

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

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

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 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 and home use.

Certificate Number:

0097499-03

Initial Certification Date:

2020-01-21

Certification Effective Date:

2023-01-20

Certification Expiry Date:

2026-01-20



intertek

A handwritten signature in black ink, appearing to read "Calin Moldovean", written over a horizontal line.

Calin Moldovean

President, Business Assurance

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

