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Product Service

# EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX, Chapter II, Section 4, 5.1
(Class C and B Devices for self-testing and near patient testing)

## No. V74 090700 0038 Rev. 00

**Manufacturer:**

**i-SENS, Inc.**
43, Banpo-daero 28-gil, Seocho-gu
Seoul 06646
REPUBLIC OF KOREA

SRN Manufacturer - KR-MF-000009173

**Authorized Representative:**

MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7, 66386 St. Ingbert, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the Technical Documentation are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX, Chapter II, Section 4, 5.1 of this regulation with a positive result.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX Chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V74 090700 0038 Rev. 00

**Report No.:** 74965928-01

**Valid from:** 2023-11-10
**Valid until:** 2028-11-09

Marta Carnielli
Head of Certification IVD

**Issue date:** 2023-11-10


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## No. V74 090700 0038 Rev. 00

| | |
|---|---|
| **Classification:** | Class C |
| **Device Group:** | W02010601 - DIABETES MONITORING |
| **Basic UDI-DI:** | 8806712BGMS/BKMS001YX |
| **Intended Purpose:** | The CareSens Dual Blood Glucose and β-Ketone 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 and β-ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the fingertip. In the clinical and hospital setting, venous, arterial, and neonatal whole blood may be used to measure blood glucose and venous whole blood may also be used to measure blood β-ketone when drawn by trained healthcare professionals. The system shall not be used for the diagnosis of or screening for diabetes or for the diagnosis of diabetic ketoacidosis. |
| **Device(s):** | [CareSens Dual Blood Glucose and beta-Ketone Monitoring System]<br>Ref. No.<br>GM01HAC-A-1010, GM01HAC-A-1111, GM01HAC-A-1112, GM01HAC-A-1121, GM01HAC-A-1211, GM01HAC-A-2111, GM01HAC-A-2112, GM01HAC-A-2121, GM01HAC-A-2122, GM01HAH-A-1111, GM01HAH-A-1112, GM01HAH-A-2111, GM01HAH-A-2112, GM01HAH-A-2121 |

| | |
|---|---|
| **Classification:** | Class C |
| **Device Group:** | W020106019099 - VARIOUS DIABETES MONITORING INSTRUMENTS - OTHER |
| **Basic UDI-DI:** | 8806712BGM/BKMME001LZ |
| **Intended Purpose:** | The CareSens Dual Blood Glucose and β-Ketone 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 and β-ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the fingertip. In the clinical and hospital setting, venous, arterial, and neonatal whole blood may be used to measure blood glucose and venous whole blood may also be used to measure blood β-ketone when drawn by trained healthcare professionals. The system shall not be used for the diagnosis of or screening for diabetes or for the diagnosis of diabetic ketoacidosis. |
| **Device(s):** | [CareSens Dual Blood Glucose and beta-Ketone Meter]<br>Model No. GM01HAC, GM01HAH<br>Ref. No.<br>GM01HAC-A-1000, GM01HAC-A-2000, GM01HAH-A-1000, GM01HAH-A-2000 |


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Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX, Chapter II, Section 4, 5.1
(Class C and B Devices for self-testing and near patient testing)

## No. V74 090700 0038 Rev. 00

| | |
|---|---|
| **Classification:** | Class C |
| **Device Group:** | W0101060101 - GLUCOSE TEST STRIPS |
| **Basic UDI-DI:** | 8806712BGMTS00239 |
| **Intended Purpose:** | The CareSens PRO Blood Glucose Test Strips are for use with the compatible meters to quantitatively measure glucose in fresh capillary whole blood from the fingertip.<br>In the clinical and hospital setting, venous, arterial, and neonatal whole blood may be used to measure blood glucose when drawn by trained healthcare professionals. |
| **Device(s):** | [CareSens PRO Blood Glucose Test Strips]<br>Model No. GSB01<br>Ref. No.<br>GSB01-1251, GSB01-1501, GSB01-1252, GSB01-1502, GSB01-2010, GSB01-2025, GSB01-2050, GSB01-2100 |

| | |
|---|---|
| **Classification:** | Class C |
| **Device Group:** | W0101060110 - KETONE TEST STRIPS (B-HYDROXYBUTYRATE TEST STRIPS) |
| **Basic UDI-DI:** | 8806712BKMTS0015B |
| **Intended Purpose:** | The KetoSens Blood β-Ketone Test Strips are for use with the compatible meters to quantitatively measure β-ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the fingertip.<br>In the clinical and hospital setting, venous whole blood may be used to measure blood β-ketone when drawn by trained healthcare professionals. |
| **Device(s):** | [KetoSens Blood beta-Ketone Test Strips]<br>Model No. KSD01<br>Ref. No.<br>KSD01-2010, KSD01-2050 |

| | |
|---|---|
| **Classification:** | Class C |
| **Device Group:** | W010106010801 - BLOOD TEST STRIPS CONTROLS |
| **Basic UDI-DI:** | 8806712BGMCS001V9 |
| **Intended Purpose:** | The CareSens PRO Glucose Control Solutions are assayed quality control materials for use with the compatible test systems to check that the meter and test strips are working together properly and that the test is performing correctly. |
| **Device(s):** | [CareSens PRO Glucose Control Solutions]<br>Model No. GCB01<br>Ref. No.<br>GCB01-2101, GCB01-2010 |


