



## Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Avioq, Inc 104 T. W. Alexander Drive Research Triangle Park North Carolina 27709 USA

Facility ID Number: F000065

Holds Certificate No:

**MDSAP 672217** 

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

The design, development and manufacture of Immunoassays for Bloodborne Pathogens and Accessories.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-02-15

Effective Date: 2024-02-15

Expiry Date: 2027-02-14

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BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit."

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. 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.

## Certificate No: MDSAP 672217

Location

**Registered Activities** 

Design development and manufacture of immunoassays for bloodborne pathogens and accessories.

Avioq, Inc 104 T. W. Alexander Drive Research Triangle Park North Carolina 27709 USA Facility ID Number: F000065

Avioq, Inc 76 T. W. Alexander Drive Research Triangle Park North Carolina 27709 USA Facility ID Number: F000065 The design, development and manufacture of screening kit HTLV I/II Microelisa System including Corporate Activities.

Original Registration Date: 2018-02-15

Effective Date: 2024-02-15

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Page: 2 of 2

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