

**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 Model/Name(s): GS3/SIBIONICS GS3 Continuous Glucose Monitoring System  
GS3/Sensor Kit  
GSS3/SIBIONICS GS3  
GSW3/SIBIONICS GSW3

Intended purpose: The Continuous Glucose Monitoring System is intended for the continuous monitoring of  
interstitial fluid glucose levels.

Basic UDI-DI: 697283164CGMGS3LQ  
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

**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 declares 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: 2025.05.19

Signature: Zhimin chen

Name: Zhimin chen

Position: Person responsible for regulatory compliance