

EU Declaration of Conformity

Legal Manufacturer: Address:	i-SENS, Inc. 43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Republic of Korea
SRN (Single Registration Number):	KR-MF-000009173
EU Authorised Representative: Address:	Medical Technology Promedt Consulting GmbH Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany
EAR SRN (Single Registration Number):	DE-AR-000000085

Product Name(s):	CareSens Air	CareSens Air app
Model No(s):	CGM-ST-002	HS-MA-11 (Mobile Android) HS-MI-11 (Mobile iOS)
Software Version	N/A	1.2.x (Mobile)
Basic UDI-DI:	8806712CGM001PS	8806712CGMUA001Y4
EMDN code:	Z12040115 BLOOD SUGAR MONITORING SYSTEMS	Z1204011599 BLOOD SUGAR MONITORING SYSTEMS - OTHER
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.	

This Declaration of Conformity is issued under the sole responsibility of i-SENS, Inc.
We hereby declare that the above-mentioned product is in conformity with all applicable provision of the following legislative acts:

- Medical Devices Regulation (EU) 2017/745
- Radio Equipment Directive 2014/53/EU
- Restriction of Hazardous Substances Directive 2011/65/EU

All supporting documentation is retained under the premises of the manufacturer.

Medical Devices Regulation (EU) 2017/745


Classification:	Class IIb - Rule 8, Rule 11
Notified Body:	TUV SUD Product Service GmbH (NB no. 0123)
EC Certificate:	G10 090700 0039 Rev. 01
Start of CE Marking:	2024-02-28
Conformity Assessment Procedure:	Annex IX Chapter I and III
Common Specifications:	N/A

Radio Equipment Directive 2014/53/EU

Harmonised Standards:	EN 300 328 V2.2.2 EN 301 489-1 V2.2.3 EN 301 489-17 V3.2.4
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Restriction of Hazardous Substances Directive 2011/65/EU

Harmonised Standards:	EN IEC 63000:2018
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Signature:	Signed for and on behalf of i-SENS  <hr/> Hanwool Kim RA Team Leader & PRRC
Place, Date of issue:	Seoul, 2025-03-24