# 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 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 ISO 13485:2016 and EN ISO 13485:2016.

The following relevant standards have been met:

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| **ISO 13485:2016/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 62366:2008**<br>Medical devices-Application of usability engineering to medical devices |
| **EN 13612:2002**<br>Performance evaluation of in vitro diagnostic devices |
| **EN 61010-2-101:2002**<br>Safety requirements for electrical equipment for measurement, control, and laboratory use --Part 2. |
| **EN 61326-2-6:2006**<br>Electrical equipment for measurement, control, and laboratory use - EMC requirements -- Part 2-6 |
| **EN 62304:2006**<br>Medical device software—Software life-cycle processes—IEC 62304:2006, November 27, 2008. |
| **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 18113-3:2011**<br>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 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*

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