**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.