EC Declaration of Conformity

Manufacturer/ Supplier Information:	**BioFire Diagnostics, LLC (bioMérieux)** 515 Colorow Drive Salt Lake City, Utah 84108, USA Phone: 1-801-736-6354 regulatory@biomerieux.com http://www.biofiredx.com

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

BIOFIRE® SPOTFIRE® 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 ISO 13485:2016.

The following relevant standards have been met:

ISO / EN ISO 13485:2016 Medical devices – Quality Management System – Requirements for regulatory purposes
ISO / 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
IEC 62366-1 Edition 1.0 b:2015 / EN 62366-1:2015 Medical devices- Part 1: Application of usability engineering to medical devices
IEC 62304 Edition 1.1 b: 2015 / EN 62304:2006 + A1:2015 Medical device software – Software life-cycle processes
BS EN 13612:2002 Performance evaluation of *in vitro* diagnostic medical devices
ISO 23640:2011 / EN ISO 23640:2015 In vitro diagnostic medical devices – Evaluation of stability of *in vitro* diagnostic reagents
ISO 20916:2019 *In vitro* diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice
ISO / EN ISO 15223-1:2021 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
ISO 18113-1:2009 / EN ISO 18113-1:2011 *In vitro* diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 1: Terms, definition and general requirements
ISO 18113-2:2009/ 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: 2023.08.31 09:44:05 -06'00'

Kevin Bourzac
VP of Regulatory and Clinical Affairs

BIOFIRE BY BIOMÉRIEUX

BFR0001-7944-02