



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-245.10.07



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 090700 0032 Rev. 00**

**Manufacturer:**

**i-SENS, Inc.**

43, Banpo-daero 28-gil, Seocho-gu  
Seoul 06646  
REPUBLIC OF KOREA

**Product Category(ies): Blood glucose measuring systems for self testing  
Self tests for Blood Ketone and/or Blood glucose Monitoring**

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 090700 0032 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:V1_090700_0032_Rev_00)

**Report no.:**

74958714

**Valid from:**

2020-12-04

**Valid until:**

2024-04-15

**Date,**

2020-12-04

Christoph Dicks  
Head of Certification/Notified Body



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**No. V1 090700 0032 Rev. 00**

**Model(s):** see page 3

**Facility(ies):**

- i-SENS, Inc.  
4th floor, 39-36, Nonhyeon-ro 46beon-gil, Namdong-gu, Incheon  
21655, REPUBLIC OF KOREA
- i-SENS, Inc.  
27-36, Gwangun-ro, Nowon-gu, Seoul 01891, REPUBLIC OF KOREA
- i-SENS Wonju Factory  
94-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do  
26365, REPUBLIC OF KOREA
- i-SENS, Inc.  
27-34, Gwangun-ro, Nowon-gu, Seoul 01891, REPUBLIC OF KOREA
- i-SENS Songdo Factory  
12, Harmony-ro 275beon-gil, Yeonsu-gu, Incheon 22014,  
REPUBLIC OF KOREA
- i-SENS, Inc.  
43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, REPUBLIC OF KOREA
- i-SENS Wonju Factory 2  
200, Gieopdosi-ro, Jijeong-myeon, Wonju-si, Gangwon-do 26354,  
REPUBLIC OF KOREA



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**Blood Glucose Monitoring System,**

- **Blood Glucose Meter**
- **Blood Glucose Test Strip**
- **Glucose Control Solution**

## Model

GM01AAA / GM01AAB  
GM01BAA / GM01BAB / GM01BAC  
GM01HAA  
GM01WAA  
GM505B  
GM505C  
GM505CAB  
GM505EA/GM505EB

GM505FA  
GM505FAB  
GM505H

GM505IA/GM505IB/GM505IC  
GM505NA/GM505NB/GM505NC  
GM505PA/GM505PB/GM505PC  
GM505PAE/GM505PBE/GM505PCE  
GM505PAB/GM505PBB/GM505PCB  
GM505PAF/GM505PBF/GM505PCF  
GM505PAC  
IGM 0002 G4

GM505K/GM505KBA  
GM505KAB/GM505KBB  
GM505Mx (x=A to E)  
GM505MxB (x=A to E)  
GM505QA  
GM505RA

GM505RAE/GM505RAC

GM505TAA/GM505TBA  
GM505UAA  
GM505VAA  
GM505WAA/GM505WBA  
GM505WAB/GM505WBB

## Brand

CareSens N Premier  
NoCoding1 Plus / TEE2 Plus  
CareSens PRO  
CareSens N Eco / AUTOCHECK GluCare  
CareSens  
CareSens II  
Injex Sens II  
CareSens POP  
Injex Sens POP  
e-CheKer  
Dana Cheker  
CareFast  
CareSens N/SAFE-Life

CareSens N NFC  
Injex Sens N  
MAXIMA  
Soul/NoCoding1/  
AccuSure Soul/TEE2  
COOL  
COOL  
AUTO-CHEK/AutoCode  
ACURA PLUS/  
alphacheck  
professional/MEDstar  
alphacheck professional,AccuSure Soul+/  
alphacheck professional NFC

CareSens PRO  
CareSens N Voice  
CareSens N Mini  
CareSens N POP



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|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| GM505LEB                          | CareSens N LINK                               |
| GM505PAD/GM505PBD/GM505PCD        | CareSens N/CareSens N Plus                    |
| GM505WAC/GM505WBC                 | CareSens N POP/CareSens N POP Plus            |
| GM505PAG/GM505PBG/GM505PCG        | CareSens N NFC/CareSens N NFC Plus            |
| GM505UAB                          | CareSens N Voice/CareSens N Voice Plus        |
| GM01JAA/GM01JAB                   | CareSens II Plus BGMS/Injex Sens II Plus BGMS |
| GM01IAC                           | GlucoWay BGMS                                 |
| GM01IAA                           | GlucoWay Plus BGMS/Nipro Premier S            |
| GM01IAB                           | Nipro Premier alpha/GlucoMen Day METER        |
| GM01NAC                           | Zing                                          |
| GM01NBC                           | CareSens S Fit                                |
| GM01NBE                           | CareSens S Fit BT                             |
| GM01NCC                           | ALLY                                          |
| Mendor Discreet                   | Mendor Discreet                               |
| GM01YAA/GM01YAB                   | CareSens H Beat/CareSens H Beat BT            |
| GM02AAA                           | mylife Aveo                                   |
| GM01LAA                           | DANA Glucose NFC                              |
| GM01ZAA, GM01ZBA/GM01ZAB, GM01ZBB | COOL Plus/COOL Plus BT                        |

## Blood $\beta$ -Ketone Monitoring System

- Blood  $\beta$ -Ketone Meter
- Blood  $\beta$ -Ketone Test Strip
- $\beta$ -Ketone Control Solution

### Model

GM01GAA

### Brand

KetoSens

## Blood Glucose / Blood $\beta$ -Ketone Monitoring System

- Blood Glucose / Blood  $\beta$ -Ketone Meter
- Blood Glucose Test Strip
- Blood  $\beta$ -Ketone Test Strip
- Glucose Control Solution
- $\beta$ -Ketone Control Solution

### Model

GM01HAC  
GM02BAA

### Brand

CareSens Dual  
GlucoMen Day METER 2K