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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Cedarlane Corporation

(FIN F006800)
Main Site: 4410 Paletta Court

Burlington, Ontario L7L 5R2 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

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

Design and development, manufacture and distribution of in-vitro diagnostic medical devices, in-vitro diagnostic reagents and test kits used in the diagnosis, management and detection of disease status and immune status. Manufacture and distribution of in-vitro diagnostic reagents and test kits used in the diagnosis, management and detection of autoimmune status. Import and distribution of in-vitro diagnostic medical devices, in-vitro diagnostic reagents and test kits used in the diagnosis, management and detection of autoimmune status, blood analytes, blood components, blood gases, blood grouping, cancer, cardiac markers, coagulation, compatibility testing, disease status, donor screening, drugs of abuse, endocrine disorders, fertility testing, genetic testing, immune status, pregnancy testing, prenatal screening, protein metabolism, sexually transmissible agents, tissue typing, transmissible agents, immunological typing, and therapeutic drug monitoring, including near patient /point of care in-vitro diagnostic devices.

Certificate Number:
0148050

Initial Certification Date:
2020-05-26

Certification Effective Date:
2023-05-02

Certification Expiry Date:
2026-03-27

ISO 13485:2016 CERTIFICATION TM

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

Calin Moldovean
President, Business Assurance

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