EC Declaration of Conformity

Manufacturer/ Supplier Information:	**BioFire Diagnostics, LLC (bioMérieux)** 515 Colorow Drive Salt Lake City, Utah 84108, USA Phone: 1-801-736-6354 regulatory@biomerieux.com https://www.biofiredx.com/

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

FilmArray® Pneumonia Panel
(REF: RFIT-ASY-0144, RFIT-ASY-0145)

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 and is covered under EC Certificate No. CE 667639.

BioFire Diagnostics' quality system is registered to ISO 13485:2016.

The following relevant standards have been met:

EN ISO 13485:2016 Medical devices – Quality Management System – Requirements for regulatory purposes
EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019 Medical devices – Application of risk management to medical devices
EN 62366:2008 Medical devices – Application of usability engineering to medical devices
EN 62304:2006 Medical device software – Software life-cycle processes
EN 13612:2002 Performance evaluation of in vitro diagnostic devices
EN ISO 23640:2015 *In vitro* diagnostic medical devices – Evaluation of the stability of *in vitro* diagnostic reagents
ISO 20916:2019 *In vitro* diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice
EN ISO 15223-1:2021 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 EC-REP BV, Pas 257, B-2440 Geel, Belgium).

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

Kevin Bourzac

Digitally signed by Kevin Bourzac
Date: 2022.11.02 08:43:03 -06'00'

Salt Lake City, UT, USA
(Place of issue)

Kevin Bourzac
Vice President, Regulatory and Clinical Affairs