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
425090	BIOFIRE SPOTFIRE Respiratory/Sore Throat *plus* (R/ST*plus*) Panel	357302BUDI002246TS

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 832356). 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

March 31, 2026
Date of issue

Karli Plenert
Digitally signed by Karli Plenert
Date: 2026.03.31 11:40:16 -06'00'

Karli Plenert
Sr Director, Regulatory Affairs

Intended Purpose

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

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/ST*plus* 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.

Intended User and Use Environment

The SPOTFIRE R/ST*plus* Panel is intended for use by trained medical professionals proficient in using the SPOTFIRE System at the point of care (POC), in near patient testing environments, 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/ST*plus* Panel test.