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

Product Service

Certificate

No. Q5 004475 0001 Rev. 00

Holder of Certificate: **R-Biopharm AG**
An der Neuen Bergstraße 17
64297 Darmstadt
GERMANY

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

Certification Mark:

tuv-sud.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 instruments and software**

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

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). See also notes overleaf.

Report No.: 713131431

Valid from: 2019-01-16
Valid until: 2022-01-15

Date, 2019-01-10

Stefan Preiß

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

A4 / 07.17

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