EC Declaration of Conformity

Manufacturer/ Supplier Information:	**BioFire Diagnostics, LLC** 515 Colorow Drive 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 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 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 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 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 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.

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 31 OCT 2019
(Place and date of issue)

Kristen Kanack
SVP of Regulatory and Clinical Affairs

BIOFIRE® A BIOMÉRIEUX COMPANY
515 Colorow Drive, Salt Lake City, UT 84108
phone 1-801-736-6354 | fax 1-801-588-0507
www.BioFireDX.com

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