# EC Declaration of Conformity

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| **Manufacturer/ Supplier Information:** | **BioFire Diagnostics, LLC**<br>515 Colorow Drive<br>Salt Lake City, Utah 84108, USA<br>Phone: 1-801-736-6354<br>regulatory@BioFireDX.com<br>http://www.BioFireDX.com |

We, BioFire Diagnositics, LLC, declare under our sole responsibility, that the product

**FilmArray® Pneumonia Panel *plus***
**(RFIT-ASY-0142, RFIT-ASY-0143)**

meets the provisions of the European Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices. The device is classified as an In Vitro Diagnostic (IVD) Device under Annex II list B. BioFire Diagnostics' quality system is registered to EN ISO 13485:2016.

The following relevant standards have been met:

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| **EN ISO 13485:2016**<br>Medical devices – Quality Management System – Requirements for regulatory purposes |
| **EN ISO 14971:2012**<br>Medical devices – Application of risk management to medical devices |
| **EN 13641:2002**<br>Elimination or reduction of risk of infection related to *in vitro* diagnostic reagents |
| **EN 62366:2008**<br>Medical devices-Application of usability engineering to medical devices |
| **EN 13612:2002**<br>Performance evaluation of *in vitro* diagnostic medical devices |
| **EN ISO 23640:2015**<br>*In vitro* diagnostic medical devices – Evaluation of stability of *in vitro* diagnostic reagents |
| **EN ISO 15223-1:2016**<br>Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements |
| **EN ISO 18113-1:2011**<br>*In vitro* diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 1: Terms, definition and general requirements |
| **EN ISO 18113-2:2011**<br>*In vitro* diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 2: *In vitro* diagnostic reagents for professional use |

Technical documentation demonstrating compliance as described in Annex IV of the European Directive 98/79/EC is kept by the manufacturer and can be made available by the authorized representative in Europe - QARAD EC-REP BV, Pas 257, B-2440 Geel, Belgium.

The notified body for this product is BSI (Notified body #2797; Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands).

Salt Lake City, UT, USA
*(Place and date of issue)*

Kevin M Bourzac
Digitally signed by Kevin M Bourzac
Date: 2020.06.25 16:46:34 -06'00'

**Kevin Bourzac**
*Vice President, Regulatory and Clinical Affairs*



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Form #: QR-106C
Rev: 02
CO: 014147
DCID: 19418