

# EU Declaration of Conformity

<b>Legal Manufacturer:</b> Address:	<b>i-SENS, Inc.</b> 43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Republic of Korea
<b>SRN (Single Registration Number):</b>	<b>KR-MF-000009173</b>
<b>EU Authorised Representative:</b> Address:	<b>Medical Technology Promedt Consulting GmbH</b> Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany
<b>EAR SRN (Single Registration Number):</b>	<b>DE-AR-000000085</b>

<b>Product Name [Trade name]:</b>	<b>alphacheck professional NFC</b>
<b>Model No.:</b>	<b>Refer to Appendix 1</b>
<b>Basic UDI-DI&amp;EMDN code:</b>	<b>Refer to Appendix 1</b>
<b>Intended Purpose</b>	<b>Refer to Appendix 2</b>

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.

<b>In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746</b>	
Classification:	Class C, Rule 4a
Notified Body:	TÜV SÜD Product Service GmbH (NB no. 0123)
EU QMS Certificate:	V10 090700 0045 Rev.00
Start of CE Marking:	2024-06-07
EU Certificate:	V74 090700 0046 Rev. 01
Conformity Assessment Procedure:	Annex IX of the Regulation (EU) 2017/746
Common Specifications:	N/A

<b>Restriction of Hazardous Substances Directive 2014/53/EU</b>	
Harmonised Standards:	EN 300 330 v2.1.1

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

<b>Signature:</b>	Signed for and on behalf of i-SENS    Hanwool Kim RA Team Leader & PRRC
<b>Place, Date of issue:</b>	Seoul, 2025-06-09

**Declaration of Conformity, Appendix 1**

## List of Products

Product list [Product name]	Model No.	EMDN code	Basic UDI-DI
alphacheck professional NFC Blood Glucose Monitoring System	-	DIABETES MONITORING : W02010601	8806712BGMS004SZ
alphacheck professional NFC Blood Glucose Meter	GM505RAC	BLOOD GLUCOSE METERS : W0201060102	8806712BGMME004VT
alphacheck professional Blood Glucose Test Strips	GSA07	GLUCOSE TEST STRIPS : W0101060101	8806712BGMTS0043D
alphacheck professional Glucose Control Solutions	GCA07	BLOOD TEST STRIPS CONTROLS: W010106010801	8806712BGMCS004VF

**Declaration of Conformity, Appendix 2**

## Intended Purpose

<b>alphacheck professional NFC Blood Glucose Monitoring System</b>
The alphacheck professional NFC Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use). The system is intended for self-testing as an aid in monitoring the effectiveness of diabetes control for individuals with diabetes mellitus or prediabetes to quantitatively measure glucose in fresh capillary whole blood from the fingertip. The system shall not be used for the diagnosis of or screening for diabetes.
<b>alphacheck professional NFC Blood Glucose Meter</b>
The alphacheck professional NFC Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use). The system is intended for self-testing as an aid in monitoring the effectiveness of diabetes control for individuals with diabetes mellitus or prediabetes to quantitatively measure glucose in fresh capillary whole blood from the fingertip. The system shall not be used for the diagnosis of or screening for diabetes.
<b>alphacheck professional Blood Glucose Test Strips</b>
The alphacheck professional Blood Glucose Test Strips are for use with the alphacheck professional NFC Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood from the fingertip.
<b>alphacheck professional Glucose Control Solutions</b>
The alphacheck professional Glucose Control Solutions are assayed quality control materials for use with the alphacheck professional NFC Blood Glucose Monitoring System to check that the meter and test strips are working together properly and that the test is performing correctly.