

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

The design, manufacture, installation and servicing of in-vitro diagnostic PCR systems for the detection of infectious diseases.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-03-13

Effective Date: 2024-09-09

Expiry Date: 2027-02-18



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 1001 South 4800 West Salt Lake City Utah 84104 USA Facility ID Number: F000086	Reagent Production.
BioFire Diagnostics, LLC 1201 South 4800 West Salt Lake City Utah 84104 USA Facility ID Number: F000086	Administration, Template Control Manufacturing and Final Product QC.

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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
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.