THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR SINOCARE – iCan i3 CONTINUOUS GLUCOSE MONITORING SYSTEM

Version number 2.0, 18.05.2026

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1. Introduction

SINOCARE – iCan i3 is a class C In vitro diagnostics belonging to the clinical chemistry specialty category. It is approved in Tanzania as a device system for use in adults only by healthcare professionals and trained general public.

1.1. Administrative Information

Registration number	TAN 25 MDR 0152
Brand Name (if relevant)	SINOCARE – iCan i3
Common name	Continuous Glucose Monitoring System
Class of the device and rule applied	Class C as per Rule 10 for classification of Medical Devices
GMDN code and term	44611, Percutaneous interstitial fluid glucose monitoring system, electrochemical
Name and complete address of the Market Authorization Holder	Sahan Healthcare and Solutions Limited Po Box 16003 Mbezi Beach Kawe (Maringo) Tel: +255 714457818
Name and address(es) of local responsible person (LRP).	Sahan Healthcare and Solutions Limited Po Box 16003 Mbezi Beach Kawe (Maringo) Tel: +255 714457818

1.2. Assessment Procedure

The application for registration of SINOCARE – iCan i3 was submitted on 28.11.2024. The product underwent full assessment. Assessment was completed in 02 rounds of evaluation. SINOCARE – iCan i3 was registered on 15.07.2025.

2. Technical information

2.1. Intended use

The intended use of SINOCARE – iCan i3 as declared by the manufacturer and approved by TMDA is a real time, continuous glucose monitoring device indicated for the management of diabetes for adult people (age 18 and older). SINOCARE – iCan i3 is approved for use in healthcare settings and point of care by trained personnel and adult

diabetes user who can read, understand and follow the iCan i3 CGM Instruction of Use and Quick Start Guide.

2.2. Device details and features

SINOCARE – iCan i3 is a complete system with accessories. SINOCARE – iCan i3 has been registered as a system which consists of Sensor Pack, Sensor- Applicator and Transmitter Pack. It is a closed system.

SINOCARE – iCan i3 is a automated device. It is used for monitoring of Diabetes mellitus. SINOCARE – iCan i3 operates by continuously monitor interstitial-fluid glucose concentrations in a patient with diabetes mellitus, using an invasive electrochemical technique. The test out-put is quantitative.

System Description

Continuous Glucose Monitoring System (hereafter referred as CGM) gives you a more complete picture of your glucose control than blood glucose (BG) monitoring alone. Using a sensor allows you to receive up to 480 sensor glucose (SG) readings every 24 hours, filling the gaps between your BG checks. CGM alerts notify you of high and low glucose values. Graphs and trend arrows show the speed and direction your glucose levels are moving

The iCan i3 CGM System consists of three main components: a Sensor Pack, a Bluetooth Low Energy (BLE) Transmitter Pack, and a mobile application (APP).

The iCan i3 CGM provides real-time glucose levels and allows you to continuously view your sensor glucose values on your selected mobile device. The system tracks your glucose every 3 minutes by measuring the amount of glucose in the interstitial fluid. A sensor, inserted in your skin, sends glucose results to the transmitter, and the transmitter sends glucose results to the iCan Health Continuous Glucose Monitoring System APP (CGM APP). The APP then displays your glucose levels and long-term glucose trends. The APP also provides alerts if your glucose is in or projected to be in an unsafe zone.

The iCan i3 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 results over time.

The iCan Health CGM APP

The iCan Health CGM APP serves as the display for the iCan i3 CGM and supports Android and iOS devices (mobile devices). The APP is available on Google Play (Android)

