ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 004475 0003 Rev. 01

Certificate Holder:

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

Certification Mark:

Digitally signed by Bolea Petru
Date: 2022.11.10 13:05:33 EET
Reason: MoldSign Signature
Location: Moldova

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

REPs Facility ID: **F002697**

Effective Date: **2022-03-16**

Expiry Date: **2025-03-11**

Date of Issue: 2022-03-31

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

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C E R T I F I C A T E

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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

Date of Issue: 2022-03-31

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Facility Scopes:

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