DECLARATION OF CONFORMITY

Name and Address of the Manufacturer	Changsha Sinocare Inc. 265 Guyuan Road, Hi-Tech Zone, Changsha, 410205, Hunan Province, P.R. China SRN: CN-MF-000012244
EU Authorized Representative	OBELIS S.A Bd. Général Wahis, 53 1030 Brussels, Belgium SRN: BE-AR-000000106
UK Authorized Representative	SUNGO Certification Company Limited 3rd floor, 70 Gracechurch Street, London. EC3V 0HR.
CH Authorized Representative	OBELIS SWISS GmbH Ruessenstrasse 12, 6340 Baar/ZG Switzerland

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

Name of the Medical Device	Continuous Glucose Monitoring System
Product Model	o3
Trademark	GlucoMen
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. 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. Interpretation of the CGM System results should be based on the glucose trends and several sequential readings over time. 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: Z1204011502 INVASIVE BLOOD SUGAR MONITORING SYSTEMS GMDN code: 44611 Percutaneous interstitial-fluid glucose monitoring system, electrochemical
Classification	Class IIb (ANNEX VIII, Rule 10)
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 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 Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment 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: 2023.12.13
Place of Issue: Changsha, China