By Royal Charter

EU Technical Documentation Assessment Certificate

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

IVDR 799673 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**

...making excellence a habit.™

EU Technical Documentation Assessment Certificate

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

IVDR 799673 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The BIOFIRE Respiratory Panel 2.1 *plus* (RP2.1*plus*) is a PCR-based multiplexed nucleic acid test intended for use with the BIOFIRE® FILMARRAY® 2.0 or BIOFIRE® FILMARRAY® TORCH Systems for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections, including COVID-19.

The following organism types and subtypes are identified using the BIOFIRE RP2.1*plus*:

Viruses	Bacteria
Adenovirus	*Bordetella parapertussis*
Coronavirus 229E	*Bordetella pertussis*
Coronavirus HKU1	*Chlamydia pneumoniae*
Coronavirus NL63	*Mycoplasma pneumoniae*
Coronavirus OC43	
Middle East respiratory syndrome coronavirus (MERS-CoV)	
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)	
Human metapneumovirus	
Human rhinovirus/enterovirus	
Influenza A virus	
Influenza A virus A/H1	
Influenza A virus A/H3	
Influenza A virus A/H1-2009	
Influenza B virus	
Parainfluenza virus 1	
Parainfluenza virus 2	
Parainfluenza virus 3	
Parainfluenza virus 4	
Respiratory syncytial virus	

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

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

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

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

EU Technical Documentation Assessment Certificate

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

IVDR 799673 R000

Nucleic acids from the respiratory viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and/or symptoms of respiratory infection is indicative of the presence of the identified microorganism and aids in the diagnosis of 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, or lower respiratory tract infection that may not be detected by an NPS specimen. Positive results do not rule out co-infection with other organisms. The agent(s) detected by the BIOFIRE RP2.1*plus* may not be the definite cause of disease. Additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.

Risk Classification: Class D

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Basic UDI-DI**
BIOFIRE® Respiratory Panel 2.1 *plus* (RP2.1*plus*)	423740	IVR 0503	357302BUDI000002SE

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

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

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

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

...making excellence a habit.™

EU Technical Documentation Assessment Certificate

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

IVDR 799673 R000

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	30034972	Issued

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

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

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

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

...making excellence a habit.™

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.
This certificate was issued electronically and is bound by the conditions of the contract.

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.
A Member of the BSI Group of Companies.