00559548

中国国际贸易促进委员会

China Council for the Promotion of International Trade
China Chamber of International Commerce

证 明 书
CERTIFICATE

244300B0/000137

号码 No.

兹证明：所附文件的影印件与原件相符。

THIS IS TO CERTIFY THAT: the annexed photostated copy of DOCUMENT is in conformity with the original.

China Council for the Promotion of International Trade

授权签字：

Authorized Signature: Wang Yuying

日期：2024年01月17日

(Date: Jan. 17, 2024)

查询网址 Website for verifying the certificate: http://www.rzccpit.com/validate.html

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 2068488-1
Manufacturer:	Changsha Sinocare Inc. 265 Guyuan Road, Hi-Tech Zone, Changsha, 410205, Hunan Province, P.R. China
EUDAMED Single Registration No.:	CN-MF-000012244
Products:	Products of Class IIb: Z120401- GENERAL MEDICINE DIAGNOSIS AND MONITORING INSTRUMENTS BLOOD SUGAR MONITORING SYSTEMS - Continuous Glucose Monitoring System GENERAL MEDICINE DIAGNOSIS AND MONITORING INSTRUMENTS - MEDICAL DEVICE SOFTWARE - Continuous Glucose Monitoring System Software
Authorized representative(s):	OBELIS S.A Bd. Général Wahis, 53 1030 Brussels, Belgium

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	10923535-100
Effective date:	2023-12-08
Expiry date:	2028-09-27
Issue date:	2023-12-08

Frank Feng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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Certificate history		
Revision:	Description:	Issue date:
0	Initial revision	2023-09-28
1	change of license holder address, Change of authorized European representative	2023-12-08

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