EC Declaration of Conformity

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Manufacturer	Artron Laboratories Inc. 3938 North Fraser Way, Burnaby, BC V5J 5H6, Canada
European Representative	MedNet EC-REP GmbH Borkstrasse 10 48163 Muenster, Germany
Analyte of the Test	COVID-19 Antigen (viral nucleoprotein)
Product Designation	COVID-19 Antigen Test
EDMA Code	15 70 90 90 00
Catalogue No.	A03-50-422 (Cassette)
Classification	Others, Self-Declaration IVD
Conformity Assessment Route	Annex III (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 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 SX60152407 0001
Start of CE-Marking	October 12, 2020
Place, Date of Issue	Burnaby, October 12, 2020

On the behalf of Artron Laboratories Inc.

Jason Liang
Regulatory Affairs

Artron