EC Declaration of Conformity

Manufacturer/Supplier Information: BioFire Diagnostics, LLC
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We, BioFire Diagnostics, LLC, declare under our sole responsibility, that the product
FilmArray 2.0 Instrument
(FLM2-ASY-0001)


The following relevant standards have been met:

| 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                                  |
| 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 bvba, Citastraat 3, B-2440 Geel, Belgium.

The notified body for this product is BSI (Notified body #0086; Ktemark Court, Davy Avenue, Knowhill, Milton Keynes, MK5 9PP, United Kingdom).

Salt Lake City, UT, USA 12.19.2018

Randy Rasmussen
President and Chief Executive Officer

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