



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:



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