

CERTIFICATE

인증번호: SAC-0932300

주식회사 아이센스

- 본사 : 서울특별시 서초구 반포대로28길 43 (Zip code : 06646)
 - 원주공장 : 강원특별자치도 원주시 문막읍 동화공단로 94-1 (Zip code : 26365)
 - 송도공장 : 인천광역시 연수구 하모니로275번길 12 (Zip code : 22014)
 - 송도2공장 : 인천광역시 연수구 인천타워대로25번길 43-10 (Zip code : 22013)
- 한국품질재단은 위 조직의 경영시스템이 아래에 기재된 표준 요구사항에 적합함을 인증함

ISO 45001:2018 / KS Q ISO 45001:2018

인증범위

- 본사 : 1. 다음 분야에서 사용되는 체외진단 장비, 시약 및 체외진단 키트의 설계 및 개발:
 - 혈당 및 베타케톤 관리(자가 검사, 현장 진단 포함)
- 혈액 가스, 전해질, 대사산물, 심장 표지자, 면역 질환, 내분비 질환, 혈액 응고 질환의 검출 및 관리(현장 진단 포함)
- 2. 다음 분야에서 사용되는 체외진단 장비의 서비스(수리):
 - 혈당 및 베타케톤 관리(자가 검사, 현장 진단 포함)
- 혈액 가스, 전해질, 대사산물, 심장 표지자, 면역 질환, 내분비 질환, 혈액 응고 질환의 검출 및 관리(현장 진단 포함)
- 3. 멸균 연속혈당측정시스템의 설계 및 개발
- 4. 연속혈당측정시스템 전용 MDSW(의료기기소프트웨어)의 설계, 개발, 생산 및 유통
- 원주공장 : 다음 분야에서 사용되는 체외진단 시약 및 체외진단 키트의 생산 및 유통:
 - 혈당 및 베타케톤 관리(자가 검사, 현장 진단 포함)
- 송도공장 : 1. 다음 분야에서 사용되는 체외진단 시약 및 체외진단 키트의 생산 및 유통:
 - 혈당 관리(자가 검사, 현장 진단 포함)
- 혈액 가스, 전해질, 대사산물, 심장 표지자, 면역 질환, 내분비 질환, 혈액 응고 질환의 검출 및 관리(현장 진단 포함)
- 2. 멸균 연속혈당측정시스템의 생산 및 유통
- 3. 임상 화학용 체외진단 시약의 제조 서비스 제공
 - 젯산 측정 시스템
- 송도2공장 : 1. 다음 분야에서 사용되는 체외진단 장비, 시약 및 체외진단 키트의 생산 및 유통:
 - 혈당 관리(자가 검사, 현장 진단 포함)
- 혈액 가스, 전해질, 대사산물, 심장 표지자, 면역 질환, 내분비 질환, 혈액 응고 질환의 검출 및 관리(현장 진단 포함)
- 2. 다음 분야에서 사용되는 체외진단 장비의 서비스(수리):
 - 혈당 및 베타케톤 관리(자가 검사, 현장 진단 포함)
- 혈액 가스, 전해질, 대사산물, 심장 표지자, 면역 질환, 내분비 질환, 혈액 응고 질환의 검출 및 관리(현장 진단 포함)
- 3. 채혈기의 생산 및 유통
- 4. 멸균 연속혈당측정시스템의 전자부품 생산

인증등록일 2025-08-24

최초인증일 2022-07-14

인증만료일 2028-08-23

개정발행일 2025-12-15



KAB-OC-01



Ji Young Song

Ji Young Song
President & CEO of KfQ



QR코드를 스캔하여(KAB) 업체명을 검색하시면 인증 유효성을 확인할 수 있습니다.

한국품질재단

www.kfq.or.kr

Q Tower, 78 Samjeon-ro, Songpa-gu, Seoul, 05606, Republic of Korea





CERTIFICATE

Certificate Number: SAC-0932300

i-SENS, Inc.