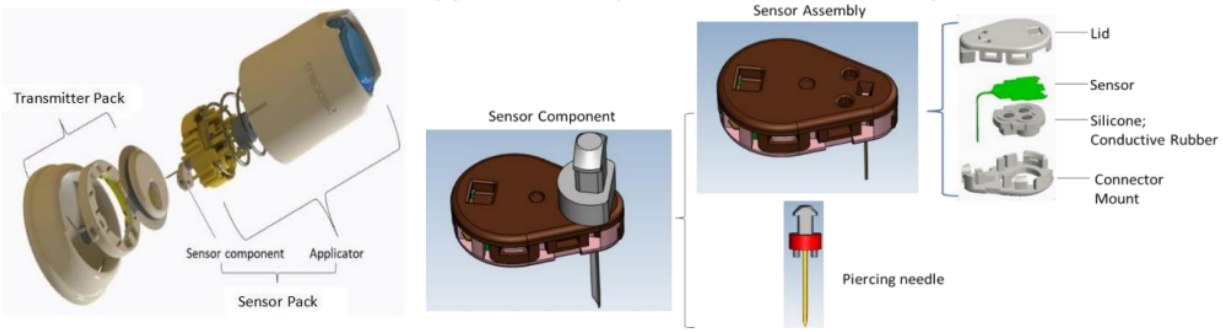
and the APP Store (iOS). To see a list of compatible mobile devices, visit the following; *iCan-cgm.com*

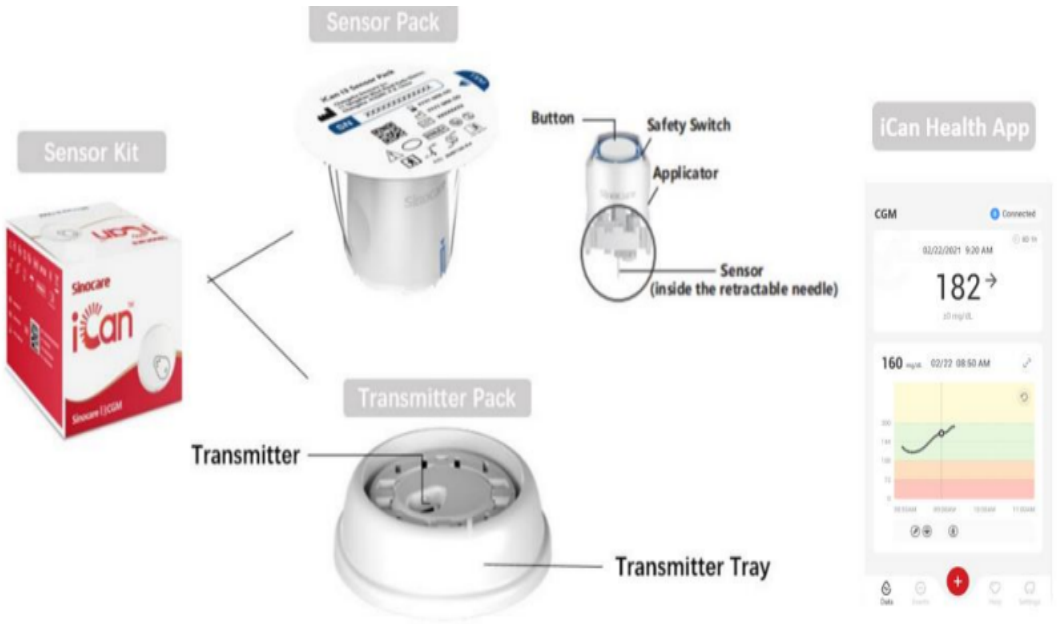
Intended Purpose

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. 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. The CGM can be used in conjunction with smart devices where the user manually controls actions for therapy decisions

- Sensor pack

The Sensor Pack is formed with Applicator component and Sensor Component.





2.3. Commercial presentation

There is one (01) approved commercial presentation as follows: One (01) Sensor pack and transmitter in a transparent plastic container. 01 Sensor pack and accessories are placed in box.

Additional contents include a Sensor Pack, a Bluetooth Low Energy (BLE) Transmitter Pack, and a mobile application (APP*).*

2.4. Items required but not submitted

Software for Android 8.1 and above, iOS 14.1 and above
Bluetooth version 5.0
WLAN (Wireless Local Area Network) or cellular network (4G and above), as well as Bluetooth function

3. Storage instructions

3.1.1. Shelf-life

18 months.

The sensor is designed for use for up to15 days

3.1.2. Storage conditions

The recommended storage conditions is 2°C to 30°C

3.1.3. Shipping conditions

The recommended shipping conditions is 2°C to 30°C (10% - 90%. RH)

4. Manufacturing site audit

The manufacturer of the device is Changsha Sinocare Inc. 265 Guyuan Road, Hi-Tech Zone, Changsha, 410205, Hunan Province, P.R. China. Email: iCansupport@sinocare.com, Website: iCan-cgm.com.

