

# EC Declaration of Conformity

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| <b>Manufacturer/<br/>Supplier Information:</b> | <b>BioFire Diagnostics, LLC</b><br>515 Colorow Drive<br>Salt Lake City, Utah 84108, USA<br>Phone: 1-801-736-6354<br><a href="mailto:regulatory@BioFireDX.com">regulatory@BioFireDX.com</a><br><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)**  
**FilmArray® Torch Duplex (HTFA-ASY-0102)**

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 EN ISO 13485:2016.

The following relevant standards have been met:

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| <b>EN ISO 13485:2016</b><br>Medical devices – Quality Management System – Requirements for regulatory purposes  |
| <b>EN ISO 14971:2012</b><br>Medical devices – Application of risk management to medical devices'  |
| <b>EN 62304:2006</b><br>Medical device software—Software life-cycle processes,—IEC 62304:2006, November 27, 2008  |
| <b>EN 62366:2008</b><br>Medical devices—Application of usability engineering to medical devices'  |
| <b>EN 13612:2002</b><br>Performance evaluation of in vitro diagnostic   |
| <b>EN 61010-2-101:2002</b><br>Safety requirements for electrical equipment for measurement, control, and laboratory use –Part 2-101: Particular requirements for in vitro diagnostic (IVD) medicinal equipment, IEC 61010-2-101:2002 (modified) December 17, 2002 |
| <b>EN 61326-2-6:2006</b><br>Electrical equipment for measurement, control and laboratory use—EMC requirements—Part 2-6: Particular requirements –in vitro diagnostic (IVD) medical equipment, IEC 61326-2-6:2006, November 27, 2008                               |
| <b>EN ISO 15223-1:2016</b><br>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><br>In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 1: Terms, definition and general requirements  |
| <b>EN ISO 18113-3:2011</b><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 EC-REP BV, Pas 257, 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**

*(Place and date of issue)*

**Kevin Bourzac**

*Vice President, Regulatory and Clinical Affairs*



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