

Presafe®



A DNV & NEMKO
COMPANY

EC Certificate

Certificate Number:

DGM – 549

This is to certify that the quality system of:

BioLytical Laboratories Inc.

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

has been approved in conformity with the requirements of

Annex IV Full quality assurance system

of Council Directive 98/79/EC concerning in vitro diagnostic medical devices, as amended and transposed into Danish law, excluding Annex IV, section 4 & 6.

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

This EC certificate is issued in accordance with Presafe Denmark A/S' terms and conditions cf. Council Directive 98/79/EC concerning in vitro diagnostic devices as amended and transposed into Danish law 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 as per the Directive.


Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue: 2017-08-17
Expires: 2019-12-08
Initial date of 2006-04-07
Reference: aur4ai1708v310f600



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

DGM

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The following products listed in Annex II, List A are covered by the certificate and by the EC Design Examination Certificate DGM-548:

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

Certificate number: DGM – 549
Certificate type: EC Certificate

Date of issue: 2017-08-17
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