ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 094600 0006 Rev. 01

Manufacturer: **Bosch Healthcare Solutions GmbH**
Stuttgarter Strasse 130
71332 Waiblingen
GERMANY

Product Category(ies): **In Vitro diagnostic devices for self testing and systems for the detection of infection markers**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1 094600 0006 Rev. 01

Report no.: 713226555-CN / 713218741

Valid from: 2022-05-02
Valid until: 2025-05-26

Date, 2022-05-02

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

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No. V1 094600 0006 Rev. 01

Model(s):

Self-Testing devices for quantitative measurements of nitric oxide in human breath to monitor airway inflammation
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Devices for nucleic acid-based detection of Chlamydia for professional use

Facility(ies):

Bosch Healthcare Solutions GmbH
Stuttgarter Strasse 130, 71332 Waiblingen, GERMANY

Bosch Healthcare Solutions GmbH
Alte Bundesstraße 50, 71332 Waiblingen, GERMANY

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