EU Technical Documentation Assessment Certificate

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

IVDR 832361 R000

Manufacturer: BioFire Diagnostics, LLC

Address:
515 Colorow Drive
Salt Lake City
Utah
84108
USA

Single Registration Number: US-MF-000003311

EU Authorised Representative: QbD RepS BV

Address:
Groenenborgerlaan 16
2610 Wilrijk
Belgium

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: **2026-03-03**

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

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

Expiry Date: **2031-03-02**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

The BIOFIRE® SPOTFIRE® Respiratory/Sore Throat *plus* (R/ST *plus*) Panel Mini is an automated multiplexed polymerase chain reaction (PCR) test intended for use with the BIOFIRE® SPOTFIRE® System for the simultaneous, qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swab (NPS) or anterior nasal swab (ANS) specimens obtained from **individuals with signs and symptoms of respiratory tract infection**, **including COVID-19**; (**Respiratory menu**) or in throat swab (TS) specimens from **individuals with signs and symptoms of pharyngitis;** (**Sore Throat menu**).

The following analytes are identified and differentiated using the SPOTFIRE R/ST *plus* Panel Mini:

Respiratory Menu	**Sore Throat Menu**
Viruses	**Viruses**
Coronavirus SARS-CoV-2	Coronavirus SARS-CoV-2
Human rhinovirus/enterovirus	Human rhinovirus/enterovirus
Influenza A virus	Influenza A virus
Influenza B virus	Influenza B virus
Respiratory syncytial virus	Respiratory syncytial virus
	Bacteria
	Streptococcus pyogenes (group A Strep)

Nucleic acids from the viral and bacterial organisms identified by this test are generally detectable in NPS/ANS/TS specimens during the acute phase of infection. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and symptoms of respiratory infection and/or pharyngitis is indicative of the presence of the identified microorganism and aids in diagnosis if used in conjunction with other clinical and epidemiological information, and laboratory findings. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

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Negative results in the setting of a respiratory illness and/or pharyngitis may be due to infection with pathogens that are not detected by this test, or a respiratory tract infection that may not be detected by an NPS, ANS, or TS specimen. Positive results do not rule out co-infection with other organisms. The agent(s) detected by the SPOTFIRE R/ST *plus* Panel Mini 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 and/or pharyngitis.

Risk Classification: Class B near patient test / professional use test

Type (Codes as per (EU) 2017/2185): IVR 0503

Device Name	Model	Basic UDI-DI
BIOFIRE® SPOTFIRE® Respiratory/Sore Throat plus (R/ST plus) Panel Mini	425091	357302BUDI002247TU

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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	30495682	Issued.

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

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