

This is to certify that

Cedarlane Corporation

4410 Paletta Court, Burlington, Ontario L7L 5R2 Canada

operates a

Quality Management System

which complies with the requirements of

ISO 13485:2016

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 diagnosis, management and detection of autoimmune status, cancer, disease status, immune status and prenatal screening. 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 No.: CERT-0126127 Original Certification Date: May 8, 2017 File No.: 1687410

Certification Effective Date: December 4, 2018 December 31, 2018 Certification Expiry Date:





CMDCAS Recognized Registrar



General Manager Technical Services SAI Global Assurance

