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 2.0 Instrument
(FLM2-ASY-0001)

meets the provisions of the European Directive 98/79/EC for *in vitro* Diagnostic Medical Devices, the European Directive 2011/65/EU on the restriction of the use of certain hazardous substances (ROHS) in electrical and electronic equipment, and the European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE). The device is classified as a General In Vitro Diagnostic (IVD) device.

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

The following relevant standards have been met:

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 62366:2008 Medical devices-Application of usability engineering to medical devices
EN 13612:2002 Performance evaluation of in vitro diagnostic devices
EN 61010-2-101:2002 Safety requirements for electrical equipment for measurement, control, and laboratory use --Part 2.
EN 61326-2-6:2006 Electrical equipment for measurement, control, and laboratory use - EMC requirements -- Part 2-6
EN 62304:2006 Medical device software—Software life-cycle processes—IEC 62304:2006, November 27, 2008.
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 18113-3:2011 In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 3: In vitro diagnostic instruments for professional use

Technical documentation demonstrating compliance as described in Annex III 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: 2020.07.16 14:56:10 -06'00'

Kevin Bourzac
Vice President, Regulatory and Clinical Affairs

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