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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Pro-Lab Diagnostics Inc.

(FIN F000934)

Main Site: 20 Mural Street, Unit #4

Richmond Hill, Ontario L4B 1K3 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)

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

United States: 21 CFR 820 **OR** 21 CFR 820.180 and 198, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

The management system is applicable to:

Design/development, manufacture and distribution of in-vitro diagnostic test kits and in-vitro diagnostic reagents used in the diagnosis and management of immune status, disease status, transmissible agents and in prenatal testing.

Certificate Number:
0079254-01

Initial Certification Date:
2018-08-06

Date of Certification Decision:
2021-08-02

Certification Effective Date:
2021-08-05

Certification Expiry Date:
2024-08-05

ISO 13485:2016 CERTIFICATION TM

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

Calin Moldovean
President, Business Assurance

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