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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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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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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