CE

Declaration of Conformity

According to Annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device we, **Humasis Co., Ltd.** declare under our sole responsibility that the following IVD.

Manufacturer:	**Humasis Co., Ltd.** Rm. 114,502,504,604,604-1,B03-1,B03-2, 88, Jeonpa-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14042, Republic of Korea
European Authorized Representative:	**MT Promedt Consulting GmbH** Altenhofstrasse 80 D-66386 St.Ingbert, Germany
Product:	***Humasis COVID-19 Ag Test***
Cat. No.	**ACOVA-7025**

meet the provisions of the Council Directive 98/79/EC concerning in vitro diagnostic medical devices which apply to them.

Conformity Assessment Route:	**Annex III section 2 to 5**
Classification:	**Professional use IVD** (EDMA Code 15. 04. 80. 90. 00)

The following standards were used to prove the products conformity with the essential requirements of the above directive : ISO standard (EN ISO 13485:2016)

Standards Applied:	EN ISO 18113-1:2011, EN ISO 18113-2:2011 EN 13612:2002/AC:2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012, EN 62366:2008, EN ISO 17511:2003, EN ISO 15223-1:2016, EN ISO 13485:2016
Start of CE-Marking:	**2020-08-21**
Place, Date of Issue:	**Anyang-si, Korea, 2020-08-21**

Signatory established within the EU who has been empowered to enter into commitments on our behalf:

C.E.O. / Chung Hak, CHA