



CERTIFICATE



This is to certify that the company

R-Biopharm AG

An der neuen Bergstraße 17
64297 Darmstadt
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:

Development, production and sales of products and raw material for clinical diagnostics: Immunology, molecular biology, specimen receptacles, microbiology, infection immunology, genetic testing and in-vitro-diagnostic equipment and software.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2003 + Cor. 1 : 2009

Certificate registration no.	019955 MP23SCC
Certificate unique ID	170656271
Effective date	2017-01-23
Expiry date	2019-02-28
Frankfurt am Main	2017-01-19



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Maxim Shkolnikov
Product Manager



Annex to certificate
Certificate registration No.: 019955 MP23SCC
Certificate unique ID: 170656271
Effective date: 2017-01-23

R-Biopharm AG

An der neuen Bergstraße 17
64297 Darmstadt
Germany

Location

R-Biopharm AG
An der neuen Bergstraße 17
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Scope

Development, production and sales of products and raw material for clinical diagnostics: Immunology, molecular biology specimen receptacles, microbiology, infection immunology, genetic testing and in-vitro-diagnostic equipment and software.

R-Biopharm Australia Pty Ltd.
34 Woodfield Boulevard
Caringbah / NSW 2229
Australia

Sales of products for clinical diagnostics: Immunology, molecular biology specimen receptacles, microbiology, infection immunology, genetic testing and in-vitro-diagnostic equipment and software.

Congen Biotechnologie GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

Development, production and sales of products for clinical diagnostics: molecular biology.

BIOSERV Diagnostics GmbH
BioTechnikum Greifswald
Walther-Rathenau-Str. 49a
17489 Greifswald
Germany

Development, production and sales of products for clinical diagnostics: Immunology.

BIOSERV Diagnostics GmbH
Doberaner Straße 151
18057 Rostock
Germany

Sales of products for clinical diagnostics: Immunology.

GWK Präzisionstechnik GmbH
Gollierstraße 70 Eingang C
80339 München
Germany

Development, production and sales of products for clinical diagnostics: in-Vitro-diagnostic equipment and software.



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Location

Scope

RefLab ApS

Ole Maaloes Vej 3
2200 Koebenhavn N
Denmark

Development, production and sales of products for clinical diagnostics: in-Vitro-diagnostic equipment and software.

R-Biopharm SAS

Parc d'affaires de Crécy
5a Rue Claude Chappe
69370 Saint Didier au Mont d'or
France

Sales of products for clinical diagnostics: Immunology, molecular biology specimen receptacles, microbiology, infection immunology, genetic testing and in-vitro-diagnostic equipment and software.

R-Biopharm Rhone Ltd.

Block 10 Todd Campus
West of Scotland Science Park
Acre Road, Glasgow
Scotland G20 0XA
United Kingdom

Sales of products for clinical diagnostics: Immunology, molecular biology specimen receptacles, microbiology, infection immunology, genetic testing and in-vitro-diagnostic equipment and software.

R-Biopharm Italia Srl

Via Morandi 10
20077 Melegnano, MI
Italy

Sales of products for clinical diagnostics: Immunology, molecular biology specimen receptacles, microbiology, infection immunology, genetic testing and in-vitro-diagnostic equipment and software.