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:	**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

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

Heruntergeladen von Gast (IP 216.73.217.12) am 09.11.2026 um 10:47 Uhr · sana.swiss

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

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