



Certificate

No. Q5 004475 0001 Rev. 01

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 products and raw material for clinical diagnostics: Immunology, Molecular biology, Specimen receptacles, Microbiology, Infection Immunology, Genetic testing and In-vitro diagnostic Instrument and related Software

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 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:Q5 004475 0001 Rev. 01

Report No.: 713214437

Valid from: 2022-01-16

Valid until: 2025-01-15

Date, 2022-01-14

Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): **R-Biopharm AG**
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and raw material for clinical diagnostics: Immunology, Molecular
biology, Specimen receptacles, Microbiology, Infection
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Reißstraße 1, 64319 Pfungstadt, GERMANY

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Immunology, Infection Immunology

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