

# EC Declaration of Conformity

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| <b>Manufacturer/ Supplier Information:</b> | <b>Maine Molecular Quality Controls, Inc.</b><br>23 Mill Brook Road<br>Saco, Maine 04072 USA<br>Phone: 1-207-885-1072<br>Email: <a href="mailto:info@mmqci.com">info@mmqci.com</a><br>Website: <a href="http://www.mmqci.com">www.mmqci.com</a> |
| <b>European Representative</b>             | <b>QARAD EC-REP BV</b><br>Pas 257<br>2440 Geel, Belgium   |

We, Maine Molecular Quality Controls Inc., declare under our sole responsibility, that the product:

## INTROL® CF Panel I Control v.02

### Catalog #: G106ac-1

meets the provisions of the European Directive 98/79/EC for *in vitro* Diagnostic Medical Devices. The device is classified as a General In Vitro Diagnostic (IVD) Device. The MMQCI quality system is registered to EN ISO 13485:2016. Conformity Assessment Method: General IVD Annex III.

The undersigned declares that the device listed above conforms to the essential requirements described in ANNEX I of the European Directive 98/79/EC. Technical documentation demonstrating compliance as described in Annex I is kept by the manufacturer and can be made available by the authorized representative in Europe - QARAD EC-REP BV, Pas 257, 2440 Geel, Belgium.

Saco, Maine USA / 03/30/2022

(Place and date of Issue)

  
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QA/RA Manager  
(Signature and Title)

