

# EC Declaration of Conformity

**Manufacturer/  
Supplier Information:**

**BioFire Diagnostics, LLC**  
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Salt Lake City, Utah 84108, USA  
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<http://www.BioFireDX.com>

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

**BioFire® Respiratory Panel 2.1 *plus* (RP2.1*plus*)  
(423740)**

meets the provisions of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices. The device is classified as an In Vitro Diagnostic (IVD) Device under Annex II list B. BioFire Diagnostics' quality system is registered to EN ISO 13485:2016.

The following relevant standards have been met:

<b>EN ISO 13485:2016</b> Medical devices – Quality Management System – Requirements for regulatory purposes
<b>EN ISO 14971:2012</b> Medical devices – Application of risk management to medical devices
<b>EN 13641:2002</b> Elimination or reduction of risk of infection related to <i>in vitro</i> diagnostic reagents
<b>EN 62366:2008</b> Medical devices-Application of usability engineering to medical devices
<b>EN 13612:2002</b> Performance evaluation of <i>in vitro</i> diagnostic medical devices
<b>EN ISO 23640:2015</b> <i>In vitro</i> diagnostic medical devices – Evaluation of stability of <i>in vitro</i> diagnostic reagents
<b>EN ISO 15223-1:2016</b> 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> <i>In vitro</i> diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 1: Terms, definition and general requirements
<b>EN ISO 18113-2:2011</b> <i>In vitro</i> diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 2: <i>In vitro</i> diagnostic reagents for professional use

Technical documentation demonstrating compliance as described in Annex IV 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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