Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, Section 3

No. CE 581998

Issued to:

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

In respect of:

The design, development and manufacture of screening test kit HTLV-I/II Microelisa System

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of the IVDD Annex IV.

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: **12 Nov 2012**

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.
For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to IVDD Annex IV (4) is required. Surveillance as referred to in Annex IV(5) is required.

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