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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 110139 0002 Rev. 00

Certificate Holder: **Bosch Healthcare Solutions GmbH**
Alte Bundesstraße 50
71332 Waiblingen
GERMANY

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution and Service of In-Vitro Diagnostic Reagents, Reagent Products and Instruments for Molecular Biological Detection of Infectious Diseases**

Design and Development, Production, Distribution and Service of In-Vitro Diagnostic Systems for Breath Analysis

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 110139 0002 Rev. 00
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

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Report No.: **713374628**
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(Renee Walker)

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C E R T I F I C A T E

No. QS6 110139 0002 Rev. 00

Regulatory Requirements:

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil
- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

Bosch Healthcare Solutions GmbH
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Facility Scopes:

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