





## **Product Service**

## **Certificate**

No. Q5 116468 0001 Rev. 00

**Holder of Certificate: Biocare Medical, LLC** 

60 Berry Drive Pacheco CA 94553

USA

**Certification Mark:** 



Design and development, production, sales and Scope of Certificate: distribution, installation, and servicing of in vitro

diagnostic (IVD) immunohistochemistry reagents/kits, IVD instruments, and general

purpose IVD laboratory equipment for use in clinical research and clinical laboratories

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). 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:Q5 116468 0001 Rev. 00

Report No.: 72180497

Valid from: 2024-05-14 Valid until: 2027-05-13

Christoph Dicks Date, 2024-05-14

Head of Certification/Notified Body





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Applied Standard(s): ISO 13485:2016

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -

Requirements for regulatory purposes

Facility(ies): Biocare Medical, LLC

114 Center Avenue, Pacheco CA 94553, USA

Production, distribution, installation, and servicing of in vitro diagnostic (IVD) reagents, kits and instruments for immunohistochemistry, and general purpose IVD laboratory equipment for use in clinical research and clinical laboratories

**Biocare Medical, LLC** 

60 Berry Drive, Pacheco CA 94553, USA

Design and development and sales of in vitro diagnostic (IVD) reagents, kits and instruments for immunohistochemistry, and general purpose IVD laboratory equipment for use in clinical research and clinical laboratories

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