- i-SENS, Inc. : 43 Banpo-daero 28-gil, Seocho-gu, Seoul, Korea (Zip code : 06646)
- Wonju Factory : 94-1 Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Korea (Zip code : 26365)
 - Songdo Factory : 12 Harmony-ro 275beon-gil, Yeonsu-gu, Incheon, Korea (Zip code : 22014)
- Songdo Factory 2 : 43-10 Incheon tower-daero 25beon-gil, Yeonsu-gu, Incheon, Korea (Zip code : 22013)

Korean Foundation for Quality certifies that The Management System of the above organization has been audited and has complied with the requirements of the following standard.

ISO 45001:2018 / KS Q ISO 45001:2018

Scope of certification

- i-SENS, Inc. : 1. 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
 - 2. 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
 - 3. Design and Development of Sterile Continuous Glucose Monitoring System
 - 4. Design and Development, Production, Distribution and Servicing of Medical Device Software for Continuous Glucose Monitoring System
- Wonju Factory : 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
 - Songdo Factory : 1. 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, coagulation disorders including Near Patient / Point of Care Testing
 - 2. Production and Distribution of Sterile Continuous Glucose Monitoring System
 - 3. The Provision of Manufacturing Service for In Vitro Diagnostic Reagents for Clinical Chemistry
 - Lactate Measuring System
- Songdo Factory 2 : 1. 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
 - 2. 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
 - 3. Production and Distribution of Lancing Devices
 - 4. Production of electronic components for Sterile Continuous Glucose Monitoring System

Registration Date 2025-08-24

Expiration Date 2028-08-23

Initial Certification Date 2022-07-14

Revision Date 2025-12-15



KAB-OC-01



Ji Young Song

Ji Young Song
President & CEO of KfQ



KfQ has been accredited in respect of ISO 45001 covered by the KAB (Accreditation Certificate Number KAB-OC-01)

Korean Foundation For Quality www.kfq.or.kr

Q Tower, 78 Samjeon-ro, Songpa-gu, Seoul, 05606, Republic of Korea



Certificate

KFQ has issued an IQNET recognized certificate that the organization:

i-SENS, Inc.

- i-SENS, Inc. : 43, Banpo-daero 28-gil, Seocho-gu, Seoul, Korea (Zip code : 06646)
- Wonju Factory : 94-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Korea (Zip code : 26365)
 - Songdo Factory : 12, Harmony-ro 275beon-gil, Yeonsu-gu, Incheon, Korea (Zip code : 22014)
- Songdo Factory 2 : 43-10 Incheon tower-daero 25beon-gil, Yeonsu-gu, Incheon, Korea (Zip code : 22013)

has implemented and maintains a
Occupational Health and Safety Management System
for the following scope

- i-SENS, Inc. : 1. 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
 - 2. 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
 - 3. Design and Development of Sterile Continuous Glucose Monitoring System
 - 4. Design and Development, Production, Distribution and Servicing of Medical Device Software for Continuous Glucose Monitoring System
- Wonju Factory : 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
- Songdo Factory : 1. 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, coagulation disorders including Near Patient / Point of Care Testing
 - 2. Production and Distribution of Sterile Continuous Glucose Monitoring System
 - 3. The Provision of Manufacturing Service for In Vitro Diagnostic Reagents for Clinical Chemistry
 - Lactate Measuring System
- Songdo Factory 2 : 1. 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
 - 2. 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
 - 3. Production and Distribution of Lancing Devices
 - 4. Production of electronic components for Sterile Continuous Glucose Monitoring System

which fulfils the requirements of the following standard

ISO 45001:2018/KS | ISO 45001:2018

Issued on : 2025-12-15

Expires on : 2028-08-23

Registration Number : KR - 0932300



Alex Stoichitoiu

Alex Stoichitoiu
President of IQNET

Ji Young Song

Ji Young Song
President & CEO of KFQ



This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

IQNET Members*:

AENOR Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic
Cro Cert Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC**
 Colombia **ICS** Bosnia and Herzegovina **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece
MSZT Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE** Mexico **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia **SIRIM**
QAS International Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Türkiye **YUQS** Serbia

* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com