intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Biocan Diagnostics Inc

Main Site: 55a & 53b Fawcett Road, Coquitlam, British Columbia, V3K6V2, Canada
(DUNS # 203720904)

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

ISO 13485:2016

Canada: Medical Devices Regulations – Part 1- SOR 98/282

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

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 the manufacture and distribution of in-vitro diagnostic analyzers including home use, near patient/point of care in vitro diagnostic devices.

Certificate Number:
0073670-02

Initial Certification Date:
2018-03-22

Certification Effective Date:
2018-07-04

Certification Expiry Date:
2021-03-21

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Calin Moldovean
President, Business Assurance

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