



America

# CERTIFICATE

No. QS6 004475 0003 Rev. 01

**Certificate Holder:****R-Biopharm AG**

An der Neuen Bergstraße 17  
64297 Darmstadt  
GERMANY

**Certification Mark:****Scope of Certificate:**

**Design, Development and Manufacture of In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits, In-Vitro Diagnostic Instrument and related Software used in the Diagnosis of Autoimmune Status, Disease Status, Allergy Testing, Genetic Testing, Immune Status, Immunological Typing, Sexually Transmissible Agents, Transmissible Agents, Therapeutic Drug Monitoring including Near Patient / Point of Care and Specimen Receptacles In-Vitro Diagnostic Medical Devices**

**Standard(s):****ISO 13485:2016****Regulatory Authority(ies):**

**Australia TGA, Brazil ANVISA, Health Canada, USA FDA.  
See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website [www.tuvsud.com/ps-cert](http://www.tuvsud.com/ps-cert)  
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:****F002697****Effective Date:****2022-03-16****Expiry Date:****2025-03-11**

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( Renee Walker )  
Manager, US Certification Body,  
Medical and Health Services



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## Regulatory Requirements: Audit/Certification Criteria

### Australia

Therapeutic Goods (Medical Devices) Regulations 2002  
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

### Brazil

- RDC ANVISA n. 16/2013  
- RDC ANVISA n. 23/2012  
- RDC ANVISA n. 67/2009

### Canada

- Medical Device Regulations – Part 1- SOR 98/282

### United States

- 21 CFR Part 803  
- 21 CFR Part 806  
- 21 CFR Part 807 – Subparts A to D  
- 21 CFR Part 820

## Facility(ies):

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

R-Biopharm AG  
Reißstraße 1, 64319 Pfungstadt, GERMANY

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**Facility Scopes:**

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