

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

Intertek Testing Services NA, Inc. 900 Chelmsford Street Lowell, MA, USA 01851





In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request. Validity of this certificate may be verified at http://www.intertek.com/business-assurance/certificate-validation/

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