

EC Declaration of Conformity

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| Manufacturer/ Supplier Information: | Maine Molecular Quality Controls, Inc. 23 Mill Brook Road Saco, Maine 04072 USA Phone: 1-207-885-1072 Email: info@mmqci.com Website: www.mmqci.com |
| European Representative | QbD RepS BV Groenenborgerlaan 16 2610 Wilrijk, Belgium |

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

FilmArray® BCID2 Control Panel M416

Catalog #: M416

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 - QbD RepS BV, Groenenborgerlaan 16, 2610 Wilrijk, Belgium.

Saco, Maine USA / 11 August 2025

(Place and date of Issue)

Mitchell D. Wright
Manager QA/QA, PRRC

(Signature and Title)