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## No. V74 090700 0038 Rev. 00

| | |
|---|---|
| **Classification:** | Class C |
| **Device Group:** | W010106010801 - BLOOD TEST STRIPS CONTROLS |
| **Basic UDI-DI:** | 8806712BKMCS001XD |
| **Intended Purpose:** | The KetoSens β-Ketone Control Solutions are assayed quality control materials for use with the compatible test systems to check that the meter and test strips are working together properly and that the test is performing correctly. |
| **Device(s):** | [KetoSens beta-Ketone Control Solutions]<br>Model No. KCD01<br>Ref. No.<br>KCD01-5110, KCD01-5001 |

| | |
|---|---|
| **Classification:** | Class C |
| **Device Group:** | W02010601 - DIABETES MONITORING |
| **Basic UDI-DI:** | 8806712BGMS/BKMS001YX |
| **Intended Purpose:** | The alphacheck CareSens Dual Blood Glucose and β-Ketone 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 and β-ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the fingertip. In the clinical and hospital setting, venous, arterial, and neonatal whole blood may be used to measure blood glucose and venous whole blood may also be used to measure blood β-ketone when drawn by trained healthcare professionals. The system shall not be used for the diagnosis of or screening for diabetes or for the diagnosis of diabetic ketoacidosis. |
| **Device(s):** | [alphacheck CareSens Dual Blood Glucose and beta-Ketone Monitoring System]<br>Ref. No.<br>01100310, 01100315 |


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## No. V74 090700 0038 Rev. 00

| | |
|---|---|
| **Classification:** | Class C |
| **Device Group:** | W020106019099 - VARIOUS DIABETES MONITORING INSTRUMENTS - OTHER |
| **Basic UDI-DI:** | 8806712BGM/BKMME001LZ |
| **Intended Purpose:** | The alphacheck CareSens Dual Blood Glucose and β-Ketone 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 and β-ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the fingertip. In the clinical and hospital setting, venous, arterial, and neonatal whole blood may be used to measure blood glucose and venous whole blood may also be used to measure blood β-ketone when drawn by trained healthcare professionals. The system shall not be used for the diagnosis of or screening for diabetes or for the diagnosis of diabetic ketoacidosis. |
| **Device(s):** | [alphacheck CareSens Dual Blood Glucose and beta-Ketone Meter]<br>Model No. GM01HAC<br>Ref. No.<br>01100311, 01100316 |

| | |
|---|---|
| **Classification:** | Class C |
| **Device Group:** | W0101060101 - GLUCOSE TEST STRIPS |
| **Basic UDI-DI:** | 8806712BGMTS00239 |
| **Intended Purpose:** | The alphacheck CareSens PRO Blood Glucose Test Strips are for use with the alphacheck CareSens Dual Blood Glucose and β-Ketone Meter to quantitatively measure glucose in fresh capillary whole blood from the fingertip.<br>In the clinical and hospital setting, venous, arterial, and neonatal whole blood may be used to measure blood glucose when drawn by trained healthcare professionals. |
| **Device(s):** | [alphacheck CareSens PRO Blood Glucose Test Strips]<br>Model No. GSB02<br>Ref. No.<br>00100320 |


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## No. V74 090700 0038 Rev. 00

| | |
|---|---|
| **Classification:** | Class C |
| **Device Group:** | W0101060110 - KETONE TEST STRIPS (B-HYDROXYBUTYRATE TEST STRIPS) |
| **Basic UDI-DI:** | 8806712BKMTS0015B |
| **Intended Purpose:** | The alphacheck KetoSens Blood β-Ketone Test Strips are for use with the alphacheck CareSens Dual Blood Glucose and β-Ketone Meter to quantitatively measure β-ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the fingertip.<br>In the clinical and hospital setting, venous whole blood may be used to measure blood β-ketone when drawn by trained healthcare professionals. |
| **Device(s):** | [alphacheck KetoSens Blood beta-Ketone Test Strips]<br>Model No. KSD03<br>Ref. No.<br>00100325 |

| | |
|---|---|
| **Classification:** | Class C |
| **Device Group:** | W010106010801 - BLOOD TEST STRIPS CONTROLS |
| **Basic UDI-DI:** | 8806712BGMCS001V9 |
| **Intended Purpose:** | The alphacheck CareSens PRO Glucose Control Solutions are assayed quality control materials for use with the alphacheck CareSens Dual Blood Glucose and β-Ketone Monitoring System to check that the meter and test strips are working together properly and that the test is performing correctly. |
| **Device(s):** | [alphacheck CareSens PRO Glucose Control Solutions]<br>Model No. GCB02<br>Ref. No.<br>01100330 |

| | |
|---|---|
| **Classification:** | Class C |
| **Device Group:** | W010106010801 - BLOOD TEST STRIPS CONTROLS |
| **Basic UDI-DI:** | 8806712BKMCS001XD |
| **Intended Purpose:** | The alphacheck KetoSens β-Ketone Control Solutions are assayed quality control materials for use with the alphacheck CareSens Dual Blood Glucose and β-Ketone Monitoring System to check that the meter and test strips are working together properly and that the test is performing correctly. |
| **Device(s):** | [alphacheck KetoSens beta-Ketone Control Solutions]<br>Model No. KCD03<br>Ref. No.<br>01100335 |


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## No. V74 090700 0038 Rev. 00

**The validity of this certificate depends on conditions and/or is limited to the following:** -

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2023-11-10 | 74965928-01 | Initial issuance |


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