

Certificate of Registration

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

This is to certify that:

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

Holds Certificate Number: MD 724361

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, distribution, service and installation of in vitro diagnostic reagents, test kits and systems for nucleic acid detection for diagnosis of infectious diseases.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2021-09-02

Latest Revision Date: 2024-08-30

Effective Date: 2024-09-02

Expiry Date: 2027-09-01

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