EC Declaration of Conformity

Manufacturer/ Supplier Information:	**BioFire Diagnostics, LLC** 390 Wakara Way Salt Lake City, Utah 84108, USA Phone: 1-801-736-6354 regulatory@BioFireDX.com http://www.BioFireDX.com

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

FilmArray Torch
(HTFA-ASY-0104, HTFA-SUB-0103)

meets the provisions of the European Directive 98/79/EC for *in vitro* Diagnostic Medical Devices. 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:

ISO 13485:2003/EN ISO 13485:2012 Medical devices – Quality Management System – Requirements for regulatory purposes
EN ISO 14971:2012 Medical devices – Application of risk management to medical devices'
EN 62304:2006 Medical device software—Software life-cycle processes,—IEC 62304:2006, November 27, 2008
EN 62366:2008 Medical devices-Application of usability engineering to medical devices'
EN 13612:2002 Performance evaluation of in vitro diagnostic
EN 61010-2-101:2002 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
EN 61326-2-6:2006 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
EN 980:2008 Symbols for use in the labelling of medical devices
ISO 15223-1:2012 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, Cipalstraat 3, B-2440 Geel, Belgium.

Salt Lake City, UT, USA 4/5/2016
(Place and date of issue)

Randy Rasmussen
President and Chief Operating Officer

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