By Royal Charter

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:

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

First Issued: **2022-08-25** Date: **2024-01-09** Expiry Date: **2027-04-06**

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UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: **UKCA 762606**
Date: **2024-01-09**
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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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