



CERTIFICATE OF REGISTRATION

This is to certify that

Cedarlane Corporation

4410 Paletta Court, Burlington, Ontario L7L 5R2 Canada

D-U-N-S: 24-392-8822

operates a

Quality Management System

which complies with the requirements of

ISO 13485:2016 and the requirements of the following regulatory authorities

Canada:

- Medical Device Regulations SOR/98-282, Part 1

United States:

- 21 CFR Part 803 - Medical Device Reporting
- 21 CFR Part 806 - Reports of Corrections and Removals
- 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing
- 21 CFR Part 820 - Quality System Regulation

for the following scope of certification

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.

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Certification Effective Date: 2020-05-26

Issue Date: 2020-05-27

Certificate Expiry Date: 2023-05-25

Heather Mahon

Global Head of Technical Services SAI Global Assurance



ISO 13485:2016

SAI Global is an MDSAP
authorized auditing organization.



Registered by:

QMI-SAI Canada Limited (SAI Global), 20 Carlson Court, Suite 200, Toronto, Ontario M9W 7K6 Canada. This registration is subject to the SAI Global Terms and Conditions for Certification. While all due care and skill was exercised in carrying out this assessment, SAI Global accepts responsibility only for proven negligence. This certificate remains the property of SAI Global and must be returned to them upon request.

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https://www.saiglobal.com/en-us/assurance/auditing_and_certification/certification_registry/



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