

## **CERTIFICATE OF REGISTRATION**

This is to certify that the management system of:

## **Biocan Diagnostics Inc**

(F000748)

Main Site: 55a & 53b Fawcett Road,

Coquitlam, British Columbia, V3K6V2, Canada

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

## ISO 13485:2016

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)

## The management system is applicable to:

The design and development, manufacture and distribution of in vitro diagnostic rapid test kits used in diagnosis, detection of cancer, cardiac markers, Inflammatory & Tumor markers, fecal antigens, drugs of abuse, fertility testing, pregnancy testing, sexually transmitted, parasitology, infectious diseases, respiratory, hormone, neonatal, serology, clinical chemistry, urinalysis; and of in-vitro diagnostic analyzers including home use, near patient/point of care in vitro diagnostic devices. Certificate Number: 0073670-06

Initial Certification Date: 2018-03-22

**Date of Certification Decision:** 2023-03-30

**Certification Effective Date:** 2023-03-30

**Certification Expiry Date:** 2024-03-21







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 <a href="http://www.intertek.com/business-assurance/certificate-validation/">http://www.intertek.com/business-assurance/certificate-validation/</a>. CT-MDSAP-2016-NA-EN-LT-P-3.JUN.21