

EU 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
425091	BIOFIRE SPOTFIRE Respiratory/Sore Throat <i>plus</i> (R/ST <i>plus</i>) Panel Mini	357302BUDI002247TU

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, Rule 6, this product is classified as Class **B-NPT** and has been certified to the requirements of Annex IX (reference CE Certificate# IVDR 735494/ IVDR 832361). 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

04-May-26

Date of issue

DocuSigned by:

Karli PLENERT

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Sr Director, Regulatory Affairs

Intended Purpose

Intended 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

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Old Document Reference IT-1407F, Rev.03

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.

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/STplus 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.

Intended User and Use Environment

The SPOTFIRE R/STplus Panel Mini is intended for use by trained medical professionals proficient in using the SPOTFIRE System at the point of care (POC), in a near patient testing environment or for laboratory professionals in a laboratory setting.

Refer to the SPOTFIRE System Operator's Manual for the appropriate physical environmental specifications and/or conditions for performing a SPOTFIRE R/STplus Panel Mini test.