MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 004475 0003 Rev. 00

Certificate Holder:

r-biopharm

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

Certification Mark:

TÜV SÜD ISO 13485

Scope of Certificate:

Design, Development and Manufacture of In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits 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 https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **32-185-0323**

Effective Date: **2019-03-12**

Expiry Date: **2022-03-11**

Date of Issue: 2019-03-18

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

TÜV®

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 004475 0003 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

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

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies): R-Biopharm AG
An der Neuen Bergstraße 17, 64297 Darmstadt, GERMANY

Facility Scopes: Design, Development and Manufacture of In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits 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
DUNS No: 32-185-0323

Date of Issue: 2019-03-18

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

TÜV®