

# UKCA Certificate - Full Quality Assurance System

Part IV of The Medical Devices Regulations 2002, Annex IV excluding Sections 4 and 6 [as modified by Part 3 of Schedule 2A to The Medical Devices Regulations 2002]

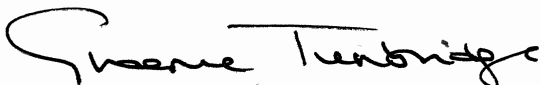
**No.** **UKCA 762606**  
**Issued To:** **BioFire Diagnostics, LLC**  
**515 Colorow Drive**  
**Salt Lake City**  
**Utah**  
**84108**  
**USA**

In respect of:

**Design and Manufacture of PCR kits for detection of Chlamydia and Cytomegalovirus.**

On the basis of our examination under the requirements of Part IV of The Medical Devices Regulations 2002, Annex IV excluding Sections 4 and 6 [as modified by Part 3 of Schedule 2A to The Medical Devices Regulations 2002], the quality system was found to meet the requirements of this regulation. For the placing on the market of List A devices covered by this certificate, a UKCA Design-Examination Certificate according to Annex IV Section 4 (modified as described above) and a letter releasing each batch according to Annex IV Section 6 (modified as described above) are required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-08-25**

Date: **2024-01-09**

Expiry Date: **2027-04-06**

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## Supplementary Information to UKCA 762606

Issued To:

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| Number                 | Device Name   | Intended purpose per IFU  |
|------------------------|---|---|
| <b>Annex II List B</b> |   |   |
| IVD 0305               | 423740, BioFire® Respiratory Panel 2.1 plus (RP2.1plus), 30 Tests<br>RFIT-ASY-0118, FilmArray® Meningitis/Encephalitis (ME) Panel, 30 Test<br>RFIT-ASY-0119, FilmArray® Meningitis/Encephalitis (ME) Panel, 6 Test<br>RFIT-ASY-0143, FilmArray® Pneumonia Panel plus, 30 Tests<br>RFIT-ASY-0142, FilmArray® Pneumonia Panel plus, 6 Tests<br>424461, BIOFIRE® SPOTFIRE® Respiratory (R) Panel | Multiplexed nucleic acid tests for the simultaneous qualitative detection and identification of pathogens including Chlamydia and Cytomegalovirus |

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## Certificate History

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| Date       | Reference Number | Action  |
|------------|------------------|---|
| 2022-08-25 | 3585660          | First Issues; Traceable to CE 667639                                |
| 2023-04-26 | 3915042          | Addition of 424461, BIOFIRE® SPOTFIRE® Respiratory (R) Panel        |
| Current    | 30078614         | Addition of RFIT-ASY-0142, FilmArray® Pneumonia Panel plus, 6 Tests |

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