EC Declaration of Conformity

Manufacturer	Artron Laboratories Inc. 3938 North Fraser Way, Burnaby, BC Canada V5J 5H6
European Representative	MedNet EC-REP GmbH Borkstrasse 10 · 48163 Muenster · Germany
Analyte of the Test	COVID-19 IgM/IgG Antibody
Product Designation	COVID-19 IgM/IgG Antibody Test
EDMA Code	15 70 90 90 00
Catalogue No.	A03-51-322 (Cassette)
Classification	Others, Self-Declaration IVD MD
Conformity Assessment Route	Annex III Applied (IVD 98/79/EC)

The undersigned hereby declares, under the sole responsibility of the manufacturer, that the medical device as specified above conforms with the essential requirements listed in the European in vitro Medical Device Directive 98/79/EC (IVD).

Standard Applied	List of (Harmonized) standards for which documented evidence for compliance can be provided Quality Assurance (EN ISO13485:2016) Certified by TUV Rheinland LGA Products GmbH– Tillystrasse 2 - 90431 Nürnberg Certificate Number SX 60119885 0001
Start of CE marking	April 16, 2020
Date of Issue	April 16, 2020
On the behalf of **Artron Laboratories Inc.**	 _____ Signature Irene Li Regulatory Affairs Specialist