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
Notified Body	**BSI** Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Notified Body Identification No: 2797

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

Product Reference	Product Name	Basic UDI-DI
RFIT-ASY-0118	FilmArray® Meningitis/Encephalitis (ME) Panel (30 pack)	357302BUDI000004SJ
RFIT-ASY-0119	FilmArray® Meningitis/Encephalitis (ME) Panel (6 pack)	

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, Rules 3b and 3c, this product is classified as Class C and has been certified to the requirements of Annex IX (reference CE Certificate# IVDR 735494). 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
Digitally signed by Karli Plenert
Date: 2025.03.28 11:37:31 -04'00'

Karli Plenert
Sr Director, Regulatory Affairs

Intended Purpose

Intended Use

The BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel is a qualitative multiplexed nucleic acid-based *in vitro* diagnostic test intended for use with BIOFIRE® FILMARRAY® Systems. The BIOFIRE ME Panel is capable of simultaneous detection and identification of multiple bacterial, viral, and yeast nucleic acids directly from cerebrospinal fluid (CSF) specimens obtained via lumbar puncture from individuals with signs and/or symptoms of meningitis and/or encephalitis. The following organisms are identified using the BIOFIRE ME Panel:

Bacteria:

- *Escherichia coli* K1
- *Haemophilus influenzae*
- *Listeria monocytogenes*
- *Neisseria meningitidis* (encapsulated)
- *Streptococcus agalactiae*
- *Streptococcus pneumoniae*

Viruses:

- Cytomegalovirus

- Enterovirus
- Herpes simplex virus 1
- Herpes simplex virus 2
- Human herpesvirus 6
- Human parechovirus
- Varicella zoster virus

Yeast:
- *Cryptococcus neoformans/gattii*

The BIOFIRE ME Panel is indicated as an aid in the diagnosis of specific agents of meningitis and/or encephalitis and results are meant to be used in conjunction with other clinical, epidemiological, and laboratory data. Results from the BIOFIRE ME Panel are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out co-infection with organisms not included in the BIOFIRE ME Panel. The agent detected may not be the definite cause of the disease. Negative results do not preclude central nervous system (CNS) infection. Not all agents of CNS infection are detected by this test and sensitivity in clinical use may differ from that described in the package insert.

The BIOFIRE ME Panel is not intended for testing of specimens collected from indwelling CNS medical devices.

The BIOFIRE ME Panel is intended to be used in conjunction with standard of care culture for organism recovery, serotyping, and antimicrobial susceptibility testing.

Intended User and Use Environment

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