ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 090700 0039 Rev. 01

Manufacturer:

i-SENS, Inc.
43, Banpo-daero 28-gil, Seocho-gu
Seoul 06646
REPUBLIC OF KOREA

SRN Manufacturer - KR-MF-000009173

Authorized Representative:

MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7, 66386 St. Ingbert, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 090700 0039 Rev. 01

Report No.: 74969769

Preceding Certificate No.: G10 090700 0039 Rev. 00

Valid from: 2025-01-10
Valid until: 2029-02-27

Date of Initial Issuance: 2024-02-28

Issue date: 2025-01-10

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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No. G10 090700 0039 Rev. 01

Classification:	Class IIb
Device Group:	Z12040115 - BLOOD SUGAR MONITORING SYSTEMS
Intended Purpose:	Indicated for continuous monitoring of glucose levels via measurement of glucose in the interstitial fluid in persons with diabetes mellitus aged 18 years and older.
The validity of this certificate depends on conditions and/or is limited to the following:	None

Revision History:

Rev.	Dated	Report	Description
00	2024-02-28	74966711	Initial issuance
01	2025-01-10	74969769	Amended: Other Supplemented: Change to the approved type(s)/device(s)

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