

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	QbD RepS BV Groenenborgerlaan 16, 2610 Wilrijk, Belgium SRN: BE-AR-000000040

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

Product Reference	Product Name	Basic UDI-DI
HTFA-ASY-0104	FilmArray® Torch System Base	357302BUDI000922TZ
HTFA-SUB-0103	FilmArray® Torch Module	
HTFA-ASY-0102	FilmArray® Torch Duplex	N/A

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
March 28, 2025

Date of issue

Karli Plenert
Sr Director, Regulatory Affairs

Intended Purpose

Intended Use

The BIOFIRE® FILMARRAY® TORCH (BIOFIRE TORCH) is an automated *in vitro* diagnostic (IVD) device intended for use with FDA-cleared or approved IVD BIOFIRE® FILMARRAY® Panels. The BIOFIRE TORCH is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The BIOFIRE TORCH interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR (nmPCR) in a closed system. The resulting PCR products are evaluated using assay-specific DNA melting analysis. The BIOFIRE TORCH software automatically determines the results and provides a test report.

The BIOFIRE TORCH is a modification of BIOFIRE® FILMARRAY® 2.0 and is composed of one to twelve BIOFIRE TORCH Modules connected to a BIOFIRE TORCH System Base running BIOFIRE TORCH Software. The BIOFIRE TORCH System Base houses up to two BIOFIRE TORCH Modules. Up to five BIOFIRE TORCH Duplex Module enclosures, each capable of housing up to two additional BIOFIRE TORCH Modules, may be added on top of the BIOFIRE TORCH System Base. Each BIOFIRE TORCH Module can be randomly and independently accessed to run a reagent pouch. The BIOFIRE TORCH software controls the function of each BIOFIRE TORCH Module and collects, analyzes, and stores data generated by each BIOFIRE TORCH Module.

Intended User and Environment

The BIOFIRE TORCH is intended for use by trained medical and laboratory professionals in a laboratory setting or under the supervision of a trained laboratory professional.