ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

**Report no.:** 74958714

**Valid from:** 2020-12-04
**Valid until:** 2024-04-15

**Date,** 2020-12-04

Christoph Dicks
Head of Certification/Notified Body


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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Heruntergeladen von Gast (IP 216.73.217.12) am 09.11.2026 um 13:45 Uhr · sana.swiss

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

**Blood Glucose Monitoring System,**
**- Blood Glucose Meter**
**- Blood Glucose Test Strip**
**- Glucose Control Solution**

| Model | Brand |
|---|---|
| GM01AAA / GM01AAB | CareSens N Premier |
| GM01BAA / GM01BAB / GM01BAC | NoCoding1 Plus / TEE2 Plus |
| GM01HAA | CareSens PRO |
| GM01WAA | CareSens N Eco / AUTOCHECK GluCare |
| GM505B | CareSens |
| GM505C | CareSens II |
| GM505CAB | Injex Sens II |
| GM505EA/GM505EB | CareSens POP<br>Injex Sens POP |
| GM505FA | e-CheKer |
| GM505FAB | Dana Cheker |
| GM505H | CareFast |
| GM505IA/GM505IB/GM505IC | CareSens N/SAFE-Life |
| GM505NA/GM505NB/GM505NC | |
| GM505PA/GM505PB/GM505PC | |
| GM505PAE/GM505PBE/GM505PCE | |
| GM505PAB/GM505PBB/GM505PCB | |
| GM505PAF/GM505PBF/GM505PCF | CareSens N NFC |
| GM505PAC | Injex Sens N |
| IGM 0002 G4 | MAXIMA |
| GM505K/GM505KBA | Soul/NoCoding1/ |
| GM505KAB/GM505KBB | AccuSure Soul/TEE2 |
| GM505Mx (x=A to E) | COOL |
| GM505MxB (x=A to E) | COOL |
| GM505QA | AUTO-CHEK/AutoCode |
| GM505RA | ACURA PLUS/ |
| GM505RAE/GM505RAC | alphacheck professional/MEDstar alphacheck professional,AccuSure Soul+/ alphacheck professional NFC |
| GM505TAA/GM505TBA | CareSens PRO |
| GM505UAA | CareSens N Voice |
| GM505VAA | CareSens N Mini |
| GM505WAA/GM505WBA | CareSens N POP |
| GM505WAB/GM505WBB | |


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## No. V1 090700 0032 Rev. 00

| | |
|---|---|
| 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 ß-Ketone Monitoring System**
**- Blood ß-Ketone Meter**
**- Blood ß-Ketone Test Strip**
**- ß-Ketone Control Solution**

| **Model** | **Brand** |
|---|---|
| GM01GAA | KetoSens |

**Blood Glucose / Blood ß-Ketone Monitoring System**
**- Blood Glucose / Blood ß-Ketone Meter**
**- Blood Glucose Test Strip**
**- Blood ß-Ketone Test Strip**
**- Glucose Control Solution**
**- ß-Ketone Control Solution**

| **Model** | **Brand** |
|---|---|
| GM01HAC | CareSens Dual |
| GM02BAA | GlucoMen Day METER 2K |


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