RTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC-CERTIFICATE

Full Quality Assurance System

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

No. G1 10 02 45163 010

Manufacturer: **Shenzhen Biocare Electronics Co., Ltd.**
5/F,Taohuayuan High-Tech Innovation Park
Baoan
518102 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

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

Product Category(ies): **Electrocardiograph, Patient Monitor, B-Ultrasonic Diagnostic Equipment, Doppler Fetal heart rate detector**

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.

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Date, 2010-03-20

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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Product Service

EC-Certificate

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No. G1 10 02 45163 010

Facility(ies):

Shenzhen Biocare Electronics Co., Ltd.
5/F,Taohuayuan High-Tech Innovation Park, Baoan, 518102
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