Certificate

Certificate No.:	MD 2241188-1
Manufacturer:	**Diagnostics Biochem Canada Inc.** 384 Neptune Crescent London ON N6M 1A1 Canada
REPs Facility ID:	F005530
Certification criteria:	ISO 13485:2016 Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009 Canada Medical Devices Regulations – Part 1 – SOR 98/282 Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
Scope:	Design, development and manufacture of in-vitro diagnostic test kits and reagents used in the detection and diagnosis of endocrine disorders, disease status, cardiac markers, autoimmune status, immune status, fertility testing and cancer. Manufacture of blood specimen collection kits including sterile and nonsterile components.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	234177830-33
Issue Date:	2021-11-18
Effective Date:	2021-11-18
Expiry Date:	2024-11-17

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Sandor Juhasz
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000013603?locale=en or calling 1-888-743-4652.

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