

# Certificate

Certificate No.: MD 687155 1140044543-40

Manufacturer: **Artron Laboratories Inc.**  
3938 North Fraser Way, Burnaby, BC, V5J 5H6, Canada

D-U-N-S No.: 20-374-8269

Certification criteria ISO 13485:2016  
Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009  
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

Scope: Design and Development, Manufacture and Distribution of Urinalysis Reagent Strips and In-vitro Diagnostic Test Kits and Analyzers used in the Detection of Cardiac Markers, Cancer, Disease status, Drugs of Abuse, Fertility Testing, Pregnancy Testing and Infectious Diseases Including Home Use, Near Patient In-vitro Diagnostic Devices

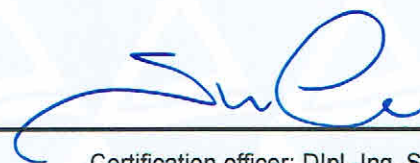
TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 50183799 002

Issue Date: 2019-02-22

Effective Date: 2019-02-22

Expiry Date: 2021-12-23



Certification officer: Dipl.-Ing. S. Pane  
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified by calling 1-888-743-4652.