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

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

Product Service

Certificate

No. Q5 004475 0001 Rev. 01

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

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

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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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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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