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. 01

Digitally signed by Bolea Petru
Date: 2022.07.27 14:26:25 EEST
Reason: MoldSign Signature
Location: Moldova

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
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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No. QS6 004475 0003 Rev. 01

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

(Renee Walker)
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No. QS6 004475 0003 Rev. 01

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 and 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: 2022-03-31

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

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 004475 0005 Rev. 00

Manufacturer:

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

SRN Manufacturer: DE-MF-000007993

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12 004475 0005 Rev. 00

Report No.: 713214437_V12

Valid from: 2022-06-29

Valid until: 2027-06-28

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-06-29

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 004475 0005 Rev. 00

Classification:	C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0605 - Devices intended to be used for monitoring of levels of medicinal products, substances or biological components

Classification:	C
Device Group:	W0105 - INFECTIOUS DISEASES
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

Classification:	C
Device Group:	W0105 - INFECTIOUS DISEASES
IVP Code:	IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
Intended Purpose:	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

Classification:	B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0603 - Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances

Classification:	B
Device Group:	W0105 - INFECTIOUS DISEASES
Intended Purpose:	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

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Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 004475 0005 Rev. 00

The validity of this certificate depends on conditions and/or is limited to the following:	-none-

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 004475 0001 Rev. 01

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

r-biopharm®

An der Neuen Bergstraße 17
64297 Darmstadt
GERMANY

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of products and raw material for clinical diagnostics: Immunology, Molecular biology, Specimen receptacles, Microbiology, Infection Immunology, Genetic testing and In-vitro diagnostic Instrument and related Software**

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 and certification regulation of 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. 01

Report No.: 713214437

Valid from: 2022-01-16
Valid until: 2025-01-15

Date, 2022-01-14

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 004475 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

Design and Development, Production and Distribution of products and raw material for clinical diagnostics: Immunology, Molecular biology, Specimen receptacles, Microbiology, Infection Immunology, Genetic testing and In-vitro diagnostic Instrument and related Software

R-Biopharm AG
Reißstraße 1, 64319 Pfungstadt, GERMANY

Production of products and raw material for clinical diagnostics: Immunology, Infection Immunology

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