

# EC Declaration of Conformity

<b>Manufacturer/ Supplier Information:</b>	<b>BioFire Diagnostics, LLC</b> 390 Wakara Way Salt Lake City, Utah 84108, USA Phone: 1-801-736-6354 <a href="mailto:regulatory@BioFireDX.com">regulatory@BioFireDX.com</a> <a href="http://www.BioFireDX.com">http://www.BioFireDX.com</a>
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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 13485:2003 and EN ISO 13485:2012.

The following relevant standards have been met:

<b>ISO 13485:2003/EN ISO 13485:2012</b> Medical devices – Quality Management System – Requirements for regulatory purposes
<b>EN ISO 14971:2012</b> Medical devices – Application of risk management to medical devices
<b>EN 13641:2002</b> Elimination or reduction of risk of infection related to <i>in vitro</i> diagnostic reagents
<b>EN 62366:2008</b> Medical devices-Application of usability engineering to medical devices
<b>EN 13612:2002</b> Performance evaluation of <i>in vitro</i> diagnostic medical devices
<b>EN 13640:2002</b> Stability testing of <i>in vitro</i> diagnostic reagents
<b>EN ISO 23640:2013</b> <i>In vitro</i> diagnostic medical devices – Evaluation of stability of <i>in vitro</i> diagnostic reagents
<b>EN 980:2008</b> Symbols for use in the labelling of medical devices
<b>ISO 15223-1:2012</b> Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
<b>EN ISO 18113-1:2011</b> <i>In vitro</i> diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 1: Terms, definition and general requirements
<b>EN ISO 18113-2:2011</b> <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, Ciplastraat 3, B-2440 Geel, Belgium.

The notified body for this product is Lloyd's Register Quality Assurance LTD (Notified body #0088; Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom).

Salt Lake City, UT, USA Jan 8, 2016  
(Place and date of issue)

  
**Randy Rasmussen**  
 President and Chief Executive Officer

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