# EC Design Examination Certificate

Certificate Number: DGM – 548

This is to certify that the quality system of:

## BioLytical Laboratories Inc.

**13351 Commerce Parkway, Suite 1108**
**Richmond, BC V6V 2X7**
**Canada**

have been approved in conformity with the requirements of

## Annex IV, section 4 - Examination of the design of the product

of Council Directive 98/79/EC concerning in vitro diagnostic medical devices as transposed into Danish law.

The certificate covers the following devices:

**Rapid testing 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 Design Examination certificate is valid provided that no substantial changes are made to the approved design that could affect conformity with the essential requirements or the conditions prescribed for use for the product without the approval of Presafe Denmark A/S. The EC-Design Examination certificate is issued in accordance with Presafe Denmark A/S' terms and conditions cf. Council Directive 98/79/EC concerning medical devices as transposed into Danish law. The certificate is based on successful evaluation of the device design.

Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

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|---|---|
| Date of issue: | 2017-08-17 |
| Expires: | 2021-04-14 |
| Initial date of issue: | 2006-04-07 |
| Reference: | aur4ai1708v310f600 |

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

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

**INSTI HIV-1/HIV-2 Antibody Test**

**48 INSTI HIV-1/HIV-2 Antibody Tests**

**INSTI HIV-1/HIV-2 Test Controls**

**INSTI HIV Self Test (no pipette variant, packaged in a box)**

**INSTI HIV Self Test (no pipette variant, packaged in a pouch)**

**INSTI HIV Self Test (with pipette variant, packaged in a box)**

**INSTI HIV Self Test (with pipette variant, packaged in a pouch)**

**INSTI Multiplex HIV-1/HIV-2/Syphilis Antibody Test**

The authorized EC representative:

**Emergo Europe**
**Prinsessegracht 20**
**2514 AP The Hague**
**The Netherlands**

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