187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu, Cheongju-si, Chungcheongbuk-do, Korea, 28159
Tel: +82-43-719-2396, Fax: +82-43-719-2330

No. of Certificate: 20200075793 Date: 2020/06/24

## **Certificate of Free Sales**

Exporting(certifying) country : Repu

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 item(s) is(are) permitted to be freely sold in overseas markets.

Manufacturer (Registered No.: IVD-6895)

## Plexense

#1-1301, 1302, 1303, 16-4 Dongbaekjungang-ro 16beon-gil, Giheung-gu, Yongin-si Gyeonggi-do

| Product-License No. | Classification   |
|---------------------|--|
| IVD-20-486          | 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] |
|                     | Product Name : ACCEL ELISA COVID-19 kit  |

★Attached : List of Product Classification and Model

Jught Lee

Director of High-Tech Medical Devices Division Department of Medical Device Evaluation National Institute of Food and Drug Safety Evaluation

Ministry of Food and Drug Safety

Osong Health Technology Administration Complex, 187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu,

Cheongju-si, Chungcheongbuk-do, Korea, 28159 Tel: +82-43-719-2396, Fax: +82-43-719-2330

No. of Certificate: 20200075793 Date: 2020/06/24

(2020/06/17)Product License No.: IVD-20-486

IVD reagents for infectious disease marker(Diagnosis of Sexually transmitted disease, Classification:

Legally designated infectious pathogens other than 'high risk pathogens', Infectious

agents with moderate infectivity), immunological method

Model(Export Name)

· AE301