

Declaration of Conformity

Manufacturer: Shenzhen SiSensing Co., Ltd.
Room 901, Building 1, Gaoshi Jiulongshan Technology Park, No. 26
Shijing Road, Fumin Community, Fucheng Street, Longhua District,
518110 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Manufacturer's SRN: CN-MF-000017945

EC Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany

EC Representative's SRN: DE-AR-000000001

Product: Continuous Glucose Monitoring System(include Sensor kit and
SIBIONICS APP)

Model: GS1

Basic UDI-DI: 697283164CGMGS1LL

EMDN: Z12040115

Regulation (EU) 2017/745 on medical devices

Classification: IIb (According to Rule 10 of Annex VIII)

Conformity Assessment Route: Annex IX Chapters I and III

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65 80339 München

Notified Body No.: 0123

EC Certificate: G10 116345 0004 Rev. 01

Start of CE-Marking: 2023-10-30

Radio Equipment Directive 2014/53/EU

Harmonised Standard: ETSI EN 301 489-1 V2.2.3(2019-11)
ETSI EN 301 489-17 V3.2.4(2020-09)
ETSI EN 300 328 V2.2.2 (2019-07)
EN 62479:2010
EN 50663:2017

Restriction of Hazardous Substances Directive 2011/65/EU

Harmonised Standard: EN IEC 63000:2018

Shenzhen SiSensing Co., Ltd. hereby declare that the above-mentioned product is in conformity with the following legislative acts:

- 2017/745 Medical Device Regulation
- 2014/53/EU Radio Equipment Directive
- 2011/65/EU Restriction of Hazardous Substances Directive

All supporting documentation is retained under the control of Shenzhen SiSensing Co., Ltd. and made available for review upon request. This declaration is issued under the sole responsibility of the legal manufacturer, Shenzhen SiSensing Co., Ltd..

Place:	Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA
Date:	2024. 04. 12
Signature:	Zhimin chen
Name:	Zhimin chen
Position:	Person responsible for regulatory compliance