

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:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2017-02-27

Latest Revision Date: 2024-10-23

Effective Date: 2024-02-19

Expiry Date: 2027-02-18

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...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 1590 South 5200 West Salt Lake City Utah 84104 USA	Distribution Warehouse
BioFire Diagnostics LLC 415 Bearcat Drive Salt Lake City Utah 84115 USA	Service
BioFire Diagnostics, LLC 1001 South 4800 West Salt Lake City Utah 84104 USA	Reagent Production
BioFire Diagnostics, LLC 1201 South 4800 West Salt Lake City Utah 84104 USA	Administration, Template Control Manufacturing and Final Product QC

Original Registration Date: 2017-02-27

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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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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