

EC Certificate Full Quality Assurance System: Certificate CN19/41013

The management system of

Shenzhen City Teveik Technology Co., Ltd.

6/F, B Bld, No.21, Pinggang Industrial Road, Shiwei Village, Gongming Street,
Guangming New District, Shenzhen City, Guangdong Province, 518106, P.R. China

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

**Reusable SpO2 (Pulse Oxygen Saturation) Sensor,
Disposable SpO2 (Pulse Oxygen Saturation) Sensor**

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

This certificate is valid from 16 December 2019 until 30 January 2024
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 03 June 2019
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered CN/SZX 49342

Authorised by



Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639

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LPM05007 - Certificate CE1639 Annex B-4_EN rev. 02

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SGS

Certificate CN13/31315

The management system of

Shenzhen City Teveik Technology Co., Ltd.

6/F, B Bld, No. 21, Pinggang Industrial Road, Shiwei Village, Gongming Street,
Guangming New District, Shenzhen City, Guangdong Province, 518106, P.R. China

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 Reusable SpO2 (Pulse Oxygen Saturation) Sensors;
Disposable SpO2 (Pulse Oxygen Saturation) Sensors;
Manufacture of ECG (Electrocardiogram) Cables**

This certificate is valid from 31 January 2022 until 31 January 2025
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 4. Certified since 08 November 2013

Authorised by

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