



Product Service

# 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](http://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



Product Service

# Certificate

No. Q5 004475 0001 Rev. 02

**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.

./.