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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 004475 0003 Rev. 02

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, Specimen Receptacles and Sterile 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. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 004475 0003 Rev. 02
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F002697**
Report No.: **713346538**
Effective Date: **2025-03-12**
Expiry Date: **2028-03-11**

Date of Issue: 2025-03-07

(Renee Walker)
Director, US Certification Body, MHS

TÜV®

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 004475 0003 Rev. 02

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. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

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: 2025-03-07

(Renee Walker)
Director, US Certification Body, MHS

TÜV®

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 004475 0003 Rev. 02

Facility Scopes:

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

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, Specimen Receptacles and Sterile Specimen Receptacles In-Vitro Diagnostic Medical Devices
REPs Facility ID: F002697

R-Biopharm AG
Reißstraße 1, 64319 Pfungstadt, GERMANY

Manufacture of In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits used in the Diagnosis of Allergy Testing, Sexually Transmissible Agents, Transmissible Agents, Therapeutic Drug Monitoring including Near Patient / Point of Care
REPs Facility ID: F002697

Date of Issue: 2025-03-07

(Renee Walker)
Director, US Certification Body, MHS

TÜV®

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com