

EC Design-Examination Certificate

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

No. **CE 691829**
Issued To: **Avioq, Inc**
104 T. W. Alexander Drive
Research Triangle Park
North Carolina
27709
USA

In respect of:

VioOne™ HIV Profile™ Supplemental Assay

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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-06-17**

Date: **2019-06-17**

Expiry Date: **2024-05-26**

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Supplementary Information to CE 691829

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
700024	VioOne™ HIV Profile™ Supplemental Assay 24-Test Kit (2x96 well plates)	N/A	The VioOne™ HIV Profile™ Supplemental Assay is an enzyme-linked immunosorbent assay (ELISA) for confirmation and differentiation of individual antibodies directed to various gene products of Human Immunodeficiency Virus Type 1 (HIV-1 Group M & Group O) and Type 2 (HIV-2) in human serum or plasma. The VioOne™ HIV Profile™ is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2. It is intended as an additional, more specific test to confirm the presence of antibodies to HIV-1 and HIV-2 for specimens repeatedly reactive in diagnosis or screening procedures, including pediatric patients (ages 2-20). Results of the HIV Profile™ can also be used to distinguish recent from longstanding HIV-1 infection and thus used for HIV-1 incidence estimation.	Annex II list A

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

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

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Certificate History

Date	Reference Number	Action
Current	8935760	First issue. Transfer from another Notified Body

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