

EC Declaration of Conformity

**Manufacturer/
Supplier Information:**

BioFire Diagnostics, LLC
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<http://www.BioFireDX.com>

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

**FilmArray® Meningitis/Encephalitis (ME) Panel
(RFIT-ASY-0118, RFIT-ASY-0119)**

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 <i>in vitro</i> diagnostic reagents
EN 62366:2008 Medical devices-Application of usability engineering to medical devices
EN 13612:2002 Performance evaluation of <i>in vitro</i> diagnostic medical devices
EN ISO 23640:2015 <i>In vitro</i> diagnostic medical devices – Evaluation of stability of <i>in vitro</i> 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 <i>In vitro</i> diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 1: Terms, definition and general requirements
EN ISO 18113-2:2011 <i>In vitro</i> diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 2: <i>In vitro</i> 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 #0086; Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom).

Salt Lake City, UT, USA 11-20-18
(Place and date of issue)


Randy Rasmussen
Chief Executive Officer



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