PCL

DECLARATION OF CONFORMITY

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

EUROPEAN REPRESENTATIVE EC REP : **MT Promedt Consulting GmbH**
Altenhofstraße 80, 66386 St. Ingbert,
Germany

PRODUCT : PCL COVID19 Ag Rapid FIA

CATALOG NO. : COV05

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

EDMA CODE : 15 70 90 90 00 (Other Virology Rapid Test)

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.

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: July 17, 2020

PLACE and DATE OF ISSUE: Seoul, Republic of Korea / July 17, 2020

SIGNATURE :

Soyoun Kim, Ph.D.

CE