EC Certificate
Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV, excluding sections 4 and 6

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 549	aur4ai2008v432f600	2020-10-02	2024-12-03	2006-04-07

This is to certify that the quality system of:

bioLytical Laboratories Inc.
406 - 13251 Delf Place
Richmond, BC V6V 2A2
Canada

has been audited under the requirements of:

Annex IV of Council Directive 98/79/EC, as transposed into Danish law.
The quality system meets the requirements of the directive.
For the placing on the market of List A devices an Annex IV section 4 certificate is required.

The scope of the certification is:

The design/development, manufacture and final inspection of near-patient in-vitro diagnostic medical devices and in-vitro medical devices for self-test used as an aid in the diagnosis of HIV status, according to Annex II, list A

The EC certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the manufacturer does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S.
This EC certificate is issued in accordance with Presafe Denmark A/S' "General terms and conditions" cf. Council Directive 98/79/EC concerning in vitro diagnostic devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits in accordance with the IVDD, Annex IV, section 5.

Presafe Denmark A/S
Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark

Heidi Jørgensen
Authorized person
For Presafe Denmark A/S

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The following products listed in Annex II List A are covered by the certificate:

Product identifier	Product name
90-1015	INSTI HIV-1/HIV-2 Antibody Test
90-1026	48 INSTI HIV-1/HIV-2 Antibody Tests
90-1036	INSTI HIV-1/HIV-2 Test Controls
90-1050 (EN) 90-1056 (Benelux) 90-1057 (GE-EN) 90-1058 (FR-EN) 90-1059 (IT-EN) 90-1060 (ES-PT-EN) 90-1063 (Swiss, GE-FR-IT) 90-1076 (FSND)	INSTI HIV Self Test (no pipette variant, packaged in a box)
90-1041	INSTI HIV Self Test (no pipette variant, packaged in a pouch)
90-1033	INSTI HIV Self Test (with pipette variant, packaged in a box)
90-1045	INSTI HIV Self Test (with pipette variant, packaged in a pouch)
90-1028	INSTI Multiplex HIV-1/2 Syphilis Ab Test

The authorized EC representative:

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands