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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Pro-Lab Incorporated, Pro-Lab Developments Inc., Pro-Lab Diagnostics Inc., and Microlink Technology Limited

Main Site: 20 Mural Street, Unit 4
Richmond Hill, Ontario, L4B 1K3, Canada
Additional site 3 Bassendale Road, Bromborough
Wirral, Merseyside, CH62 3QL, United Kingdom

has been registered by Intertek as conforming to the requirements of:

ISO 13485:2016

The management system is applicable to:

Main Site: The 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.

Additional Site: The 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 pre-natal testing, as well as the installation and servicing of analytical laboratory equipment.

Certificate Number:
9190-13

Initial Certification Date:
16 April 2004

Certificate Issue Date:
21 August 2018

Certificate Expiry Date:
21 August 2021

SCC Accredited CB-MS
OCSM Accrédité CCN
TM

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Pro-Lab Diagnostics Inc.

(DUNS # 203383500)

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:
0079254-00

Initial Certification Date:
2018-08-06

Certification Effective Date:
2018-08-06

Certification Expiry Date:
2021-08-05

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Calin Moldovean
President, Business Assurance

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