

EU Technical Documentation Assessment Certificate

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

IVDR 832356 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

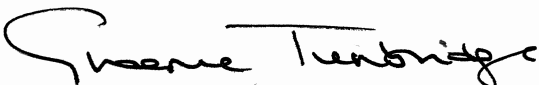
Address:

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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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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Device Schedule:

Intended Purpose as per the Instructions for Use:

The BIOFIRE® SPOTFIRE® Respiratory/Sore Throat *plus* (R/ST*plus*) Panel (SPOTFIRE R/ST*plus* Panel) test kit is a single product with **two intended uses**, where the intended use for a given test is based upon the sample type selected by the operator based on patient signs and symptoms and sample type collected.

The SPOTFIRE R/ST*plus* Panel 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) specimens obtained from **individuals with signs and symptoms of respiratory tract infections, including COVID-19; (Respiratory)** or from **individuals with signs and/or symptoms of pharyngitis** (using a throat swab (TS); **Sore Throat**).

The following organism types and subtypes are identified and differentiated using the SPOTFIRE R/ST*plus* Panel:

Viruses (Respiratory and Sore Throat)	Bacteria (Respiratory and Sore Throat)
Adenovirus	<i>Chlamydia pneumoniae</i>
Coronavirus (seasonal)	<i>Mycoplasma pneumoniae</i>
Coronavirus SARS-CoV-2	Bacteria (Respiratory Only)
Human metapneumovirus	<i>Bordetella parapertussis</i>
Human rhinovirus/enterovirus	<i>Bordetella pertussis</i>
Influenza A virus	Bacteria (Sore Throat Only)
Influenza A virus A/ H1-2009	<i>Streptococcus dysgalactiae (group C/G Strep)</i>
Influenza A virus A/H3	<i>Streptococcus pyogenes (group A Strep)</i>
Influenza B virus	
Parainfluenza virus	
Respiratory syncytial virus	

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Intended Purpose as per the Instructions for Use (Cont.):

Nucleic acids from the viral and bacterial organisms identified by this test are generally detectable in NPS/TS 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 and/or pharyngitis are 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.

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 lower respiratory tract infection that may not be detected by an NPS or TS specimen. Positive results do not rule out coinfection with other organisms. The agent(s) detected by the SPOTFIRE R/STplus Panel 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/STplus) Panel	425090	357302BUDI002246TS

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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	30495680	Issued



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