



Product Service

# 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](http://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**  
**An der Neuen Bergstraße 17, 64297 Darmstadt, GERMANY**

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

**R-Biopharm AG**  
**Reißstraße 1, 64319 Pfungstadt, GERMANY**

Production of products and raw material for clinical diagnostics:  
Immunology, Infection Immunology

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