Quality audit of the manufacturing facility was conducted through site visit on 17th July, 2019. The site was found to be compliant to ISO 13485 requirements.

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device was established through the following test parameters: accuracy (trueness) and precision.

5.2. Clinical Performance

Clinical performance was conducted at Peking University People's Hospital Beijing Pinggu Hospital, China

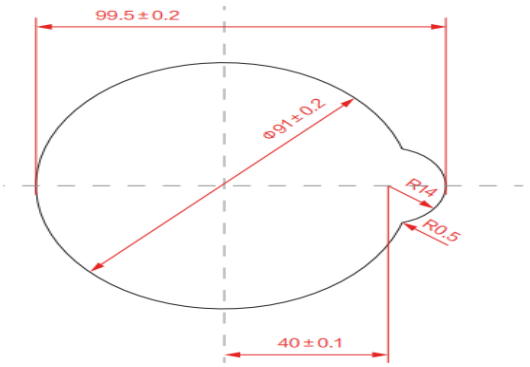
The results after clinical performance was having an accuracy of 100%

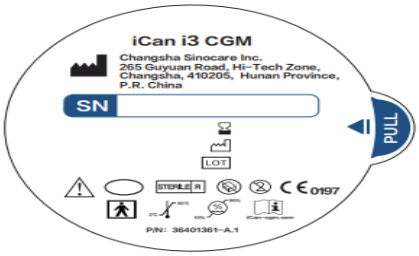
6. Product label and instructions for use

The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout and design. The label contains sufficient information for proper identification of the device and post marketing follow up of the product in the market.

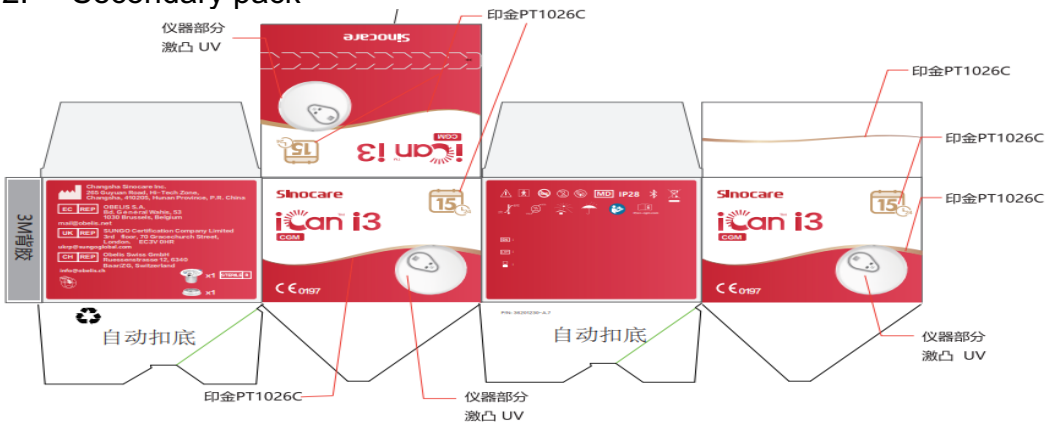
The package inserts and instructions for use includes all the relevant information to ensure correct and safe use of the device by intended user.

6.1. Primary pack





6.2. Secondary pack



6.3 Instructions for use/Package insert
Click here for IFU

PDF
Instruction for Use.pdf

7. Risk – Benefit Analysis

On basis of the data submitted, the current state of knowledge and compliance of the manufacturer to ISO 13485, the benefit of the product outweighs the risks associated with its use when used in accordance to the manufacturer instruction. SINOCARE – iCan i3 is recommended for registration.

8. Post-approval updates

8.1. Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
NA	NA	NA	NA	NA

8.2. Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response
No any recorded Adverse Event	NA	NA

8.3. Re-registration applications

NA

CHANGE HISTORY

Version number	Date	Description of update	Section(s) Modified	Approval date