EC DECLARATION OF CONFORMITY

According to Directive 98/79/EC, Annex III, on *in vitro* Diagnostic Medical Devices

Manufacturer:	BTNX Inc., 570 Hood Rd. #23, Markham, Ontario, L3R 4G7 Canada
Product Name:	Rapid Response® COVID-19 Antigen Saliva Test Kit
Product Code(s):	COV-2PEN, COV-2PEN1, COV-2PEN20
EDMA / GMDN:	15.70.90.08
GMDN:	64912
EDMA Description:	Coronavirus RT & POC
Risk Classification:	Other
Authorized EC Rep.:	MDSS GmbH, Schiffgraben 41, 30175 Hannover, Germany

We, the manufacturer, declare under our sole responsibility that the above-mentioned products meet all the provision of the council directive 98/79/EC for *in vitro* Diagnostic Medical Devices that apply to it. This self-declaration is according to Annex III (excluding Section 6) of the Directive.

Markham, Ontario, Canada, as of 2021-03-25 for BTNX Inc.,

Christine Qian

RA&QA Manager
BTNX Inc., 570 Hood Road, Unit 23
Markham, ON, L3R 4G7, CANADA

BTNX Inc. is a medical device manufacturer certified under:
ISO 13485:2016
by Intertek Testing Services Canada

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