EC Declaration of Conformity

<table>
<thead>
<tr>
<th>Manufacturer/Supplier Information:</th>
<th>BioFire Diagnostics, LLC</th>
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<tr>
<td></td>
<td>515 Colorow Drive</td>
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<tr>
<td></td>
<td>Salt Lake City, Utah 84108, USA</td>
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<td>Phone: 1-801-736-6354</td>
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<td><a href="mailto:regulatory@BioFireDX.com">regulatory@BioFireDX.com</a></td>
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<td><a href="http://www.BioFireDX.com">http://www.BioFireDX.com</a></td>
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We, BioFire Diagnostics, LLC, declare under our sole responsibility, that the product

FilmArray® Respiratory Panel 2 (RP2) (RFIT-ASY-0129, RFIT-ASY-0130)


The following relevant standards have been met:

  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 ISO 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 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).

Kevin Bourzac
Vice President, Regulatory and Clinical Affairs

Salt Lake City, UT, USA
(Place and date of issue)

Digitally signed by Kevin Bourzac
Date: 2021.11.23 13:12:59 -07'00'