

## 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

: EC Declaration of Conformity (Self-Declaration)

ASSESSMENT ROUTE

***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 9, 2020

**SIGNATURE**

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Soyoun Kim, Ph.D.

