







Certificate

No. Q5 110139 0001 Rev. 00

Bosch Healthcare Solutions GmbH Holder of Certificate:

> Alte Bundesstraße 50 71332 Waiblingen **GERMANY**

Certification Mark:



Design and Development, Production, Distribution Scope of Certificate:

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.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 110139 0001 Rev. 00

Report No.: 713374628

Valid from: 2025-07-15 Valid until: 2027-03-19

2025-07-15

Christoph Dicks

Head of Certification/Notified Body



Date,





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Applied Standard(s): ISO 13485:2016

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -

Requirements for regulatory purposes

Facility(ies): Bosch Healthcare Solutions GmbH

Alte Bundesstraße 50, 71332 Waiblingen, GERMANY

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