



Product Service

# EC-CERTIFICATE

## Production Quality Assurance System

(Annex V of the Directive 93/42/EEC on Medical Devices)

No. G2 08 10 50440 007

**Manufacturer:** **Shenzhen Carewell Electronics Co., Ltd.**

5A, Huating 3  
Time City, Chuangye Road  
Nanshan  
518054, Shenzhen  
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:** **Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80  
20537 Hamburg  
GERMANY

**Product Category(ies):** **CUS B Type Ultrasound Diagnostic System, Electrocardiograph**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective products / product categories according to Annex V, 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 IIb and III products an additional Annex III - certificate is mandatory. See also notes overleaf.

**Report No.:** SH0826506

**Valid until:** 2011-03-16

**Date,** 2008-12-19

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.

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**Facility(ies):**

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5A, Huating 3, Time City, Chuangye Road,  
Nanshan, 518054, Shenzhen, PEOPLE'S REPUBLIC  
OF CHINA

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PEOPLE'S REPUBLIC OF CHINA