

## Manufacturer's Certificate to Cover Exports of Medical Devices

We, the undersigned, manufacturer of the following devices,

Please see the next 1-page attachment, "Product Description List"

## do hereby certify that

- (a) each device is manufactured, produced and sold in Canada in accordance with the requirements of Canada's *Food and Drugs Act* and *Regulations* there under; and
- (b) tests have been conducted in respect of each device and that the tests indicate that the nature of the benefits claimed to be obtainable through the use of each device and the performance characteristics of each device are justified.

## MANUFACTURER INFORMATION

**Artron Laboratories Inc.** 

3938 North Fraser Way Burnaby, BC Canada V5J 5H6

March 19, 2020

Date

Irene Li Regulatory Affairs Officer

Title and Signature of Authorized Person

It is hereby certified that

(a) devices manufactured, produced and sold in the manner above described would not, by reason of the method of manufacture thereof, be in violation of the *Food and Drugs Act* of Canada and the *Regulations* there under; and

(b) devices manufactured and sold in compliance with said *Act* and *Regulations* may be

exported without restriction.

The Richmond Chamber of Commerce on the basis of information supplied to us hereby certifies that, to the best of our knowledge and belief, the information contained in this document is correct.

MAR 1 9 2020

Dated

at Richmond, B.C.

Authorized Signatory - Richmond Chamber of Commerce

Richmond Chamber of Commerce

SIGNED BEFORE ME at Burnalby Pro

A Commissioner for taking affidavits for British Columbia

Joyce Ling
Barrister & Solicitor
Unit 310, 4885 Kingsway
Burnaby, BC V5H 4T2

Phone: (604)558-2258 Fax:(604)558-4023

## **Product Description List**

Device Name	Format	Device Identifier
COVID-19 IgM/IgG Antibody Test	CASSETTE STRIP CASSETTE	A03-51-322 A03-51-313 A03-51-222
COVID-19 IgM Antibody Test	CASSETTE STRIP CASSETTE	A03-52-322 A03-52-313 A03-52-222
COVID-19 IgG Antibody Test	CASSETTE STRIP CASSETTE	A03-53-322 A03-53-313 A03-53-222
COVID-19 IgM & IgG Antibody Combo Test	CASSETTE STRIP CASSETTE	A03-54-322 A03-54-313 A03-54-222
COVID-19 Antibody Test	CASSETTE STRIP CASSETTE	A03-55-322 A03-55-313 A03-55-222
COVID-19 Ag Test	CASSETTE STRIP	A03-50-422 A03-50-413

Feng Yiki also known ers (rene Li SIGNED BEFORE ME at the Province of British Columbia, this 19 day of March, 20

A Commissioner for taking affidavits for British Columbia

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