

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 : 20200033210 Date : 2020/03/26

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
20-217	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: STANDARD™ Q COVID-19 Ag Test

₩Attached : List of Product Classification and Mode!

hugh-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

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Product License No.: 20-217 (2020/03/25)

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 Classification #

Model(Export Name)

[∞] STANDARD[™] Q COVID-19 Ag Test(Q-NCOV-01G)

