# 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

ISO 13485:2016 CERTIFICATION TM

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

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President, Business Assurance

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