

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 799675 R000

Manufacturer: BioFire Diagnostics, LLC

Address:

515 Colorow Drive
Salt Lake City
Utah
84108
USA

Single Registration Number: US-MF-000003311

EU Authorised Representative: bioMérieux SA

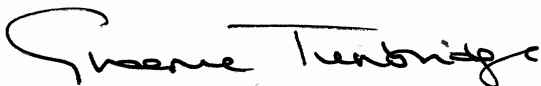
Address:

376 Chemin de l'Orme
69280 Marcy-l'Étoile
France

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2026-08-03**

Current Issue Date: **2026-08-03**

Starting Validity Date: **2026-08-03**

Expiry Date: **2031-08-02**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
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Device Schedule:

Intended Purpose as per the Instructions for Use:

The BIOFIRE® FILMARRAY® Pneumonia Panel *plus* (BIOFIRE Pneumonia Panel *plus*) is a multiplexed nucleic acid test intended for use with BIOFIRE® FILMARRAY® 2.0 (BIOFIRE 2.0) or BIOFIRE® FILMARRAY® TORCH (BIOFIRE TORCH) systems for the simultaneous detection and identification of multiple respiratory viral and bacterial nucleic acids, as well as select antimicrobial resistance genes, in sputum-like specimens (induced or expectorated sputum, or endotracheal aspirates) or bronchoalveolar lavage (BAL)-like specimens (BAL or mini-BAL) obtained from individuals suspected of lower respiratory tract infection.

The following bacteria are reported semi-quantitatively with bins representing approximately 10^4 , 10^5 , 10^6 , or $\geq 10^7$ genomic copies of bacterial nucleic acid per millilitre (copies/mL) of specimen, to aid in estimating relative abundance of nucleic acid from these common bacteria within a specimen:

Bacteria reported with bins of 10^4 , 10^5 , 10^6 , or $\geq 10^7$ copies/mL		
<i>Acinetobacter calcoaceticus-baumannii</i> complex	<i>Klebsiella oxytoca</i>	<i>Serratia marcescens</i>
<i>Enterobacter cloacae</i> complex	<i>Klebsiella pneumoniae</i> group	<i>Staphylococcus aureus</i>
<i>Escherichia coli</i>	<i>Moraxella catarrhalis</i>	<i>Streptococcus agalactiae</i>
<i>Haemophilus influenzae</i>	<i>Proteus</i> spp.	<i>Streptococcus pneumoniae</i>
<i>Klebsiella aerogenes</i>	<i>Pseudomonas aeruginosa</i>	<i>Streptococcus pyogenes</i>

The following atypical bacteria, viruses, and antimicrobial resistance genes are reported qualitatively:

Atypical Bacteria		
<i>Chlamydia pneumoniae</i>	<i>Legionella pneumophila</i>	<i>Mycoplasma pneumoniae</i>
Viruses		
Adenovirus	Human rhinovirus/enterovirus	Middle East respiratory syndrome coronavirus (MERS-CoV)
Coronavirus	Influenza A virus	Parainfluenza virus
Human metapneumovirus	Influenza B virus	Respiratory syncytial virus
Antimicrobial Resistance Genes		
CTX-M	NDM	mecA/C and MREJ (MRSA)
IMP	OXA-48-like	KPC
VIM		

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The detection and identification of specific viral and bacterial nucleic acids, as well as the estimation of relative abundance of nucleic acid from common bacterial analytes, within specimens collected from individuals exhibiting signs and/or symptoms of a respiratory infection, aids in the diagnosis of lower respiratory infection if used in conjunction with other clinical and epidemiological information. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test, pathogens below the limit of detection, or in the case of bacterial analytes, present at levels below the lowest reported 10^4 copies/mL bin. Detection of analytes does not rule out co-infection with other organisms; the agent(s) detected by the BIOFIRE Pneumonia Panel *plus* may not be the definite cause of disease. Additional laboratory testing may be necessary when evaluating a patient with possible lower respiratory tract infection.

Detection of bacterial nucleic acid may be indicative of colonizing or normal respiratory flora and may not indicate the causative agent of pneumonia. Semi-quantitative Bin (copies/mL) results generated by the BIOFIRE Pneumonia Panel *plus* are not equivalent to CFU/mL and do not consistently correlate with the quantity of bacterial analytes compared to CFU/mL. For specimens with multiple bacteria detected, the relative abundance of nucleic acids (copies/mL) may not correlate with the relative abundance of bacteria as determined by culture (CFU/mL). Clinical correlation is advised to determine significance of semi-quantitative Bin (copies/mL) for clinical management.

The antimicrobial resistance gene detected may or may not be associated with the agent(s) responsible for disease. Negative results for these antimicrobial resistance gene assays do not indicate susceptibility to corresponding classes of antimicrobials, as multiple mechanisms of antimicrobial resistance exist.

Antimicrobial resistance can occur via multiple mechanisms. A "Not Detected" result for a genetic marker of antimicrobial resistance does not indicate susceptibility to associated antimicrobial drugs or drug classes. A "Detected" result for a genetic marker of antimicrobial resistance cannot be definitively linked to the microorganism(s) detected. Culture is required to obtain isolates for antimicrobial susceptibility testing, and BIOFIRE Pneumonia Panel *plus* results should be used in conjunction with culture results for determination of bacterial susceptibility or resistance.

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NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
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Due to the genetic similarity between human rhinovirus and enterovirus, the test cannot reliably differentiate them. A positive Rhinovirus/Enterovirus result should be followed up using an alternate method (e.g., cell culture or sequence analysis) if differentiation is required.

Positive results for MERS-CoV should be reported to state or local health departments. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Culture is required to identify pathogens not detected by the BIOFIRE Pneumonia Panel *plus*, to further speciate analytes in genus, complex, or group results if desired, to identify bacterial pathogens present below the 10⁴ copies/mL bin if desired, and for antimicrobial susceptibility testing.

Risk Classification: Class D

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Basic UDI-DI
BIOFIRE® FILMARRAY® Pneumonia Panel <i>plus</i>	RFIT-ASY-0143 (30 Tests) RFIT-ASY-0142 (6 Tests)	IVR 0503	357302BUDI002137TL

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	30034974	Issued



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