



Certificate

No. Q5 090700 0031 Rev. 02

Holder of Certificate: **i-SENS, Inc.**
43, Banpo-daero 28-gil, Seocho-gu
Seoul 06646
REPUBLIC OF KOREA

Certification Mark:



Scope of Certificate: Design, Development, Production and Distribution of Blood Glucose Monitoring System, Continuous Glucose Monitoring System, Medical device software for continuous glucose monitoring system, Electrolyte Analyzer, Blood Ketone Monitoring System, IVD Reagent kit and analyzer using Enzymatic, Immunoturbidimetry and Chemical Assay for detection of clinical chemistry parameters, GAS Analyzer and Lancing Device, Prothrombin Time / INR Monitoring System, IVD Reagent Kit and analyzer for immunochemistry.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 090700 0031 Rev. 02

Report No.: 74964320, 74964320_CN

Valid from: 2023-04-01
Valid until: 2026-03-31

Date, 2023-03-29

Christoph Dicks
Head of Certification/Notified Body

Certificate

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

i-SENS, Inc.

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

Design and Development of Blood Glucose Monitoring System, Continuous Glucose Monitoring System, Medical device software for continuous glucose monitoring system, Electrolyte cartridge & Analyzer, Blood Ketone Monitoring System, IVD Reagent kit and analyzer using Enzymatic, Immunoturbidimetry and Chemical Assay for detection of clinical chemistry parameters, GAS cartridge & analyzer and Lancing Device, Prothrombin Time / INR Monitoring System, IVD Reagent Kit and analyzer for immunochemistry.

i-SENS Wonju Factory

94-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do 26365, REPUBLIC OF KOREA

Production and Distribution of Blood Glucose Monitoring System, Blood Ketone Monitoring System and Lancing Device

i-SENS Songdo Factory

12, Harmony-ro 275beon-gil, Yeonsu-gu, Incheon 22014, REPUBLIC OF KOREA

Production and Distribution of Blood Glucose Monitoring System, Continuous Glucose Monitoring System, IVD Reagent kit using Enzymatic, Immunoturbidimetry and Chemical Assay for detection of clinical chemistry parameters, IVD Reagent Kit for immunochemistry.

i-SENS Wonju Factory 2

200, Gieopdosi-ro, Jijeong-myeon, Wonju-si, Gangwon-do 26354, REPUBLIC OF KOREA

Production and Distribution of Blood Glucose Monitoring System

i-SENS, Inc.

4th floor, 39-36, Nonhyeon-ro 46beon-gil, Namdong-gu, Incheon 21655, REPUBLIC OF KOREA

Production and Distribution of Blood Glucose Monitoring System and Analyzer using Enzymatic, Immunoturbidimetry and Chemical Assay for detection of clinical chemistry parameters and Prothrombin Time / INR Monitoring System,

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Analyzer for immunochemistry, Electrolyte and GAS Analyzer,
Continuous Glucose Monitoring System

i-SENS, Inc.

27-36, Gwangun-ro, Nowon-gu, Seoul 01891, REPUBLIC OF
KOREA

Production and Distribution of Electrolyte Analyzer and GAS
Analyzer (reagent part)

i-SENS, Inc.

27-34, Gwangun-ro, Nowon-gu, Seoul 01891, REPUBLIC OF
KOREA

Production and Distribution of Electrolyte Analyzer and GAS
Analyzer (reagent part)

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