

Declaration of Conformity

PRODUCT IDENTIFICATION

Product name	Model/number
INSTI HIV SELF TEST	Catalogue No.: 90-1057

MANUFACTURER

Name of company	Address	Representative
bioLytical Laboratories Inc.	13351 Commerce Parkway, Suite 1108 Richmond, BC V6V 2X7 Canada	Hans Croukamp

AUTHORIZED REPRESENTATIVE

Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP, The Hague The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax Europe@emergogroup.com

REGISTRATION INFORMATION

Notified Body and ID #	CE certificate number
Presafe Denmark, 0543 (for HIV-1/HIV-2)	DGM-548 DGM-549

CONFORMITY ASSESSMENT

Device classification	Route to compliance
Class: Annex II List A	Annex IV of IVDD 98/79/EC Council Directive (for HIV-1/HIV-2)

bioLytical Laboratories Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Hans Croukamp

TITLE: Senior Director, Operations

SIGNATURE: _____

DATE: 2018 - APRIL - 24
YYYY-MM-DD