

VERIFICATION OF COMPLIANCE

Verification Report No.	: EZ/2006/70006C-01
Representative Model	: NVK Series (NVK001-NVK100)
Product Name	: ECG Cable, ECG Lead wires, EKG Cables, Reusable SpO2 Sensors, and SpO2 Adapter Cables
Product Class	: Class I as determined by the applicant
Applicant	: New V-Key Technology Co., Ltd.
Address of Applicant	: 8F., No.965, Jhongjheng Rd., Jhonghe City, Taipei County 235, Taiwan (R.O.C.)
TCF Number	: C & S – 2006 – 01(Revised at 2010)
Date of Issue	: July 22, 2010
Applicable Standards	: ANSI/AAMI EC53: 1995; Amendment 1998; ECG cables and leadwires, 1ed and Amendment.

Conclusion

Based upon a review of the worksheets and the Technical Construction File according to Annex VII of 93/42/EEC with amendment 2007/47/EC, the apparatus is deemed to meet the requirements of the above standards and hence fulfils the requirements of:

Medical Devices: Directive 93/42/EC with amendment 2007/47/EC

Note : This verification is only valid for the equipment and configuration described and in conjunction with the technical data detailed above.

The CE mark as shown below can be used, under the responsibility of the manufacturer, after completion an EC Declaration of Conformity and compliances with all relevant EC Directives.

Authorized Signatory:



SGS TAIWAN LTD.

Jason Lin

Technical Manager



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