

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]

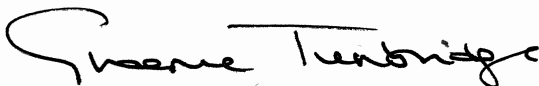
No. UKCA 762606
Issued To: BioFire Diagnostics, LLC
 515 Colorow Drive
 Salt Lake City
 Utah
 84108
 USA

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 Global Regulatory & Quality

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

Date: **2025-11-14**

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

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.
 This certificate was issued electronically and is bound by the conditions of the contract.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000
 Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
 A member of BSI Group of Companies.

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Supplementary Information to UKCA 762606

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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	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
2024-01-09	30078614	Addition of RFIT-ASY-0142, FilmArray® Pneumonia Panel plus, 6 Tests
Current	30553245	Removal of "BIOFIRE SPOTFIRE Respiratory (R) Panel" from certificate scope.

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