# EC Declaration of Conformity

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| **Manufacturer** | Artron Laboratories Inc.<br>3938 North Fraser Way, Burnaby, BC Canada V5J 5H6 |
| **European Representative** | Wellkang Ltd<br>Suite B, 29 Harley Street<br>London England, United Kingdom W1G 9QR |
| **Product Designation**<br>**EDMA Code**<br>**Catalogue No.** | Artron Strep A (Group A Streptococcus) Test Kit<br>15.70.01.03<br>A03-19-422(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 Annex I of the European in vitro Medical Device Directive 98/79/EC (IVD).**

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| **Standard Applied** | List of (Harmonized) standards for which documented evidence for compliance can be provided<br><br>Quality Assurance (EN ISO13485:2016) Certified by<br>TUV Rheinland LGA Products GmbH– Tillystrasse 2 - 90431 Nürnberg<br>Certificate Number<br>SX 60119885 0001 |
| **Start of CE marking** | Feb 02, 2016 |
| **Date of Issue** | Sep 17, 2018 |
| **On the behalf of**<br>**Artron Laboratories Inc.** |  <br>Signature<br><br>Steve Xu<br>Regulatory Affairs Specialist |