



# CERTIFICATE

## DQS Medizinprodukte GmbH

hereby certifies that the company

### R-Biopharm AG

An der neuen Bergstraße 17  
64297 Darmstadt  
Germany

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

Scope:

Development, production and sales  
of products for clinical diagnostics

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

## EN ISO 13485 : 2003 + AC : 2007

Certificate registration no. 019955 MP27  
Certification ID 170498970  
Date of certification 2010-04-25  
Valid until 2011-01-09



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
ZLG-ZQ-987.99.07-46

Frank Graichen  
Managing Director

Stefan Hofmann  
Head of Certification Body



**Annex to Certificate  
Registration No. 019955 MP27  
Certificate ID 170498970**

**R-Biopharm AG**

An der neuen Bergstraße 17  
64297 Darmstadt  
Germany

**Sales units**

**Scope**

R-Biopharm Inc.  
7950 Old US 27 South Marshall  
Michigan 49068  
USA

Sales of products for  
clinical diagnostics

R-Biopharm SRL  
Via dell'Artigianato 13  
20070 Cerro Al Lambro (MI)  
Italy

Sales of products for  
clinical diagnostics

R-Biopharm SAS.  
Parc d'affaires de Crécy,  
17 avenue Charles de Gaul  
69370 Saint Didier au Mont D'Or  
France

Sales of products for  
clinical diagnostics

R-Biopharm Rhône Ltd.  
Block 10 Todd Campus  
West of Scotland Science Park  
Acre Road, Glasgow  
Scotland G20 0XA

Production and sales of products  
for clinical diagnostics

R-Biopharm Australia Pty Ltd.  
Serenity Cove Corporate Park  
Unit 7 260 Captain Cook Drive  
Kumell 2231  
Australia

Sales of products for  
clinical diagnostics