

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

BioFire Defense LLC
79 West 4500 South, Suite 14
Salt Lake City
Utah
84107
USA

Facility ID Number: F004607

Holds Certificate No:

MDSAP 722829

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

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

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

Design, Development, Manufacture, Distribution, and Service of In Vitro Diagnostic PCR Instruments, Software, Reagents, and Test Kits used for Detection of Infectious Diseases.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2021-10-19

Effective Date: 2024-09-02

Expiry Date: 2027-09-01



BSI Group America Inc. is an MDSAP recognised auditing organization

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