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 216.73.217.10) am 23.11.2026 um 07:08 Uhr · sana.swiss

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

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

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

Heruntergeladen von Gast (IP 216.73.217.10) am 23.11.2026 um 07:08 Uhr · sana.swiss

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

TÜV SÜD 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

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 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	

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 216.73.217.10) am 23.11.2026 um 07:08 Uhr · sana.swiss

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

TÜV SÜD 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

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

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 216.73.217.10) am 23.11.2026 um 07:08 Uhr · sana.swiss