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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX, Chapter II, Section 4, 5.1
(Class C and B Devices for self-testing and near patient testing)

No. V74 094600 0008 Rev. 00

Manufacturer:

Bosch Healthcare Solutions GmbH
Stuttgarter Strasse 130
71332 Waiblingen
GERMANY

SRN Manufacturer: DE-MF-000024061

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the Technical Documentation are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX, Chapter II, Section 4, 5.1 of this regulation with a positive result.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX Chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V74 094600 0008 Rev. 00

Report No.: 713226090

Valid from: 2022-10-21
Valid until: 2027-10-20

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-10-21

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	B
Device Group:	W02010199 - CHEMISTRY INSTRUMENTS - OTHER
Basic UDI-DI:	4059233900157
Intended Purpose:	The Bosch Vivatmo pro system is intended for quantitative measurement of fractional nitric oxide (FeNO) in human breath. Measurement of changes in the fractional nitric oxide concentration in expired breath aids in evaluating a patient's response to anti-inflammatory therapy, as an adjunct to establish clinical and laboratory assessments of inflammatory processes such as asthma. The Bosch Vivatmo pro system is an automated non-invasive near patient testing measuring device intended to be used in health care environment (in vitro diagnostic use) by healthcare professional users only. The results of the Vivatmo pro should not be used as a sole parameter for the diagnosis or screening of airway diseases.
Device(s):	Vivatmo pro Western Europe Vivatmo pro Eastern Europe Vivatmo pro Asia Vivatmo pro Handheld Vivatmo pro basestation

Classification:	B
Device Group:	W02010199 - CHEMISTRY INSTRUMENTS - OTHER
Basic UDI-DI:	4059233900164
Intended Purpose:	Component/Mouthpiece to measure Fractional Exhaled Nitric Oxide (FeNO) in human breath with the Vivatmo pro.
Device(s):	Vivatmo pro Oxycap

Classification:	B
Device Group:	W02010199 - CHEMISTRY INSTRUMENTS - OTHER
Basic UDI-DI:	4059233900171
Intended Purpose:	Component/Mouthpiece to produce a zero-NO (QC) measurement with the Vivatmo pro.
Device(s):	Vivatmo pro Level 0

The validity of this certificate depends on conditions and/or is limited to the following:	-none-

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