

EC Declaration of Conformity

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

Product Designation COVID-19 Antigen Home Test

GIVD Code 15.70.90.08

Catalogue No. A03-50-422S1
A03-50-422S5
A03-50-422S25

Classification Self-testing

Conformity Assessment Route
IVDD 98/79/EC Annex IV, excluding section 4 and 6

We hereby declare that the above mentioned product meet the provisions of the Annex I of IVDD 98/79/EC for in-vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer and Notified Body 0197, TÜV Rheinland LGA Products GmbH, Say Building , TillystraBe 2, 90431 Nürnberg, Germany.

Certificate Number HL 1272611-1

Start of CE-Marking Nov. 29, 2021

Place, Date of Issue Nov. 29, 2021

On the behalf of
Artron Laboratories Inc.



Uma Gaur

Regulatory Affairs

