

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Biocare Medical, LLC

(FIN F000749)

Main Site: 60 Berry Drive, Pacheco, California 94553 USA

Additional Site1: 114 Center Ave, Pacheco, California 94553 USA

Additional Site2: 110 Willow, Pacheco, California, 94553 USA

has been registered by Intertek, an MDSAP recognized auditing organization,  
as conforming to the requirements of:

## ISO 13485:2016

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1  
(excluding Part 1.6)

**Brazil:** RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

**Canada:** Medical Devices Regulations – Part 1- SOR 98/282

**United States:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

**Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

### The management system is applicable to:

*Design, manufacture and distribution of in vitro diagnostic (IVD),  
immunohistochemistry reagents/kits, fluorescence in situ hybridization probes and  
reagents and design, manufacture, distribution, installation and service of general  
purposes laboratory equipment medical devices.*

*Main site: Management, design & development, manufacturing of instruments,  
installation, service & repair.*

*Additional Site 1: Manufacturing of reagents & instruments, receiving, installation,  
service & repair, storage & shipping.*

*Additional Site 2: Manufacturing of only FISH products.*

**Certificate Number:**

0097626

**Revision Level:** 05

**Initial Certification Date:**

2019-12-30

**Certification Effective Date:**

2025-12-29

**Certification Expiry Date:**

2028-12-29



**intertek**



A handwritten signature in black ink, appearing to read "Rathin Grover".

**Rathin Grover**

President, Business Assurance

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