

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

BTNX Inc.

(FIN F000761)

Main Site: 722 Rosebank Rd,
Pickering, Ontario, L1W 4B2, 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, Part 1.1 - Medical Devices for an Urgent Public Health Need

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, development and manufacture of in vitro diagnostic analyzers, screening and diagnostic medical devices, diagnostic reagents, and test kits (including sterile components) intended for use in drugs of abuse, alcohol addiction testing, infectious diseases, urinalysis, vitamins, cancer screening, diabetes, and blood glucose monitoring.

The manufacture and distribution of in vitro diagnostic analyzers, screening and diagnostic medical devices, diagnostic reagents, and test kits medical devices, intended for screening, monitoring and diagnostic use in cancer screening, drugs of abuse, alcohol addiction, pregnancy and fertility, menopause, infectious diseases, vitamins, urinalysis, general wellness, blood glucose, cholesterol, diabetes, and ECG monitoring; and sterile lancing devices.

Certificate Number:

0097499

Revision Level: 06

Initial Certification Date:

2020-01-21

Certification Effective Date:

2026-01-20

Certification Expiry Date:

2029-01-20



intertek

A handwritten signature in black ink that reads "Rathin Grover".

Rathin Grover

President, Business Assurance

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

