Certificate

No. Q5 004475 0001 Rev. 02

Holder of Certificate: **R-Biopharm AG**
An der Neuen Bergstraße 17
64297 Darmstadt
GERMANY

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In-vitro Diagnostic Instruments with related Software, In-vitro Diagnostic Reagents for Immunochemistry (Immunology), Infectious Immunology, Microbiology, Genetic Testing including Specimen Receptacles, Sterile Specimen Receptacles. The Provision of Raw Materials for In-vitro Diagnostic Reagents.**

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 004475 0001 Rev. 02

Report No.: 713346538

Valid from: 2025-01-16
Valid until: 2028-01-15

Date, 2025-01-13

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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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):

R-Biopharm AG
An der Neuen Bergstraße 17, 64297 Darmstadt, GERMANY

Design and Development, Production and Distribution of In-vitro
Diagnostic Instruments with related Software, In-vitro Diagnostic
Reagents for Immunochemistry (Immunology), Infectious
Immunology, Microbiology, Genetic Testing including Specimen
Receptacles, Sterile Specimen Receptacles. The Provision of Raw
Materials for In-vitro Diagnostic Reagents.

R-Biopharm AG
Reißstraße 1, 64319 Pfungstadt, GERMANY

Production of In-vitro Diagnostic Reagents for Immunochemistry
(Immunology), Infectious Immunology.

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