# DECLARATION OF CONFORMITY

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| **Name and Address of the Manufacturer** | Changsha Sinocare Inc.<br>265 Guyuan Road, Hi-Tech Zone, Changsha, 410205, Hunan Province, P.R. China |
| **EU Authorized Representative** | OBELIS S.A<br>Bd. Général Wahis, 53<br>1030 Brussels,<br>Belgium<br>BE-AR-000000106 |
| **UK Authorized Representative** | SUNGO Certification Company Limited<br>3rd floor, 70 Gracechurch Street, London. EC3V 0HR. |
| **CH Authorized Representative** | OBELIS SWISS GmbH<br>Ruessenstrasse 12, 6340<br>Baar/ZG<br>Switzerland |

As the manufacturer of the following medical device, we herewith declare under our sole responsibility that the stated medical device:

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| **Name of the Medical Device:** | Continuous Glucose Monitoring System |
| **Trademark** | Sinocare<br>iCan |
| **Product Model** | i3 |
| **Intended Purpose** | Continuous Glucose Monitoring System (CGM System) is a real time, continuous glucose monitoring device indicated for the measuring glucose in the interstitial fluid in persons age 2 years and older. It is intended to replace fingerstick blood glucose testing for diabetes treatment decisions.<br>The CGM System also detects trends and tracks patterns, and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.<br>Interpretation of the CGM System results should be based on the glucose trends and several sequential readings over time.<br><br>The CGM System can be used in conjunction with smart devices with corresponding application where the user manually controls actions for therapy decisions. |
| **Basic UDI-DI** | 6934175005A0001PM |
| **Product Code** | EMDN code: Z12040115<br>INVASIVE BLOOD SUGAR MONITORING SYSTEMS<br>GMDN code: 44611<br>Percutaneous interstitial-fluid glucose monitoring system, electrochemical |
| **Classification** | Class IIb (ANNEX VIII, Rule 10) |

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| **Conformity Assessment Procedure** | MDR Annex IX Chapter I, Section 2 and 3 and Chapter III |
| **EU Certificate No.** | HZ 2068488-1 |
| **Issue Date** | 2023-12-08 |
| **Expiry Date** | 2028-09-27 |
| **Notified Body** | TÜV Rheinland LGA Products GmbH<br>Tillystraße 2,90431 Nürnberg, Germany |
| **Notified Body Identification Number** | 0197 |
| **Applicable Common Specifications** | None |
| **Applicable Union Regulations/Directive(s)** | Regulation (EU) 2017/745 on medical devices<br>Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment<br>Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment |

is in conformity with Regulation (EU) 2017/745 and with any other relevant Union legislation that provides for the issuing of this EU Declaration of Conformity. The declaration is valid in connection with the "final inspection report" of the device.

Full Name: Yuanyuan Yu
Position: RA Director
Signature:
Date of Issue: 2023.01.13
Place of Issue: Changsha, China