

Ministry of Food and Drug Safety

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Certificate of Free Sales

¬No. of Certificate

20200112860

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 overseas market only.

O 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,

ess · Gyeonggi-do,14042, Republic of Korea

- Registered No: Manufacturer IVD-3001

No. and date of product-license, comments	Classification
IVD-20-789 / SEP. 08. 2020	IVD reagents for infectious disease marker(Diagnosis of Sexually transmitted disease, Legally designated infectious pathogens other than 'high risk pathogens', Infectious agents with moderate infectivity), immunological method [3]

* Attached, if necessary (approved product information)

■ Model(Export Name)

☐ Medical Device Accessaries

☐ Manufacturer/Legal manufacturer

☐ Combined/Composite medical device

Issued date: SEP. 11. 2020 (Certificate No.20200112860)

Certified by

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

Attachment

Product License No.:

IVD-20-789

(SEP. 08. 2020)

Classification:

IVD reagents for infectious disease marker(Diagnosis of Sexually transmitted disease, Legally designated infectious pathogens other than 'high risk pathogens', Infectious agents with moderate

infectivity), immunological method

Model(Export Name)

· Humasis COVID-19 Ag Test

