** 20. Oktober 2027

Date and place of issue:
Ort und Datum der Ausstellung

Name, Function, and signature of authorized persons:
Name, Funktion und Unterschrift der autorisierten Personen:

Waiblingen, 24.02.2025

Marc Meier
Chief Executive Officer

i.V.
Kay Scherer
Person Responsible for Regulatory Compliance

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Supplement to EU Declaration of Conformity
Vivalytic Bacterial Meningitis
Anhang zur EU-Konformitätserklärung
Vivalytic Bacterial Meningitis

We hereby confirm that all products listed in the referenced Declaration of Conformity comply with the criteria in the following standards:
Wir bestätigen hiermit, dass alle Produkte in der referenzierten Konformitätserklärung die Anforderungen der folgenden Standards erfüllen:

Identification No.	Description/Title
DIN EN 13612:2002 (+AC)	EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
DIN EN 13641:2002	EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019/A11:2021	EN ISO 14971:2019/A11:2021 Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2019)
EN 62366-1:2015 + AC:2015 + A1:2020	EN 62366-1:2015 + AC:2015 + A1:2020 Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)
EN ISO 13485:2016/A11:2021	EN ISO 13485:2016/A11:2021 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 15223-1:2021	EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
EN ISO 18113-1:2011	EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
DIN EN ISO 20417:2021	EN ISO 20417:2021Medical devices - Information supplied by the manufacturer (ISO 20417:2021, corrected version 2021-12)
EN ISO 20916:2024	EN ISO 20916:2024 In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice
EN ISO 23640:2015	EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
DIN EN 13427:2004	EN 13427:2004 Packaging - Requirements for the use of European Standards in the field of packaging and packaging waste
DIN EN 13428:2004	EN 13428:2004 Packaging - Requirements specific to manufacturing and composition - Prevention by source reduction
DIN EN 13430:2004	EN 13430:2004 Packaging - Requirements for packaging recoverable by material recycling

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Ort und Datum der Ausstellung

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