EC Design Examination Certificate

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

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 944	artIVD4a2105v461f600	2021-07-07	2024-05-26	2021-07-07

This is to certify that the design dossier relating to the devices manufactured by:

bioLytical Laboratories Inc.
406 – 13251 Delf Place
Richmond, BC V6V 2A2
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:

In vitro diagnostic medical devices for rapid HCV testing according to Annex II, list A

The Design Examination certificate is valid provided that no 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' "General terms and conditions" cf. Council Directive 98/79/EC concerning medical devices. The certificate is based on successful evaluation of the device design dossier in accordance with the IVDD, Annex IV, section 4.

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

Zeshaan Sayd
Authorized person
For Presafe Denmark A/S

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The following devices from Annex II, List A, are covered by the certificate:

Product identifier	Product name
90-1062	INSTI HCV Antibody Test Single
90-1105	INSTI HCV Antibody Test 50 tests
90-1067	INSTI HCV test Controls

The authorized EC representative:

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands