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

FilmArray® Respiratory Panel
(RFIT-ASY-0124, RFIT-ASY-0125)

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.

The following relevant standards have been met:

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
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<tbody>
<tr>
<td>EN ISO 14971:2012</td>
<td>Medical devices – Application of risk management to medical devices</td>
</tr>
<tr>
<td>EN 13641:2002</td>
<td>Elimination or reduction of risk of infection related to in vitro diagnostic reagents</td>
</tr>
<tr>
<td>EN 62366:2008</td>
<td>Medical devices - Application of usability engineering to medical devices</td>
</tr>
<tr>
<td>EN 13612:2002</td>
<td>Performance evaluation of in vitro diagnostic medical devices</td>
</tr>
<tr>
<td>EN ISO 15223-1:2016</td>
<td>Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements</td>
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<tr>
<td>EN ISO 18113-1:2011</td>
<td>In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 1: Terms, definition and general requirements</td>
</tr>
<tr>
<td>EN ISO 18113-2:2011</td>
<td>In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 2: In vitro diagnostic reagents for professional use</td>
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</tbody>
</table>

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 bvba, Cipalstraat 3, B-2440 Geel, Belgium.

The notified body for this product is BSI (Notified body #2707; Gay Building, John M. Keynesplein 0, 1086 CM Amsterdam, Netherlands).

Salt Lake City, UT, USA 31 Oct 2019

Kristen Kanack
SVP of Regulatory and Clinical Affairs

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