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 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2012-11-12** Date: **2022-04-22** Expiry Date: **2025-05-26**

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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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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

First Issued: **2012-11-12** Date: **2022-04-22** Expiry Date: **2025-05-26**

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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.
9 November 2017	8853509	Certificate renewal.
26 February 2019	7942611	Traceable to NB 0086.
Current	3655589	Renewal

First Issued: **2012-11-12** Date: **2022-04-22** Expiry Date: **2025-05-26**

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Supplementary Information to CE 582807 - Non-significant changes approved after the 26th May 2022 as per the Transitional Provisions of IVDR Article 110.3

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

Date: 28 September 2022

Changes Approved:

Date	Reference Number	Action
28 September 2022	3753309	Addition of alternate supplier for key device component: HTLV-I/II Microelisa Strips

Inspiring trust for a more resilient world.

28 September 2022

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

To whom it may concern,

The transitional provisions specified in IVDR Article 110(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26th May 2022.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under IVDR Article 110(3) and as per the guidance provided in MDCG 2022-6. The related IVDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 582807	98/79/EC Annex IV Section 4	3753309	Addition of alternate supplier for key device component: HTLV-I/II Microelisa Strips

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices