Certificate TW17/00500

The management system of

Sigknow Biomedical Co., Ltd.

6F., No.760, Sec. 4, Bade Rd., Songshan Dist.,
Taipei City 105, Taiwan

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design and manufacture of wearable, single-patient-use Electrocardiograph (ECG) monitors, and associated analysis software

This certificate is valid from 25 March 2022 until 25 March 2025
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 3. Certified since 10 May 2017

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

UKAS MANAGEMENT SYSTEMS
0005

21HC 13485 2016 0421

EC Certificate Full Quality Assurance System: Certificate TW19/20042

The management system of

Sigknow Biomedical Co., Ltd.

6F., No.760, Sec. 4, Bade Rd., Songshan Dist., Taipei City 105, Taiwan

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Wearable ECG system- ECG recorder and ECG analysis system (APP)
Model: UG01, UG02

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 03 February 2020 until 25 March 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 14 June 2017
and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered TW/TPE 607271

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noordertaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

UPMD6807 - Certificate CE1639 Annex II-4_EN rev. 02