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

BioFire® Respiratory/Sore Throat (R/ST) Panel
(423485)

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, labelling 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)

Ajay Bhatia

Digitally signed by Ajay Bhatia
Date: 2022.04.01 03:04:43 +05'30'

Ajay Bhatia
Director, Regulatory Affairs

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BFR0001-7944-01

RST IVDD DoC Updates (BFR0001-7944)		
Revision	**Description**	**Date Signed**
Rev 01	Initial Release	2022-04-01
Amendment 01	• Updated panel name from BioFire R/ST Panel to BIOFIRE SPOTFIRE R/ST Panel • Updated standards to include ISO editions for EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 23640:2015, EN ISO 23640:2015, EN ISO 18113-1:2011, and EN ISO 18113-2:2011 Additionally, the following standards were added to the standard list: • ISO 20916:2019 In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice • IEC 62304 Edition 1.1 b: 2015 / EN 62304:2006 + A1:2015 Medical device software – Software life-cycle processes	2023-08-31
Amendment 02	• 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	2025-08-05
Amendment 03	• 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	2026-07-01