EC Declaration of Conformity

Manufacturer/Supplier Information	**BioFire Diagnostics, LLC** 515 Colorow Drive Salt Lake City, Utah 84108, USA SRN: US-MF-000003311
EU Authorized Representative	**QARAD EC-REP BV** Pas 257, B-2440 Geel, Belgium SRN: BE-AR-000000040

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

Product Reference	Product Name	Basic UDI-DI
FAST-ASY-0001	BioFire® SpotFire® Control Station	357302BUDI000917U8
FAST-ASY-0002	BioFire® SpotFire® Module	

Meets the provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

According to Annex VIII, Rule 5b this product is classified as Class A and is thus a self-certified product. Technical documentation has been drawn up as set out in Annexes II and III. BioFire Diagnostics' quality system is registered to EN ISO 13485:2016. There are no common specifications (CS) applicable to this product.

Salt Lake City, Utah, USA
Place of issue
November 03, 2022
Date of issue

Kevin Bourzac
Digitally signed by Kevin Bourzac
Date: 2022.11.03 14:17:15 -06'00'

Kevin Bourzac, PhD
VP of Regulatory and Clinical Affairs

Intended Purpose

Intended Use:

The BIOFIRE® SPOTFIRE® System is an automated in vitro diagnostic (IVD) device intended for use with compatible BIOFIRE® IVD Panels to detect multiple nucleic acid targets contained in patient specimens. The BIOFIRE SPOTFIRE System interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex polymerase chain reaction (nmPCR) in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The software automatically determines the results and provides a test report.

The BIOFIRE SPOTFIRE System is composed of one to four BIOFIRE SPOTFIRE Modules connected to a BIOFIRE SPOTFIRE Control Station running BIOFIRE SPOTFIRE Software. Each Module can be randomly and independently accessed to run a reagent pouch. The software controls the function of each Module and collects, analyzes, and stores data generated by each Module.

Intended User and Use Environment:

The BIOFIRE SPOTFIRE System is intended for use by medical and/or laboratory professionals in professional healthcare facilities, such as physician offices, clinics, long-term care facilities, laboratories, and hospitals.