

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **BioFire Diagnostics, LLC**  
515 Colorow Drive  
Salt Lake City  
Utah  
84108  
USA

Facility ID Number: F000086

Holds Certificate No: **MDSAP 680085**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Brazil:** RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

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

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-03-13

Effective Date: 2023-04-04

Expiry Date: 2024-02-18



BSI Group America Inc. is an MDSAP recognised auditing organization

Certificate No: **MDSAP 680085**

Location	Registered Activities
BioFire Diagnostics, LLC 515 Colorow Drive Salt Lake City Utah 84108 USA Facility ID Number: F000086	Design, Manufacture, Installation and Servicing of In Vitro Diagnostic PCR Systems for Detection of Infectious Diseases.
BioFire Diagnostics, LLC 1590 South 5200 West Salt Lake City Utah 84104 USA Facility ID Number: F000086	Distribution Warehouse
BioFire Diagnostics LLC 415 Bearcat Drive Salt Lake City Utah 84115 USA Facility ID Number: F000086	Service
BioFire Diagnostics LLC 650 Komas Drive Salt Lake City Utah 84108 USA Facility ID Number: F000086	Administration, Quality Control.
BioFire Diagnostics, LLC 1001 South 4800 West Salt Lake City Utah 84104 USA Facility ID Number: F000086	Reagent Production.

Original Registration Date: 2018-03-13

Effective Date: 2023-04-04

Expiry Date: 2024-02-18

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This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 680085**

Location

BioFire Diagnostics, LLC  
1201 South 4800 West  
Salt Lake City  
Utah  
84104  
USA  
Facility ID Number: F000086

Registered Activities

Administration (Finance, Marketing, Quality, Purchasing) and  
Final Pouch QC.



Original Registration Date: 2018-03-13

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