

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, 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

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

Additional Site2: Manufacturing of only FISH products

Certificate Number:

0097626

Revision Level: 04

Initial Certification Date:

2019-12-30

Certification Effective Date:

2025-04-02

Certification Expiry Date:

2025-12-29



intertek

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

Rathin Grover

President, Business Assurance

Intertek Testing Services NA, Inc.
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