

# 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:** Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012;  
RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

**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, and design, manufacture, distribution,  
installation and service of general purposes laboratory equipment medical devices.*

*Main site: Management, Design & development*

*Additional Site1: Manufacturing of reagents & instruments, receiving, installation,  
service & repair, storage & shipping*

*Additional Site2: Manufacturing of only FISH products*

**Certificate Number:**

0097626-03

**Initial Certification Date:**

2019-12-30

**Date of Certification Decision:**

2022-12-30

**Certification Effective Date:**

2022-12-30

**Certification Expiry Date:**

2025-12-29



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**Calin Moldovean**

President, Business Assurance

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