

**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:	Article no(s):	Classification, incl. Rule:	Basic UDI-DI:	Contents of package:
Name:	Artikelnummer(n):	Klassifizierung, inkl. Rule:	Basis UDI-DI:	Packungsinhalt:
Vivalytic Mycoplasma	F09G301080	C according to Rule 3a gemäß Regel 3a	4059233MYP000RX	15 Cartridges 15 Kartuschen

Short Intended Purpose:

Kurzer Verwendungszweck:

PCR test for M. genitalium, M. hominis, U. parvum/urealyticum

PCR Test für M. genitalium, M. hominis, U. parvum/urealyticum

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, 27.02.2025


 Marc Meier
 Chief Executive Officer


 Kay Scherer
 Person Responsible for Regulatory Compliance

**BOSCH**

Healthcare Solutions

EU DECLARATION OF CONFORMITY
EU-KONFORMITÄTSERKLÄRUNG**Supplement to EU Declaration of Conformity****Vivalytic Mycoplasma**

Anhang zur EU-Konformitätserklärung

Vivalytic Mycoplasma

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
EN ISO 13485:2016 + AC 2018 + A11.2021	Medical devices - Quality management systems – System requirements for regulatory purposes
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019	Medical devices - Application of Risk Management to medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements
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 20916:2024	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
EN 62366-1:2021	Medical devices - Application of usability engineering to medical devices

Date and place of issue:

Ort und Datum der Ausstellung

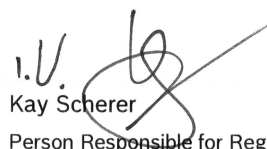
Name, Function and signature of authorized persons:

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Waiblingen, 27.02.2025


Marc Meier

Chief Executive Officer


Kay Scherer

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