



## 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 116468 0002 Rev. 00**

### Manufacturer:

**Biocare Medical, LLC**

60 Berry Drive  
Pacheco CA 94553  
USA

SRN Manufacturer - US-MF-000034581

### Authorized Representative:

Emergo Europe B.V.  
Westervoortsedijk 60, 6827 AT Arnhem, THE NETHERLANDS

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. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V12 116468 0002 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:V12_116468_0002_Rev._00)

**Report No.:** 72180497

**Valid from:** 2024-05-14

**Valid until:** 2029-05-13

Marta Carnielli  
Head of Certification IVD

**Issue date:** 2024-05-14



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



Product Service

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**Classification:** Class C  
**Device Group:** W0102019099 - SPECIFIC PROTEINS - OTHER  
**IVP Code:** IVP 3007 - In vitro diagnostic devices which require knowledge  
 regarding immunoassays  
**Intended Purpose:** IVR 0301 - Devices intended to be used in screening, diagnosis,  
 staging or monitoring of cancer

**The validity of this certificate -  
 depends on conditions and/or  
 is limited to the following:**

### Revision History:

Rev.	Dated	Report	Description
00	2024-05-14	72180497	Initial issuance