

# EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

**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 98/79/EC Annex IV.

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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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.

This certificate was issued electronically and is bound by the conditions of the contract.

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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**Research Triangle Park**  
**North Carolina**  
**27709**  
**USA**

**Subcontractor:**

**Service(s) supplied**

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

**Regulatory Compliance**

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Emergo Europe B.V.  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands

**EU Representative**

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# EC Certificate - Full Quality Assurance Certificate History

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 USA

Date	Reference Number	Action
12 November 2012	7779712	First Issue
23 December 2016	8632524	Addition of subcontractor for regulatory compliance: Avioq, Inc, 76 T. W. Alexander Drive, Research Triangle Park, North Carolina 27709, USA
01 August 2017	8778311	Change of EU representative address.
Current	8853382	Certificate renewal.