DECLARATION OF CONFORMITY

MANUFACTURER : **PCL, Inc.**
#701,99, Digital-ro 9-gil Geumcheon-gu, Seoul, 08510, Republic of Korea

EUROPEAN REPRESENTATIVE : **MT Promedt Consulting GmbH**
Altenhofstr. 80
D-66386 St. Ingbert, Germany

PRODUCT : PCL COVID19 Ag Gold Saliva

CATALOG NO. : COV04S

CLASSIFICATION : General IVDs (Neither listed in the Annex II of the Directive 98/79/EC, nor self-testing device)

EDMA code/ Term : 15 70 90 90 00 (Other Other Virology Rapid Tests)

CONFORMITY ASSESSMENT ROUTE : EC Declaration of Conformity (Self-Declaration)

We here with declare that the above mentioned products meet the provisions of the council directive 98/79/EC for In Vitro diagnostic medical device. All supporting documentation is retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

STANDARDS APPLIED :
EN ISO 13485:2016, EN 13612:2002, EN ISO 13641:2002, EN ISO 14971:2012, EN ISO 15223-1:2016, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 23640:2015

START DATE OF CE MARKING: November 9, 2020

PLACE and DATE OF ISSUE : Seoul, Republic of Korea/ November 19, 2020

SIGNATURE :

Soyeun Kim, Ph.D.

CE