EU 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

BioFire® Respiratory Panel 2.1 *plus* (RP2.1p/us)
(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:

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 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).

Salt Lake City, UT, USA

(Place and date of issue)

Kevin Bourzac

Digitally signed by Kevin Bourzac
Date: 2021.11.23 13:12:17 -07'00'

Kevin Bourzac
Vice President, Regulatory and Clinical Affairs

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RP2.1plus IVDD DoC Updates (BFR0000-9353)		
Revision	**Description**	**Date Signed**
Rev 01-02	Previous Releases	2021-11-03
Non-significant changes approved after the 26th May 2022 as per the Transitional Provisions of IVDR Article 110.3		

Amendment 01	• Updated EN ISO 15223-1:2016 to EN ISO 15223-1:2021
	
	• Added the following standards:
	  • EN 62304:2006 Medical device software – Software life-cycle processes
	  • ISO 20916:2019 In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice
		2022-11-02

Amendment 02	• Included ISO version of standards to 13485:2016, 14971:2019, and 15223-1:2021 • Updated to EN 62366-1 from 2008 to 2015 version • Added IEC version of 62366-1 Edition 1.0 b:2015 • Added IEC version of 62304 Edition 1.1 b: 2015 • Included ISO 18113-1:2009 and ISO 18113-2:2009 versions	2023-11-03
Amendment 03	• The European Authorized Representative has been updated to: QbD RepS BV Groenenborgerlaan 16 2610 Wilrijk Belgium • Updated IEC 62366-1 Edition 1.0 b:2015 to IEC 62366-1 Edition 1.0 b:2020 / EN 62366-1:2015 + A1:2020 • Added EN ISO 20916:2024 • Updated ISO 18113-1:2009 / EN ISO 18113-1:2011 to ISO 18113-1:2022 / EN ISO 18113-1:2024 • Updated ISO 18113-2:2009 / EN ISO 18113-2:2011 to ISO 18113-2:2022 / EN ISO 18113-2:2024	2025-05-01
Amendment 04	• Changed “EC Declaration of Conformity” to “EU Declaration of Conformity” • The European Authorized Representative has been updated to: bioMérieux SA 376, Chemin de l’Orme 69280 Marcy l’Etoile France	2026-05-01