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:** Klassifizierung:	**Basic UDI-DI:** Basis UDI-DI:	**Contents of package:** Packungsinhalt:
Vivalytic One	**F.09G.300.115**	**A**	**4059233900195**	**F.09G.300.061**

Meet(s) all the provisions of the directives on:
allen Anforderungen der Richtlinien über:

Regulation on In vitro diagnostic medical devices (EU) 2017/746
Verordnung für In-vitro-Diagnostika (EU) 2017/746

Radio Equipment Directive 2014/53/EU
Richtline für Funkanlagen 2014/53/EU

Restricted Hazardous Substances 2011/65/EU (RoHS)
Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten 2011/65/EU (RoHS)

Directive 2006/42/EC on Machinery
Richtlinie 2006/42/EC für Maschinen

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

Conformity assessment procedure:
Konformitätsbewertungsverfahren:

ANNEX II and III (Technical Documentation) of the In Vitro Diagnostic Medical Devices Regulation 2017/746
Anhang II und III (Technische Dokumentation) der In-vitro-Diagnostik Regulation 2017/746

Valid until:
Gültg bis:

DD-MM-YYYY
13-03-2026

Date and place of issue:
Ort und Datum der Ausstellung

Waiblingen, 13.03.2023

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

Markus Thürsam
Chief Technical Officer

Kay Scherer
Person Responsible for Regulatory Compliance

BOSCH
Healthcare Solutions

EU DECLARATION OF CONFORMITY
EU-KONFORMITÄTSERKLÄRUNG

Supplement to EU Declaration of Conformity
Vivalytic One
Anhang zur EU Konformitätserklärung
Vivalytic One

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 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 ISO 15223-1:2016, Corrected version 2016-12-15)
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-3:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009); German version EN ISO 18113-3:2011
DIN EN 61010-1:2020-03; Cor1:2022-02 IEC 61010-1:2010 + COR:2011 + A1:2016, modifiziert + A1:2016/ COR1:2019	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements
EN 61010-2-010:2014	Safety requirements for electrical equipment, control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of Materials
EN 61010-2-101:2017	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2006 + Cor.:2008 + A1:2015+ A1:2020 IEC 62304:2006 + A1:2015+ A1:2020	Medical device software – Software life-cycle processes
EN 62366-1:2015+AC:2015 IEC 62366-1:2015 + Cor1:2016	Medical devices – Application of usability engineering to medical devices
EN 300 328 V2.2.2	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques;
EN 301 489-1 V2.2.3	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU

BOSCH
Healthcare Solutions

EU DECLARATION OF CONFORMITY
EU-KONFORMITÄTSERKLÄRUNG

EN 301 489-3 V2.1.1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for short range devices; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-17 V3.2.4	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/30/EU
EN 50581:2012 Replaced by EN IEC 63000: 2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
EN 13427:2004	Packaging - Requirements for the use of European Standards in the field of packaging and packaging waste
EN 13428:2004	Packaging – Requirements specific to manufacturing and composition – Prevention by source reduction
EN 13430:2004	Packaging – Requirements for packaging recoverable by material recycling
EN 50419:2006	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)
EN IEC 60721-3-2:2018	Classification of environmental conditions –Part 3-2: Classification of groups of environmental parameters and their severities – Transportation and Handling
ISO 9022-2:2015	Optics and photonics – Environmental test methods – Part 2: Cold, heat and humidity
ISO 9022-3:2015	Optics and photonics –Environmental test methods –Part 3: Mechanical stress
BSI-CS 132 V1.0 (2.5.2018)	Cyber-Sicherheitsanforderungen an netzwerkfähige Medizinprodukte

Date and place of issue:
Ort und Datum der Ausstellung

Waiblingen, 13.03.2023

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

Markus Thürsam
Chief Technical Officer

Kay Scherer
Person Responsible for Regulatory Compliance