EC Declaration of Conformity

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

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

FilmArray® Respiratory Panel 2 *plus* (RP2 *plus*)
(RFIT-ASY-0136, RFIT-ASY-0137)

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 ISO 13485:2016 and EN ISO 13485:2016.

The following relevant standards have been met:

ISO 13485:2016/EN ISO 13485:2016 Medical devices – Quality Management System – Requirements for regulatory purposes
EN ISO 14971:2012 Medical devices – Application of risk management to medical devices
EN 13641:2002 Elimination or reduction of risk of infection related to *in vitro* diagnostic reagents
EN 62366:2008 Medical devices-Application of usability engineering to medical devices
EN 13612:2002 Performance evaluation of *in vitro* diagnostic medical devices
EN ISO 23640:2015 *In vitro* diagnostic medical devices – Evaluation of stability of *in vitro* diagnostic reagents
EN ISO 15223-1:2016 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 *In vitro* diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 1: Terms, definition and general requirements
EN ISO 18113-2:2011 *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 bvba, Cipalstraat 3, 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 31 Oct 2019
(Place and date of issue)

Kristen Kanack
Kristen Kanack
SVP of Regulatory and Clinical Affairs

Digitally signed by Olaru Victoria
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