ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 14 03 50972 028

Manufacturer:
Contec Medical Systems Co., Ltd.
No.112 Qinhuang West Street
Economic& Technical Development Zone
066004 Qinhuangdao, Hebei Province
PEOPLE'S REPUBLIC OF CHINA

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

Product Category(ies):
Patient Monitor, Fetal Monitor, B-Ultrasound Diagnostic System, Pulse Oximeter, Electrocardiograph, Pocket Fetal Doppler, Visual Electronic Stethoscope, Multi-functional Visual Stethoscope, Dynamic ECG Systems, Digital Brain Electric Activity Mapping, Syringe Pump, Infusion Pump,Spirometer, Ambulatory Blood Pressure Monitor, Electronic Sphygmomanometer, EMG/EP System, Portable ECG Monitor, Temperature Probe, Pulse Oximeter Probe, Tele Pulse Oximeter,Tele Breather, Multi-parameter Vital Signs Monitor, Sleep apnea screen meter.

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 devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: BJ1490207
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Date, 2014-04-25

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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Facility(ies):

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Development Zone, 066004 Qinhuangdao, Hebei Province,
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