

DECLARATION OF CONFORMITY

Radio Equipment	
Product:	iCan i3 Continuous Glucose Monitoring (CGM) System
Type:	Continuous Glucose Monitor which supports Bluetooth Low Energy wireless technology.
Intended Purpose:	<p>The Continuous Glucose Monitoring System is a real-time, continuous glucose monitoring device indicated for the management of diabetes for adult people (age 18 and older). It is intended to replace fingerstick blood glucose testing for diabetes treatment decisions.</p> <p>The CGM 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 System results should be based on the glucose trends and several sequential readings over time.</p> <p>The CGM can be used in conjunction with smart devices with corresponding application where the user manually controls actions for therapy decisions.</p>

Manufacturer	
Name:	Changsha Sinocare Inc.
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Authorized Representative	
Name:	OBELIS S.A.
Address:	Bd. Général Wahis, 53 1030 Brussels, Belgium

Changsha Sinocare Inc. hereby declare that the product above is in conformity with the following relevant Union legislation(s):

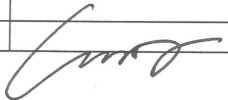
Directive 2014/53/EU on Radio Equipment

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Health and Safety (Art. 3(1)(a)):	EN 62479: 2010 EN 60601-1:2006 + A11:2011 + A1:2013 + A12:2014 + A2:2021, EN 60601-1-11:2015+A1:2021
EMC (Art. 3(1)(b)):	EN 301 489-1 V2.2.3 EN 301 489-17 V3.2.4 IEC 60601-1-2:2014 IEC 60601-1-2:2014/AMD1:2020
Spectrum (Art. 3(2)):	EN 300 328 V2.2.2

Notified Body:	TÜV Rheinland
Notified Body Identification No.:	0197
Issued the EU-type examination certificate:	RT 60175487 0001

This declaration of conformity is issued under the sole responsibility of the manufacturer. All supporting documents can be available for review upon request.

Signed for and on behalf of	Changsha Sinocare Inc.
Place and date of issue:	Changsha, China, 2024.03.11
Signature:	
Name, function:	



Regulatory Affairs Director