



Certificate

No. Q5 075369 0056 Rev. 01

Holder of Certificate: **SD Biosensor, Inc.**
C-4th&5th, 16, Deogyong-daero
1556beon-gil, Yeongtong-gu
Suwon-si, Gyeonggi-do 16690
REPUBLIC OF KOREA

Certification Mark:



Scope of Certificate: **Design, Development, Production and Distribution of Blood Glucose Monitoring System, Lipid Test System, G6PD Test System, Hemoglobin A1c Test System, In Vitro Diagnostic Medical Device for Immunochemistry, In Vitro Diagnostic Kits for ELISA, Molecular Diagnostic reagent kit used in the detection of infectious diseases, DNA/ RNA extraction kit and service of respective instruments**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 075369 0056 Rev. 01

Report No.: 74961292_CN

Valid from: 2022-03-26
Valid until: 2025-03-25

Date, 2022-03-25

Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

SD Biosensor, Inc.
C-4th&5th, 16, Deogyong-daero, 1556beon-gil, Yeongtong-gu,
Suwon-si, Gyeonggi-do 16690, REPUBLIC OF KOREA

Design, Development, Production and Distribution of Blood
Glucose Monitoring System, Lipid Test System, G6PD Test
System, Hemoglobin A1c Test System, In Vitro Diagnostic Medical
Device for Immunochromatography, In Vitro Diagnostic Kits for
ELISA, Molecular Diagnostic reagent kit used in the detection of
infectious diseases, DNA/ RNA extraction kit and service of
respective instruments

SD Biosensor, Inc.
74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do 28161, REPUBLIC OF KOREA

Production and Distribution of Blood Glucose Monitoring System,
Lipid Test System, G6PD Test System, Hemoglobin A1c Test
System, In Vitro Diagnostic Medical Device for
Immunochromatography, In Vitro Diagnostic Kits for ELISA,
Molecular Diagnostic reagent kit used in the detection of infectious
diseases, DNA/ RNA extraction kit and service of respective
instruments

SD Biosensor, Inc.
4-18, Dongbu-daero, Jinwi-myeon, Pyeongtaek-si, Gyeonggi-do
17712, REPUBLIC OF KOREA

Quality control and service of instrument

SD Biosensor, Inc.
688, Dureungyuri-ro, Ochang-eup, Cheongwon-gu, Cheongju-si,
Chungcheongbuk-do 28107, REPUBLIC OF KOREA

Warehouse and Distribution of Blood Glucose Monitoring System,
Lipid Test System, G6PD Test System, Hemoglobin A1c Test
System, In-Vitro Diagnostic Medical Device for
Immunochromatography, In Vitro Diagnostic Kits for ELISA,
Molecular Diagnostic reagent kit used in the detection of infectious
diseases and DNA/RNA extraction kit

SD Biosensor, Inc.
A-402, 16, Deogyong-daero, 1556beon-gil, Yeongtong-gu,
Suwon-si, Gyeonggi-do 16690, REPUBLIC OF KOREA

Production and Quality control of Molecular Diagnostic reagent kit
used in the detection of infectious diseases and DNA/RNA
extraction kit

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SD Biosensor, Inc.
C-1st&3rd, D-1st&2nd&3rd, 745-46, Yeoncheong-ro, Bugang-
myeon, Sejong-si 30071, REPUBLIC OF KOREA

Warehouse and Quality control of raw materials of Blood Glucose Monitoring System, Lipid Test System, G6PD Test System, Hemoglobin A1c Test System, In Vitro Diagnostic Medical Device for Immunochemistry, In Vitro Diagnostic Kits for ELISA, Molecular Diagnostic reagent kit used in the detection of infectious diseases and DNA/RNA extraction kit.

SD Biosensor, Inc.
221, Simogoecheon-ro, Hyeondo-myeon, Seowon-gu, Cheongju-si, Chungcheongbuk-do 28211, REPUBLIC OF KOREA

Warehouse of raw materials and product of Blood Glucose Monitoring System, Lipid Test System, G6PD Test System, Hemoglobin A1c Test System, In Vitro Diagnostic Medical Device for Immunochemistry, In Vitro Diagnostic Kits for ELISA, Molecular Diagnostic reagent kit used in the detection of infectious diseases and DNA/RNA extraction kit.

SD Biosensor, Inc.
18-29, Cheomdangieop 2-ro, Sandong-eup, Gumi-si, Gyeongsangbuk-do 39174, REPUBLIC OF KOREA

Production and Quality control of Molecular Diagnostic reagent kit used in the detection of infectious diseases and DNA/RNA extraction kit

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