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 C. auris	F09G301032	**C** **according to Rule 3c** gemäß Regel 3c	4059233900225	15 Cartridges 15 Kartuschen

Short Intended Purpose:
Kurzer Verwendungszweck: **PCR test for Candida auris**
PCR Test für Candida auris

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, 22.08.2024

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 C. auris

Anhang zur EU-Konformitätserklärung

Vivalytic C. auris

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 + AC2018 + A11:2021	Medical devices - Quality management systems – System requirements for regulatory purposes
EN 13612:2002 (+AC)	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 (+ A11:2021)	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
EN 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 62366-1:2015 + AC:2015 + A1:2020	Medical devices - Application of usability engineering to medical devices

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