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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:
0097626-02

Initial Certification Date:
2019-12-30

Date of Certification Decision:
2022-09-29

Certification Effective Date:
2022-09-29

Certification Expiry Date:
2022-12-29

ISO 13485:2016 CERTIFICATION TM

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

Calin Moldovean
President, Business Assurance

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