



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zflg.de  
BS-IVDR-099



Product Service

## EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,  
Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and  
Companion Diagnostics)

**No. V12 004475 0005 Rev. 00**

**Manufacturer:** **R-Biopharm AG**  
An der Neuen Bergstraße 17  
64297 Darmstadt  
GERMANY

**SRN Manufacturer:** DE-MF-000007993

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).

The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V12 004475 0005 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:V12 004475 0005 Rev. 00)

**Report No.:** 713214437\_V12

**Valid from:** 2022-06-29

**Valid until:** 2027-06-28

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2022-06-29



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**Classification:** C  
**Device Group:** W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)  
**IVP Code:** IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays  
**Intended Purpose:** IVR 0605 - Devices intended to be used for monitoring of levels of medicinal products, substances or biological components

**Classification:** C  
**Device Group:** W0105 - INFECTIOUS DISEASES  
**IVP Code:** IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays  
**Intended Purpose:** IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

**Classification:** C  
**Device Group:** W0105 - INFECTIOUS DISEASES  
**IVP Code:** IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)  
**Intended Purpose:** IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

**Classification:** B  
**Device Group:** W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)  
**Intended Purpose:** IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

**Classification:** B  
**Device Group:** W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)  
**Intended Purpose:** IVR 0603 - Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances

**Classification:** B  
**Device Group:** W0105 - INFECTIOUS DISEASES  
**Intended Purpose:** IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents



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The validity of this certificate -none-  
depends on conditions and/or  
is limited to the following: