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® Blood Culture Identification (BCID) Panel
(RFIT-ASY-0126, RFIT-ASY-0127)

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.

The following relevant standards have been met:

ISO 13485:2003 Medical devices – Quality Management System – Requirements for regulatory purposes
EN ISO 14971:2012 Medical devices – Application of risk management to medical devices
EN 62366:2008 Medical devices-Application of usability engineering to medical devices
EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
EN 23640:2013 In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
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 18113-2:2011 In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 2: In vitro diagnostic reagents 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 7/16/2015
(Place and date of issue)

Randy Rasmussen
President and Chief Executive Officer

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