

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 antibody screening test kits for HTLV-I/II and of supplemental antibody test kits for HIV 1 and 2

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2012-11-12**

Date: **2019-06-14**

Expiry Date: **2022-11-11**

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Page 1 of 1

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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Date: **2019-06-14**
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104 T. W. Alexander Drive
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North Carolina
27709
USA

Subcontractor:	Service(s) supplied
Avioq, Inc 76 T. W. Alexander Drive Research Triangle Park North Carolina 27709 USA	Regulatory Compliance
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	EU Representative

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: CE 581998
Date: 2019-06-14
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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.
09 November 2017	8853382	Certificate renewal.
26 February 2019	7942611	Traceable to NB 0086.
Current	9721126	Change to scope