# *Declaration of Conformity*

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| **MANUFACTURER:** | **i-SENS, Inc.**<br>**43, Banpo-daero 28-gil, Seocho-gu,**<br>**Seoul 06646, Korea** |
| **MANUFACTURING FACILITY:** | **i-SENS Wonju Factory**<br>**94-1, Donghwagongdan-ro, Munmak-eup,**<br>**Wonju-si, Gangwon-do 26365, Korea** |
| **EUROPEAN REPRESENTATIVE:** | **Medical Technology Promedt Consulting GmbH**<br>**Altenhofstrasse 80,**<br>**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.**

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| **STANDARD APPLIED:** | **See List of Applied Standards** |
| **NOTIFIED BODY:** | **TÜV SÜD PRODUCT SERVICE GmbH**<br>**Ridlerstraβe 65, 80339 Munich, Germany**<br>**(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**<br>**Geun Sig Cha** |