



Ministry of Food and Drug Safety

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Certificate of Free Sales

No. of Certificate : 20210060977
Exporting(certifying) country : Republic of Korea
Importing(requesting) country :

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following product(s) is(are) permitted to be freely sold in domestic and overseas markets.

○ Applicant (=Product-license holder)

(This certificate shall not be issued to others than the product-license holder)

- Name : Humasis Co., Ltd.

- Address : #114, #502, #504, #604, #604-1, #B03-1, #B03-2, 88, Jeonpa-ro, Dongan-gu, Anyang-si,
Gyeonggi-do, 14042, Republic of Korea

- Registered No : Manufacturer IVD-3001

No. and date of product-license, comments	Classification
IVD-21-321 / APR. 23. 2021	IVD reagent for infectious disease, immunological method [3]

※ Attached, if necessary (approved product information)

- ☒ Model(Export Name) ☐ Medical Device Accessories ☐ Manufacturer/Legal manufacturer
☐ Combined/Composite medical device

Issued date : MAY. 06. 2021 (Certificate No.20210060977)

Certified by

정현철

Director
Director for Novel Products Approval
Ministry of Food and Drug Safety

Attachment

Product License No. : IVD-21-321 (MAY. 03, 2021)

Classification : IVD reagent for infectious disease, immunological method

Model(Export Name)

디아트리스트 코로나19 항원 홈 테스트 (Celltrion DiaTrust™ COVID-19 Ag Home Test)

