



Product Service

CERTIFICATE

No. Q1N 08 10 50972 009

Holder of Certificate: Contec Medical Systems

Co., Ltd.

No.24 Huanghe West Road

Economic& Technical Development Zone 066004 Qinhuangdao, Hebei Province PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Contec Medical Systems Co., Ltd.

No.24 Huanghe West Road, Economic& Technical Development

Zone, 066004 Qinhuangdao, Hebei Province, PEOPLE'S

REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design, Development, Production, Sales, Installation and Servicing of Dynamic EEG System, Dynamic ECG System, Digital Brain **Electric Activity Mapping, Patient Monitor,** Patient Monitor System, B-Ultrasound Diagnostic System, ECG Recorder, ECG Workstation, ECG Monitor System, Medical Image Workstation, Fetal Monitor, Ventilator, Anesthetic Machine, High Frequency Surgical Unit, Pulse Oximeter, Ultrasonic Pocket Doppler, Visual Stethoscope, Electric Suction Apparatus, Transcranial Doppler Analysis System, Maternal/Fetal Monitor

Applied Standard(s):

EN ISO 13485:2003/AC:2007

ISO 13485:2003

Medical Devices - Quality Management Systems -

Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

BJ890202

Valid until:

2010-06-30

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Hans-Heiner Junker



TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstr. 65 · 80339 München Germany





CERTIFICATE

No. Q1N 08 10 58103 001

Holder of Certificate: Tianjin Hanaco Xingda Medical

Product Co., Ltd.

No. 4 Qijing Road Dongli Development Area

300300 Tianjin

PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Tianjin Hanaco Xingda Medical Product Co., Ltd.

No. 4 Qijing Road, Dongli Development Area, 300300 Tianjin,

PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design, Development, Production, Sales and

Distribution of Disposable Sterile Hypodermic

Syringe, Disposable Infusion Sets

Applied

EN ISO 13485:2003/AC:2007

Standard(s):

ISO 13485:2003 Medical Devices - Quality Management Systems -

Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

BJ899301

Valid until:

2011-10-30

Date, 2008-11-14

Hans-Heiner Junker

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