



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



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



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

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



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 β -Ketone Monitoring System

- Blood β -Ketone Meter
- Blood β -Ketone Test Strip
- β -Ketone Control Solution

Model

GM01GAA

Brand

KetoSens

Blood Glucose / Blood β -Ketone Monitoring System

- Blood Glucose / Blood β -Ketone Meter
- Blood Glucose Test Strip
- Blood β -Ketone Test Strip
- Glucose Control Solution
- β -Ketone Control Solution

Model

GM01HAC
GM02BAA

Brand

CareSens Dual
GlucoMen Day METER 2K