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Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4)

No. CE 582807

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

In respect of:

Avioq HTLV-I/II Microelisa System

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV (4), the design of the device conforms to the requirements of the IVDD.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **12 Nov 2012** Date: **20 Jul 2013**

Expiration Date: **11 Nov 2017**

Conditions of Approval
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

...making excellence a habit.™

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL UK. A member of the BSI Group of Companies.

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Supplementary Information to CE 582807

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

Product:

Avioq HTLV-I/II Microelisa 192 Test Kit 500192

Avioq HTLV-I/II Microelisa 576 Test Kit 500576

Avioq HTLV-I/II Microelisa 9600 Test Kit 509600

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

History of Certificate

Date	Reference Number	Action
12 November 2012	10113487	First Issue
27 March 2013	10140550	Addition of product code. Addition of the VERSEIA sampling handling system as part of the ORTHO® Summit System. Change from Tween 20 to Triton X-100 as the non ionic detergent in the Wash Buffer Concentrate used with the assay.
20 July 2013	10143067	Extension of product life to 28 months.

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