By Royal Charter

EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No. **CE 667639**

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 Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2017-03-02** Date: **2022-04-07** Expiry Date: **2025-05-26**

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Supplementary Information to CE 667639

Issued To:

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515 Colorow Drive
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Number	Device Name	Intended purpose per IFU
Annex II List B		
IVD0305	423485, BioFire® Respiratory/Sore Throat (R/ST) Panel, 30 Tests 424091, BioFire® Pneumonia 1.1 plus (PN1.1plus) Panel, 30 Tests 424461, BioFire® Respiratory/Sore Throat Pro (R/ST Pro) Panel, 30 Tests 423740, BioFire® Respiratory Panel 2.1 *plus* (RP2.1*plus*), 30 Tests RFIT-ASY-0124, FilmArray® Respiratory Panel (RP), 30 Tests RFIT-ASY-0125, FilmArray® Respiratory Panel (RP), 6 Tests RFIT-ASY-0118, FilmArray® Meningitis/Encephalitis (ME) Panel, 30 Test RFIT-ASY-0119, FilmArray® Meningitis/Encephalitis (ME) Panel, 6 Test RFIT-ASY-0129, FilmArray® Respiratory Panel 2 (RP2), 30 Tests RFIT-ASY-0130, FilmArray® Respiratory Panel 2 (RP2), 6 Tests RFIT-ASY-0136, FilmArray® Respiratory Panel 2 *plus* (RP2*plus*), 30 Tests RFIT-ASY-0137, FilmArray® Respiratory Panel 2 *plus* (RP2*plus*), 6 Tests RFIT-ASY-0144, FilmArray® Pneumonia Panel, 30 Tests RFIT-ASY-0145, FilmArray® Pneumonia Panel, 6 Tests 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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EC Certificate - Full Quality Assurance Certificate History

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Date: **2022-04-07**
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Date	Reference Number	Action
02 March 2017	8674813	First Issue. Transfer from another Notified Body.
27 April 2017	8729824	Head Office site move.
31 May 2018	8957420	Certificate Renewal.
28 February 2019	8868563	Traceable to NB 0086.
03 July 2020	3224708	Addition of BioFire® Respiratory Panel 2.1 (RP2.1) and BioFire® Respiratory Panel 2.1 *plus* (RP2.1*plus*) to scope of certificate. Change to EU Representative name and address.
20 August 2020	3278786	Scope reduction to remove BioFire® Respiratory Panel 2.1 (RP2.1) from the scope of certificate.
07 April 2022	3656815	Certificate Renewal and addition of BioFire® Respiratory/Sore Throat (R/ST) Panel, BioFire® Respiratory/Sore Throat Pro (R/ST Pro) Panel and BioFire® Pneumonia 1.1 plus (PN1.1plus) Panel to the scope of the certificate.
Non-significant changes approved after the 26th May 2022 as per the Transitional Provisions of IVDR Article 110.3		
19 January 2023	3847346	Restricted – removal of device FilmArray® Respiratory Panel 2 (REF: RFIT-ASY- 0129, RFIT-ASY-0130) and the FilmArray® Panel 2 plus (REF: RFIT-ASY- 0136, RFIT-ASY-0137) no longer on the markets

Inspiring trust for a more resilient world.

19 January 2023

BioFire Diagnostics, LLC
515 Colorow Drive
Salt Lake City
Utah
84108
USA

To whom it may concern,

The transitional provisions specified in IVDR Article 110(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26th May 2022.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under IVDR Article 110(3) and as per the guidance provided in MDCG 2022-6. The related IVDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 667639	98/79/EC Annex IV excl sec 4 & 6	3847346	Restricted – removal of device FilmArray® Respiratory Panel 2 (REF: RFIT-ASY- 0129, RFIT-ASY-0130) and the FilmArray® Panel 2 plus (REF: RFIT-ASY- 0136, RFIT-ASY-0137) no longer on the markets

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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