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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

MediBeacon Inc.

Main Site: 425 N. New Ballas Road, Suite 100,

St. Louis, Missouri, 63141, United States (FIN F008003)

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, as applicable

The management system is applicable to:

Design, development, manufacturing and service of monitoring systems for kidney function, gastrointestinal permeability, and other light-activated diagnostics, including sterile fluorescent tracer agent.

Certificate Number:
0221131

Revision Level: 00

Initial Certification Date:
2025-08-05

Certification Effective Date:
2025-08-05

Certification Expiry Date:
2028-08-04

ISO 13485:2016 CERTIFICATION TM intertek

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

Rathin Grover
President, Business Assurance

Intertek Testing Services NA, Inc.
4700 Broadmoor SE, Suite 200
Kentwood, MI, USA, 49512

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

MDSAP Certificate (DOC-1549) Ver. 0

Approved By:

Kallen Withers - Author

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