



Osong Health Technology Administration Complex,
187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu,
Cheongju-si, Chungcheongbuk-do, Korea, 28159
Tel: +82-43-719-2346, Fax: +82-43-719-1000

No. of Certificate : 20200027308

Date : 2020/03/16

Certificate of Free Sales

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

Manufacturer (Registered No. : 4413)

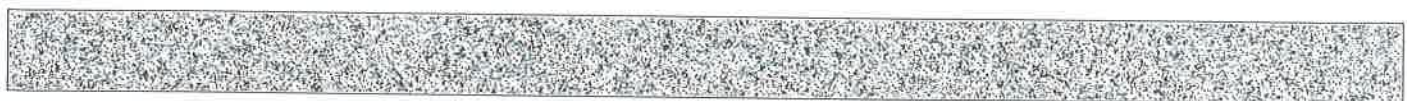
SD Biosensor, Inc.

74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do

Product-License No.	Classification
20-177	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 : List of Product Classification and Model

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



※ This certificate is issued on the Internet, you can check whether to forge or modify in homepage(emed.mfds.go.kr). Furthermore, You can also check it by barcode exploiting document check program for scanner

Osong Health Technology Administration Complex,
187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu,
Cheongju-si, Chungcheongbuk-do, Korea, 28159
Tel: +82-43-719-2346, Fax: +82-43-719-1000

No. of Certificate : 20200027308

Date : 2020/03/16

Product License No. : 20-177 (2020/03/11)

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)

STANDARD™ Q COVID-19 IgM/IgG Duo Test(Q-NCOV-01D)