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 under our sole responsibility of the manufacturer that the above-mentioned products meet the provision of the Council Directive 98/79/EC for in vitro diagnostic medical devices. 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** **Ridlerstraβe 65, 80339 Munich, Germany** **(Notified Body Number 0123)**
CERTIFICATE:	**V1 090700 0028 Rev. 00**
START OF CE-MARKING:	**See List of Products**
PLACE, DATE OF ISSUE:	**Seoul, 2019-09-16**

SIGNATURE:

CEO
Geun Sig Cha

Declaration of Conformity, Attached 1

List of Products

Brand Name/Model

CareSens Dual Blood Glucose / Blood β-Ketone Monitoring System,
Model GM01HAC

- CareSens Dual Blood Glucose / Blood β-Ketone Meter, EDMA: 21 06 01 / 21 06 11
- CareSens PRO Blood Glucose Test Strips, EDMA: 11 70 01 01 00
- KetoSens Blood β-Ketone Test Strips, EDMA: 11 70 01 90 00
- CareSens PRO Glucose Control Solutions, EDMA: 11 50 90 90 00
- KetoSens β-Ketone Control Solutions, EDMA: 11 50 90 90 00

*** Start of CE Marking: 2016-04-04**

Declaration of Conformity, Attached 2

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
EN ISO 14971: 2012	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: 2002	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	Medical device software - Software life cycle processes
EN 62366: 2008	Medical devices - Application of usability engineering to medical devices