TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Artron Laboratories Inc.
3938 North Fraser Way
Burnaby BC V5J 5H6
Canada

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of In-vitro Diagnostic Medical Devices (see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2017-10-02
Certificate Registration No.:	SX 60119885 0001
An audit was performed. Report No.:	16803636 005
This Certificate is valid until:	2020-10-01

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2017-09-18

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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Doc. 1/1, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60119885 0001
Report No.: 16803636 005

Organization:
Artron Laboratories Inc.
3938 North Fraser Way
Burnaby BC V5J 5H6
Canada

Scope:

Products included:

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

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