

EU Declaration of Conformity

Legal Manufacturer:	i-SENS, Inc.	
Address:	43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Republic of Korea	
SRN (Single Registration Number):	KR-MF-000009173	
EU Authorised Representative:	Medical Technology Promedt Consulting GmbH	
Address:	Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany	
EAR SRN (Single Registration Number):	DE-AR-00000085	

Product Name:	alphacheck CareSens Dual	
Model No:	Refer to Appendix 1	
Basic UDI-DI&EMDN code:	Refer to Appendix 1	
Start of CE Marking:	2023-11-10	

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

•Radio Equipment Directive 2014/53/EU

•Restriction of Hazardous Substances Directive 2011/65/EU

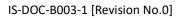
All supporting documentation is retained under the premises of the manufacturer.

In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746			
Classification:	Class C		
Notified Body:	TÜV SÜD Product Service GmbH (NB no. 0123)		
EU Certificate:	V74 090700 0038 Rev.00		
Conformity Assessment Procedure:	Annex IX of the Regulation (EU) 2017/746		

Radio Equipment Directive 2014/53/EU		
Harmonised Standards:	EN 300 328 V2.2.2	
Conformity Route:	Module A	

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

	Signed for and on behalf of i-SENS
Signature:	They
	Joon Ho Jung
	RA Team Leader & PRRC
Place, Date of issue:	Seoul, 2023-11-10





Declaration of Conformity, Appendix 1

List of Products

Product	Model no.	EMDN code	Basic UDI-DI
alphacheck CareSens Dual Blood Glucose and β-Ketone Monitoring System	-	DIABETES MONITORING: W02010601	8806712BGMS/BKMS001YX
alphacheck CareSens Dual Blood Glucose and β-Ketone Meter	GM01HAC	VARIOUS DIABETES MONITORING INSTRUMENTS - OTHER: W020106019099	8806712BGM/BKMME001LZ
alphacheck CareSens PRO Blood Glucose Test Strips	GSB02	GLUCOSE TEST STRIPS: W0101060101	8806712BGMTS00239
alphacheck KetoSens Blood β-Ketone Test Strips	KSD03	KETONE TEST STRIPS (B HYDROXYBUTYRATE TEST STRIPS): W0101060110	8806712BKMTS0015B
alphacheck CareSens PRO Glucose Control Solutions	GCB02	BLOOD TEST STRIPS CONTROLS: W010106010801	8806712BGMCS001V9
alphacheck KetoSens β- Ketone Control Solutions	KCD03	BLOOD TEST STRIPS CONTROLS W010106010801	8806712BKMCS001XD