

Declaration of Conformity

MANUFACTURER:	i-SENS, Inc. 43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Korea
MANUFACTURING FACILITY:	i-SENS Wonju Factory 94-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do 26365, Korea
EUROPEAN REPRESENTATIVE:	Medical Technology Promedt Consulting GmbH Altenhofstrasse 80, 66386 St. Ingbert, Germany
PRODUCT:	Blood Glucose Monitoring System
Model:	See List of Products
CLASSIFICATION:	List B according to Annex II of IVDD
CONFORMITY ASSESSMENT ROUTE:	IVDD ANNEX IV without section 4 and 6 Applied

We herewith declare that the above-mentioned products meet the provision of the Council Directive 98/79/EC for in vitro diagnostic medical devices under the exclusive responsibility of manufacturer. All supporting documentation is retained at the premises of the manufacturer.

STANDARD APPLIED:	See List of Applied Standards
NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GmbH Ridlerstraße 65, 80339 Munich, Germany (Notified Body Number 0123)
CERTIFICATE:	V1 090700 0032 Rev. 01 (Valid until: 2024-04-15)
START OF CE-MARKING:	See List of Products
PLACE, DATE OF ISSUE:	Seoul, 2022-04-13
SIGNATURE:	



**CEO
Geun Sig Cha**

List of Products

Brand Name/Model

CareSens N Premier Blood Glucose Monitoring System, Model GM01AAA/GM01AAB/GM01AAC

- CareSens N Premier Blood Glucose Meter, EDMA: 21 06 01
- CareSens N Blood Glucose Test Strips, EDMA: 11 70 01 01 00
- CareSens Glucose Control Solutions, EDMA: 11 50 90 90 00

*** Start of CE Marking: 2015-08-03 (GM01AAA/GM01AAB), 2022-04-13 (GM01AAC)**

List of Applied Standards

Document Number	Title of Document
EN ISO 13485: 2016	Medical devices - Quality management systems -Requirements for regulatory purposes
EN ISO 18113-1: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-4: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 4: In vitro diagnostic reagents for self-testing
EN ISO 18113-5: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 5: In vitro diagnostic instruments for self-testing
EN ISO 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 13532: 2002	General requirements for in vitro diagnostic medical devices for self-testing
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640: 2015	In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
ISO 14971: 2019	Medical devices - Application of risk management to medical devices
EN ISO 15197: 2015	In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
EN ISO 17511: 2003	In vitro diagnostic medical devices - Measurements of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials
EN 61010-1: 2010 Third edition	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1 : General requirements
EN 61010-2-101: 2017	Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61326-1: 2013	Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements
EN 61326-2-6: 2013	Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment
EN 60068-2-64: 2008	Environmental testing. Tests. Test Fh. Vibration, broadband random and guidance
EN 62304: 2006+AMD1:2015	Medical device software - Software life cycle processes
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN 301 489-1: 2017	Electromagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 1: Common Technical Requirements
EN 301 489-17: 2017	Electromagnetic Compatibility (EMC) Standard for Radio Equipment Part 17: Specific Conditions for Broadband data Transmission Systems