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® Gastrointestinal (GI) Panel
(RFIT-ASY-0104, RFIT-ASY-0116)

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 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 14971:2019 Medical devices – Application of risk management to medical devices
EN 13641:2002 Elimination or reduction of risk of infection related to *in vitro* diagnostic reagents
EN 62366:2008 Medical devices-Application of usability engineering to medical devices
EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
EN 23640:2015 In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
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 18113-2:2011 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 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
Digitally signed by Kevin Bourzac
Date: 2021.11.23 13:12:46 -07'00'

Kevin Bourzac
Vice President, Regulatory and Clinical Affairs

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