

# 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® Torch System Base (HTFA-ASY-0104)**  
**FilmArray® Torch Module (HTFA-SUB-0103)**

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 13485:2003 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 <sup>1</sup>
<b>EN 62304:2006</b> Medical device software—Software life-cycle processes,—IEC 62304:2006, November 27, 2008
<b>EN 62366:2008</b> Medical devices—Application of usability engineering to medical devices <sup>1</sup>
<b>EN 13612:2002</b> Performance evaluation of <i>in vitro</i> diagnostic
<b>EN 61010-2-101:2002</b> Safety requirements for electrical equipment for measurement, control, and laboratory use –Part 2-101: Particular requirements for <i>in vitro</i> diagnostic (IVD) medicinal equipment, IEC 61010-2-101:2002 (modified) December 17, 2002
<b>EN 61326-2-6:2006</b> Electrical equipment for measurement, control and laboratory use—EMC requirements—Part 2-6: Particular requirements – <i>in vitro</i> diagnostic (IVD) medical equipment, IEC 61326-2-6:2006, November 27, 2008
<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 18113-3:2011</b> <i>In vitro</i> diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 3: <i>In vitro</i> 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, Ciplastraat 3, B-2440 Geel, Belgium.

Salt Lake City, UT, USA 9.26.2016  
(Place and date of issue)

Kristen J. Kanack  
**Kristen J. Kanack**  
VP, Regulated Products & Clinical Affairs