



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 090700 0031 Rev. 07

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

Certification Mark:



Scope of Certificate:

Design and Development, Production, and Distribution of In Vitro Diagnostic Instruments, Reagents and Kits used in the area of:

- the management of the Blood Glucose / Blood β -Ketone including home use, Near Patient / Point of Care Testing
- the detection and management of blood gases, electrolytes, metabolites, cardiac markers, immune status, endocrine disorders, coagulation disorders including Near Patient / Point of Care Testing

Design and Development, Production and Distribution of Sterile Continuous Glucose Monitoring System, and Medical Device Software for continuous glucose monitoring system Servicing of In Vitro Diagnostic Instruments used in the area of :

- management of the Blood Glucose / Blood β -Ketone including home use, Near Patient / Point of Care Testing
- the detection and management of blood gases, electrolytes, metabolites, cardiac markers, immune status, endocrine disorders, coagulation disorders including Near Patient / Point of Care Testing

Servicing of Medical Device Software for continuous glucose monitoring system Production and Distribution of Lancing Devices
The Provision of Manufacturing Service for In Vitro Diagnostic Reagents for Clinical Chemistry - Lactate Measuring System

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, Certification, Validation and Verification Regulations 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. 07

Report No.: 74973274

Valid from: 2026-04-01
Valid until: 2029-03-31

Date, 2026-02-23

Christoph Dicks
Head of Certification/Notified Body



Product Service

Certificate

No. Q5 090700 0031 Rev. 07

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **i-SENS, Inc.**
43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, REPUBLIC OF KOREA

Design and Development of In Vitro Diagnostic Instruments, Reagents and Kits used in the area of:

- the management of the Blood Glucose / Blood β -Ketone including home use, Near Patient / Point of Care Testing
- the detection and management of blood gases, electrolytes, metabolites, cardiac markers, immune status, endocrine disorders, coagulation disorders including Near Patient / Point of Care Testing

Servicing of In Vitro Diagnostic Instruments used in the area of :

- management of the Blood Glucose / Blood β -Ketone including home use, Near Patient / Point of Care Testing
- the detection and management of blood gases, electrolytes, metabolites, cardiac markers, immune status, endocrine disorders, coagulation disorders including Near Patient / Point of Care Testing

Design and Development of Sterile Continuous Glucose Monitoring System

Design and Development, Production, Distribution and Servicing of Medical Device Software for Continuous Glucose Monitoring System

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

Production and Distribution of In Vitro Diagnostic Reagents and Kits used in the area of the management of the Blood Glucose / Blood β -Ketone including home use, Near Patient / Point of Care Testing

i-SENS Songdo Factory
12, Harmony-ro 275beon-gil, Yeonsu-gu, Incheon 22014, REPUBLIC OF KOREA

Production and Distribution of In Vitro Diagnostic Reagents and Kits used in the area of:

- the management of the Blood Glucose including home use, Near Patient / Point of Care Testing
- the detection and management of blood gases, electrolytes, metabolites, cardiac markers, immune status, endocrine disorders,



Product Service

Certificate

No. Q5 090700 0031 Rev. 07

coagulation disorders including Near Patient / Point of Care Testing
Production and Distribution of Sterile Continuous Glucose Monitoring System
The Provision of Manufacturing Service for In Vitro Diagnostic Reagents for Clinical Chemistry - Lactate Measuring System

i-SENS Songdo Factory 2

43-10, Incheon tower-daero 25beon-gil, Yeonsu-gu, Incheon
22013, REPUBLIC OF KOREA

Production and Distribution of In Vitro Diagnostic Instruments, Reagents and Kits used in the area of:

- the management of the Blood Glucose / Blood β -Ketone including home use, Near Patient / Point of Care Testing
- the detection and management of blood gases, electrolytes, metabolites, cardiac markers, immune status, endocrine disorders, coagulation disorders including Near Patient / Point of Care Testing

Servicing of In Vitro Diagnostic Instruments used in the area of :

- management of the Blood Glucose / Blood β -Ketone including home use, Near Patient / Point of Care Testing
- the detection and management of blood gases, electrolytes, metabolites, cardiac markers, immune status, endocrine disorders, coagulation disorders including Near Patient / Point of Care Testing

Production and Distribution of Lancing Devices

Production and Distribution of Sterile Continuous Glucose Monitoring System

./.