

Declaration of Conformity

According to the Medical Devices Directive 93/42/EEC

Holder: Kveina Technology Group Limited

Address: 4/F, Building A, Zhongcheng Industrial Zone, Industry East, Load, Longhua

Town, Shenzhen, Guangdong, China.

Manufacturer Name: Kveina Technology Group Limited

Manufacturer Address: 4/F, Building A, Zhongcheng Industrial Zone, Industry East, Load, Longhua

Town, Shenzhen, Guangdong, China.

Authorized representative: CKMedical International

Laan van cattenbroeck 10, Zeist, The Netherlands, postcode 3703BM.

Product Name: ECG cable, Spo2 adapter cable, IBP cable

MDD-Classification: Class I

Product Part Number: As Appendix II

Person responsible for making this declaration:

Name : Jerry Liu

Position/Title: Sales Manager

We Hereby Declares that the Medical device as indicated above conforms with the essential requirement listed in the Annex V of the European Medical Device Directive 93/42/EEC.



Jan. 18th. 2013
Date of issue

[Signature]
signature



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



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

21HC 13485 2016 0421

Page 1 of 1



0005



This document is issued by the Company subject to its General Conditions of
Certification Services accessible at www.sgs.com/terms_and_conditions.htm.
Attention is drawn to the limitations of liability, indemnification and jurisdictional
issues established therein. The authenticity of this document may be verified at
<http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>.
Any unauthorized alteration, forgery or falsification of the content or appearance
of this document is unlawful and offenders may be prosecuted to the fullest
extent of the law.