

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

BTNX Inc.

(FIN F000761)

Main Site: 570 Hood Rd. Units #23, 21, 13, 6, 3, 14 and 5

Markham, Ontario L3R 4G7 Canada

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

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 manufacture, design and development of in vitro diagnostic analyzers, diagnostic medical devices, lancets and lancing devices, diagnostic reagents and test kits used in the diagnosis, management and screening of cancer (tumor markers), drugs of abuse, alcohol addiction, pregnancy and fertility, menopause, infectious diseases, urinalysis, blood glucose and diabetes monitoring, for laboratory, point of care, home use, and forensic use.

Certificate Number:

0097499

Initial Certification Date:

2020-01-21

Certification Effective Date:

2020-01-21

Certification Expiry Date:

2023-01-20



Intertek

Calin Moldovean

President, Business Assurance

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