



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 075369 0058 Rev. 01

Manufacturer:

SD Biosensor, Inc.

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

**Product Category(ies): Products for determination of infection markers
and products for self testing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. 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:V1_075369_0058_Rev.01

Report no.: 713210456

Valid from: 2021-06-04

Valid until: 2024-05-26

Date, 2021-06-04

Christoph Dicks
Head of Certification/Notified Body



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Model(s):

**Screening test for Hepatitis C marker
Blood glucose measuring system for self testing, self test
systems for Lipid Test and HbA1c Test, and self test
for detection of SARS-CoV-2 antigen**

see as specified in section Parameters

Facility(ies):

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

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

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



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No. V1 075369 0058 Rev. 01

Parameters:

Products according to Annex II List A Devices:

Products for determination of infection markers for HCV as specified in the corresponding Design Examination Certificates.

Products for self testing:

1. Blood Glucose Monitoring System

1) Blood Glucose Meter / Blood Glucose Test Strip / STANDARD Glucose Check Strip / STANDARD Glucose Control Solution

Model name

- SD CHECK GOLD
- SD CodeFree / STANDARD CodeFree Plus / STANDARD CodeFree Plus BT / STANDARD CodeFree Plus NFC
- STANDARD Mentor / STANDARD Link0.3
- STANDARD Mentor BT / STANDARD Mentor NFC / STANDARD Link0.3 NFC/ Pic GlucoTest Diary

2) Blood Glucose Meter / Blood Glucose Test Strip / STANDARD Glucose Check Strip / STANDARD GlucoNavii Control Solution

Model name

- STANDARD GlucoNavii GDH
- STANDARD GlucoNavii NFC

3) Blood Glucose Meter / Blood Glucose Test Strip / Pic Glucose Check Strip / Pic Control Solution

Model name

- Pic GlucoTest

4) Blood Glucose Meter / Blood Glucose Test Strip / QuantLife Neo Glucose Check Strip / QuantLife Neo Control Solution

Model name

- QuantLife Neo

5) Blood Glucose Meter / Blood Glucose Test Strip / STANDARD GlucoNavii Control Solution

Model name

- GlucoNavii PRO
- GlucoNavii PRO BT



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Products for self testing:

2. Lipid Test System (with/without glucose measurement)

1) Analyzer / Lipid Test Strip- Lipid Profile / Lipid Test Strip- Total Cholesterol / Lipid Test Strip- HDL / Lipid Test Strip- Triglycerides / Lipid Test Strip- TC-HDL / STANDARD Lipid Check Strip / SDB Lipid Control Solution

For glucose measurement

Blood Glucose Test Strip / STANDARD Glucose Check Strip / STANDARD Glucose Control Solution

Model name

- STANDARD LipidoCare

2) Analyzer / Lipid Test Strip- Lipid Profile / Lipid Test Strip- Total Cholesterol / Lipid Test Strip- HDL / Lipid Test Strip- Triglycerides / Lipid Test Strip- TC-HDL / STANDARD Lipid Check Strip / SDB Lipid Control Solution

For glucose measurement

Blood Glucose Test Strip / STANDARD Glucose Check Strip / STANDARD GlucoNavii Control Solution

Model name

- STANDARD LipidoCare Plus

3) Analyzer / Lipid Test Strip- Lipid Profile / Lipid Test Strip- Total Cholesterol / Lipid Test Strip- HDL / Lipid Test Strip- Triglycerides / Lipid Test Strip- TC-HDL / STANDARD Lipid Check Strip / SDB Lipid Control Solution

For glucose measurement

Blood Glucose Test Strip / STANDARD Glucose Check Strip / Lumiratek Lipid Glucose Control Solution

Model name

- Lumiratek Lipid

3. HbA1c Test System

1) Analyzer / Test Kit / SDB HbA1c Check Strip / SDB HbA1c Control

Model name

- STANDARD A1cCare

4. SARS-CoV-2 Antigen Self Test

1) Test Strip / Buffer

Model name

- SARS-CoV-2 Antigen Self Test Nasal