Declaration of Conformity

PRODUCT IDENTIFICATION

Product name	Model/number
INSTI® HCV Antibody Test	Catalogue No.: 90-1062

MANUFACTURER

Name of company	Address	Representative
Biolytical Laboratories Inc.	406-13251 Delf Place, Richmond, BC V6V 2A2, Canada	Rosanne Lee Kwen

AUTHORIZED REPRESENTATIVE

Name of company	Address	
Emergo Europe B.V.	Prinsessegracht 20 2514 AP, The Hague, The Netherlands	Tel: (31) (0) 70 345-8570 Email: EmergoEurope@ul.com

REGISTRATION INFORMATION

Notified Body and ID #	CE certificate number
Presafe Denmark, 0543	DGM-944 and DGM-549

CONFORMITY ASSESSMENT

Device classification	Route to compliance
Class: Annex II List A	Annex IV of IVDD 98/79/EC Council Directive

Biolytical Laboratories Inc. declares that the above-mentioned products comply with the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices and Directive 98/79/EC as transposed in the national laws of the Members States.

COMPANY REPRESENTATIVE: Rosanne Lee Kwen

TITLE: QA Manager

SIGNATURE: R. Lee Kwen

DATE: 2021-11-17
YYYY-MM-DD