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
Product Designation **EDMA Code** **Catalogue No.**	Artron HIV 1/2 Antibody Rapid Test (Serum/Plasma) 15.70.03.02 A02-07-222 (Cassette)
Classification	List A, (IVDD 98/79/EC)
Conformity Assessment Route	Annex 4.4 + Annex 4.3 + Annex 4.6 (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 60152407 0001
Start of CE marking	May 09, 2009
Date of Issue	October 11, 2020
On the behalf of **Artron Laboratories Inc.**	Signature Jason Liang Regulatory Affairs Specialist

ARTRON LABORATORIES INC. Artron CANADA

Digitally signed by Talpiș Andrei
Date: 2021.05.11 09:41:15 EEST
Reason: MoldSign Signature
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