

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

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

Holds Certificate Number:

**MD 667679**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, Manufacture, Installation and Servicing of In Vitro Diagnostic PCR Systems for Detection of Infectious Diseases.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-02-27

Latest Revision Date: 2020-12-30

Effective Date: 2021-02-19

Expiry Date: 2024-02-18

Page: 1 of 3



003

...making excellence a habit.™

Certificate No: **MD 667679**

Location	Registered Activities
BioFire Diagnostics, LLC 515 Colorow Drive Salt Lake City Utah 84108 USA	Design and Manufacture of PCR Systems for the Detection of Pathogens, Administration
BioFire Diagnostics, LLC 400 Wakara Way Salt Lake City Utah 84108 USA	Reagent Production
BioFire Diagnostics, LLC 1590 South 5200 West Salt Lake City Utah 84104 USA	Distribution Warehouse
BioFire Diagnostics, LLC 500 Huntsman Way Salt Lake City Utah 84108 USA	Marketing, Customer Support
BioFire Diagnostics, LLC 410 Chipeta Way Salt Lake City Utah 84108 USA	Administration
BioFire Diagnostics, LLC 420 Wakara Way Salt Lake City Utah 84108 USA	Administration, Purchasing

Original Registration Date: 2017-02-27

Latest Revision Date: 2020-12-30

Effective Date: 2021-02-19

Expiry Date: 2024-02-18

Page: 2 of 3

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

Certificate No: **MD 667679**

Location	Registered Activities
BioFire Diagnostics LLC 415 Bearcat Drive Salt Lake City Utah 84115 USA	Service
BioFire Diagnostics LLC 650 Komac Drive Salt Lake City Utah 84108 USA	Administration, Final Product QC
BioFire Diagnostics, LLC 1001 South 4800 West Salt Lake City Utah 84104 USA	Reagent Production



Original Registration Date: 2017-02-27

Latest Revision Date: 2020-12-30

Effective Date: 2021-02-19

Expiry Date: 2024-02-18

Page: 3 of 3

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.  
An electronic certificate can be authenticated [online](#).  
Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.