By Royal Charter

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV Section 4

No. **CE 582807**

Issued To: **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 of the design dossier relating to the device under the requirements of Council Directive 98/79/EC, Annex IV Section 4, the design of the device conforms to the requirements of 98/79/EC.

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

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2012-11-12** Date: **2017-11-09** Expiry Date: **2022-11-11**

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EC Design-Examination Certificate

Supplementary Information to CE 582807

Issued To:

Avioq, Inc
104 T. W. Alexander Drive
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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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Certificate History

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.
20 April 2015	10152444	Addition of cadaveric blood specimens to sample type.
Current	8853509	Certificate renewal.

First Issued: **2012-11-12** Date: **2017-11-09** Expiry Date: **2022-11-11**

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