

## 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):**

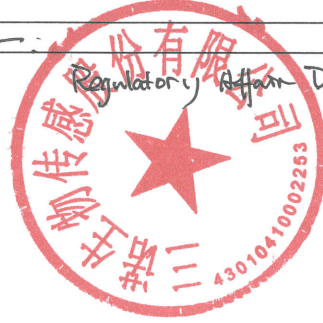
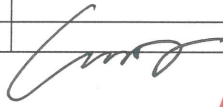
Directive 2014/53/EU on Radio Equipment

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