EC Declaration of Conformity

Manufacturer	Artron Laboratories Inc. 3938 North Fraser Way, Burnaby, BC V5J 5H6, Canada
European Representative	MedNet EU REP GmbH Address: Borkstrasse 10, 48163 Muenster, Germany
Product Designation	COVID-19 IgM/IgG Antibody Test Kit
Catalogue No.	A03-51-322 (Cassette)
Classification	Others, Self-Declaration IVD MD
Conformity Assessment Route	Annex III Applied (IVDD 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 Annex I of 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	Mar 12, 2020
Place, Date of Issue	Burnaby, Mar 12, 2020

On the behalf of Artron Laboratories Inc.

Irene Li
Regulatory Affairs Specialist