



America

# CERTIFICATE

No. QS6 094600 0009 Rev. 00

**Certificate Holder:** **Bosch Healthcare Solutions GmbH**  
Stuttgarter Strasse 130  
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\\_094600\\_0009\\_Rev\\_00](http://www.tuvsud.com/ps-cert?q=cert:QS6_094600_0009_Rev_00)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F006890**  
**Report No.:** **713297156**  
**Effective Date:** **2024-01-19**  
**Expiry Date:** **2027-01-18**

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Date of Issue: 2024-01-24

( Renee Walker )  
Director, US Certification Body, MHS

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**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**

Stuttgarter Strasse 130, 71332 Waiblingen, GERMANY

**Bosch Healthcare Solutions GmbH**

Alte Bundesstraße 50, 71332 Waiblingen, GERMANY

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**Facility Scopes:**

**Bosch Healthcare Solutions GmbH**

Stuttgarter Strasse 130, 71332 Waiblingen, GERMANY

Management

REPs Facility ID: F006890

**Bosch Healthcare Solutions GmbH**

Alte Bundesstraße 50, 71332 Waiblingen, GERMANY

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