



Product Service

# EC - CERTIFICATE

## Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 10 09 48669 012

**Manufacturer:** **Newtech, Inc.**  
R1-B1, Hi-Tech Industrial Park  
Nanshan District  
518057 Shenzhen, Guangdong  
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:** **Shanghai International Holding Corp. GmbH (Europe)**  
Eiffestraße 80  
20537 Hamburg  
GERMANY

**Product Category(ies):** **Pulse Oximeter, Multi-parameter Patient Monitor and Vital Signs Monitor**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

**Report No.:** BJ1084307

**Valid until:** 2015-11-10

**Date,** 2010-11-26

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

Page 1 of 2



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**Facility(ies):**

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