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

Digitally signed by Olaru Victoria
Date: 2020.11.23 09:17:36 EET
Reason: MoldSign Signature
Location: Moldova

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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-03-02** Date: **2020-07-03** Expiry Date: **2023-07-23**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 667639

Issued To:

BioFire Diagnostics, LLC
515 Colorow Drive
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Utah
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Number	Device Name	Intended purpose per IFU
Annex II List B		
IVD0305	423742, BioFire® Respiratory Panel 2.1 (RP2.1), 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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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 667639**
Date:	**2020-07-03**
Issued To:	**BioFire Diagnostics, LLC** **515 Colorow Drive** **Salt Lake City** **Utah** **84108** **USA**

Subcontractor:	**Service(s) supplied**
Qarad EC-REP BV Pas 257 B-2440 Geel Belgium	**EU Representative**

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 667639**

Date: **2020-07-03**

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515 Colorow Drive
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Utah
84108
USA

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.
Current	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.