

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:	CareSens N
Model No:	Refer to Appendix 1
Basic UDI-DI&EMDN code:	Refer to Appendix 1
Start of CE Marking:	2023-12-20


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:

- In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746
- Restriction of Hazardous Substances Directive 2011/65/EU

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

In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746	
Classification:	Class C
Notified Body:	TÜV SÜD Product Service GmbH (NB no. 0123)
EU Certificate:	TBD
Conformity Assessment Procedure:	Annex IX of the Regulation (EU) 2017/746

Restriction of Hazardous Substances Directive 2011/65/EU	
Harmonised Standards:	EN IEC 63000:2018

Signature:	Signed for and on behalf of i-SENS  <hr style="width: 20%; margin-left: auto; margin-right: 0;"/> Joon Ho Jung RA Team Leader & PRRC
Place, Date of issue:	Seoul, 2023-12-20

Declaration of Conformity, Appendix 1**List of Products**

Product	Model No.	EMDN code	Basic UDI-DI
CareSens N Blood Glucose Monitoring System	-	DIABETES MONITORING: W02010601	8806712BGMS002SV
CareSens N Blood Glucose Meter	GM505PAD GM505PBD	BLOOD GLUCOSE METERS: W0201060102	8806712BGMME001VM
CareSens N Blood Glucose Test Strips	GSA02	GLUCOSE TEST STRIPS: W0101060101	8806712BGMTS00137
CareSens Glucose Control Solutions	GCA01	BLOOD TEST STRIPS CONTROLS: W010106010801	8806712BGMCS001V9