



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 18 04 75369 046**

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



**EC-Representative:** **MT Promedt Consulting GmbH**  
Altenhofstrasse 80  
66386 St. Ingbert  
GERMANY

**Product Category(ies):** **Blood glucose measuring systems for self testing and Self test systems for Lipid Test and HbA1c Test**

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. See also notes overleaf.

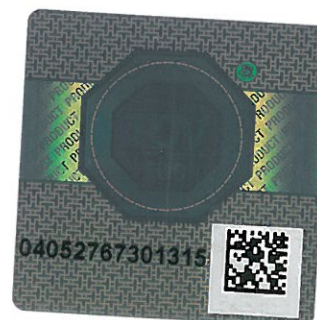
**Report No.:** 74950656

**Valid from:** 2018-04-09

**Valid until:** 2021-03-01

**Date,** 2018-04-09

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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### 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 18 04 75369 046

**Model(s):** see attachment

**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



Product Service

Attachment for Certificate no V1 18 04 75369 046  
valid from 2018-04-09

Supplement 001 dated 2018-04-09 (project no. 74956056)

### 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

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 Gluco Test

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

Model name

- QuantLife Neo

### 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 / Lumiratek Lipid Check Strip / Lumiratek Lipid Control Solution

*For glucose measurement*

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

Model name

- Lumiratek Lipid

### 3. HbA1c Test System

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

Model name

- STANDARD A1cCare

Munich, MHS-CRT, 2018-04-09

Stefan Preiß